Iowa Department of Human Services

SSDC

IOWA MEDICAID SUPPLEMENTAL DRUG REBATE AGREEMENT

1. PARTIES/PERIOD

This Agreement is made and entered into this _____ day of _____ (YEAR), by and between the State of Iowa (State), represented by the Department of Human Services (Department), and _____ (Manufacturer), Labeler Code _____. The parties, in consideration of the covenants, conditions, agreements, and stipulations expressed in this Agreement, do agree as follows:

2. PURPOSE

It is the intent of this Agreement that the Department will receive a Supplemental Rebate for the Medicaid population, in addition to rebates received under the CMS Rebate Agreement, pursuant to Section 1927 of the Social Security Act (42 USC 1396r-8), for the Manufacturer's Covered Product(s) quarterly utilization in the Iowa Medicaid Program. The parties also intend for this Agreement to meet the requirements of federal law at Section 1927 of the Social Security Act (42 USC 1396r-8).

3. DEFINITIONS

3.1 **AMP** shall mean the Average Manufacturer Price as set forth in 42 USC 1396r-8; as such statute may be amended from time to time excluding State Supplemental Rebate amounts.

3.2 **Best Price** shall mean Best Price as set forth in 42 USC 1396r-8; as such statute may be amended from time to time, excluding State Supplemental Rebate amounts.

3.3 **CMS Agreement** means the Manufacturer's drug rebate contract with the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration), entered pursuant to Section 1927 of the Social Security Act (42 USC 1396r-8).

3.4 **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 Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act [42 USC 1396r-8(c)(1) and 42 USC 1396r-8(c)(3)].

3.5 **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 Section 1927(c)(2) of the Social Security Act [42 USC 1396r-8(c)(2)].

3.6 **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.

3.7 **Covered Product(s)** means any prescription drug product listed in Attachment A.

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

3.9 **Medicaid Utilization Information** means 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 USC 256b(a)(4) in accordance with Title 42 USC 256b(a)(4)(A) and 1396r-8(a)(5)(C).

3.10 **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.

3.11 **National Rebate** shall mean any discount provided by a Manufacturer pursuant to 42 USC 1396r-8.

3.12 **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 Sections 249A.20A.

3.13 **Quarter** means calendar quarter unless otherwise specified**.**

3.14 **Recommended Drug List** (RDL) shall mean the list of drugs excluded from the Preferred Drug List pursuant to Iowa Code Sections 249A.20A. The Pharmaceutical and Therapeutics Committee (P & T Committee) shall review the list of excluded drug categories and make recommendations to the Department. 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.

3.15 **State Supplemental Rebate** means, with respect to the Covered Product(s), the quarterly payment by the Manufacturer pursuant to Section 4.2 of this Agreement.

3.16 **Step Care** shall mean a potentially defined order of therapeutic choices within either the preferred or non-preferred drug list categories.

3.17 **Unit** 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).

3.18 **WAC** shall mean the Wholesale Acquisition Cost, which is the price, paid by a wholesaler for drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug. 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 Red Book 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.

4. MANUFACTURER'S RESPONSIBILITIES

4.1 Nothing in this agreement shall be construed to relieve the Manufacturer from its obligation to provide the Department a CMS Rebate for the Covered Product(s), including but not limited to the CMS Basic Rebate and as appropriate, the CMS CPI Rebate (hereinafter referred to collectively as "CMS Rebates").

4.2 In addition to the CMS Rebates described in Section 4.1 of this Agreement, the Manufacturer will remit to the Department a State Supplemental Rebate for Covered Product(s) included on the Preferred Drug List and/or Recommended Drug List. 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 CMS Rebates.

4.3 The quarters to be used for calculating the Rebates in Sections 4.1 and 4.2 of this Agreement will be those ending on March 31, June 30, September 30 and December 31 of each calendar year during the term of this Agreement.

4.4 Except as provided under Section 6.2, to make such rebate payments for each calendar quarter within 30 days after receiving from the State the Medicaid Utilization Information defined in this agreement. Although a specific amount of information has been defined in Section 3.9 of this agreement, the Manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at a minimum, information on the number of units paid, by NDC number.

4.5 The Manufacturer will pay the State Supplemental Rebate, including any applicable interest in accordance with Section 1903(d)(5) of the Act. Interest on the Rebates payable under Section 4.1 and 4.2 of 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. For Rebates invoiced for first Contract Quarter _____ (YEAR) or thereafter, if the date of mailing of the Rebate payable under Section 4.2 of this Agreement is 69 days or more from the date of mailing of the invoice, Manufacturer shall include interest with payment of the Rebate. Interest will be calculated as required under federal guidelines

4.6 Nothing in this Agreement shall be construed to prohibit 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 Preferred Drug List and/or Recommended Drug List. 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."

4.7 Unless notified otherwise, the Manufacturer will send Rebate payments by certified mail, return receipt requested, to the following address.

_____
Name

_____
Department

_____
Street Address

_____
City, State, Zip Code

5. DEPARTMENT RESPONSIBILITIES

5.1 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 Section 1927(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.

5.2 Recommended Drug List: The Department shall place Covered Products on a recommended list of drugs that promotes cost-effective clinical choices. Some drugs may be designated as recommended due to the voluntary offer by the Manufacturer of a supplemental rebate. The Department will publish the Recommended Drug List directed at providers. Non-recommended drugs will not be subject to prior authorization.

5.3 The Department will provide State Medicaid Utilization Information to the Manufacturer on a quarterly basis. The Department will report to the Manufacturer, within ninety (90) days of the last day of each quarter, and in a manner prescribed by the Federal Drug Rebate program, Medicaid Utilization Information paid for during the quarter. This data will be based on paid claims data (data used to reimburse pharmacy providers) for the Iowa Medicaid Program.

5.4 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 Rebates. In the event material discrepancies are discovered, the Department will promptly justify its data or make an appropriate adjustment, which may include an adjustment to the amount of the Rebates. Any such payment adjustment shall be included on the next quarterly invoice.

5.5 The Department shall maintain electronic claims records for the most recent four Contract Quarters that will permit the Manufacturers 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.

5.6 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 which 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.

5.7 The Department warrants that it received CMS authorization to receive State Supplemental Rebates as provided under this Agreement and that the Manufacturer's participation in the Iowa Supplemental Drug Rebate Program will not affect the Manufacturer's Best Price and the AMP.

6. DISPUTE RESOLUTION

6.1 Utilization disputes will be handled in the same manner as the Federal Drug Rebate program.

6.2 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 prior to the due date in Section 4.4. Any Manufacturer claim, regarding State Supplemental Rebates, not raised in the timeframe provided in Section 4.4 of this Agreement shall be forever waived.

6.3 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 rebate claimed which is not disputed by the required date in Section 4.4. The balance in dispute, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid by the Manufacturer by the due date of the next quarterly payment after resolution of the dispute.

6.4 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.

6.5 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

7. CONFIDENTIALITY PROVISIONS

7.1 Pursuant to 42 USC 1396r-8(b)(3)(D), the parties agree that information disclosed by the Manufacturer under this Agreement in a form which discloses the identity of a specific Manufacturer or the prices charged for drugs by the Manufacturer is confidential and shall not be disclosed except as necessary to carry out the Agreement or as may be required by judicial order. Therefore, the Department agrees that confidential information provided to the Department under this Agreement, including the Agreement itself is exempted from disclosure by statute. 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.

7.2 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. The foregoing shall not prevent the disclosure by the Manufacturer to the Department of information regarding the National Rebates for Covered Products.

7.3 The Manufacturer will hold the 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 Utilization Information to auditors who agree to keep such information confidential.

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

8. NONRENEWAL OR TERMINATION

8.1 This Agreement shall be effective on _____ (MONTH, DAY, YEAR) and shall continue in force until _____ (MONTH, DAY, YEAR).

8.2 This Agreement may be terminated, in whole or in part, by either party by giving written notice to the other party as indicated:

(a) During the Agreement period, if the generic equivalent of any Covered Product should become available, written notice of termination of the agreement for the covered product shall be at least sixty (60) days prior to the effective date of the termination. Termination shall become effective the 60th day after a party gives written notice of termination.

(b) During the Agreement period for a Covered Product for which no generic equivalent is available, written notice of termination of the agreement for the covered product shall be at least one hundred and eighty (180) days prior to the effective date of the termination. Termination shall become effective the 180th day after a party gives written notice requesting termination.

(c) In the event that the Department determines, as a result of a drug utilization therapeutic review, that a specific Covered Product of the Manufacturer or a therapeutic class of Covered Products included on the Iowa Medicaid Preferred Drug List, should require prior authorization for appropriateness of therapy based on best clinical practice standards, and the specific Covered Product is disadvantaged relative to the other preferred brand products in that class, the parties agree that written notice of termination of the agreement for the covered product shall be at least sixty (60) days prior to the effective date of the prior authorization implementation. Termination shall become effective on the effective date of the prior authorization implementation.

Up until the effective date of termination, the Manufacturer's Covered Product(s) will not be discouraged or disadvantaged in any way relative to any other brand name pharmaceutical product on Iowa's Medicaid Preferred Drug List. After the effective date of the termination, the Manufacturer's Covered Product(s) will be available to the Iowa Medicaid Program beneficiaries only through prior authorization, and the Manufacturer's obligation to pay State Supplemental Rebates will terminate

8.3 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 USC 1320a-7b(b) prohibiting illegal remunerations. (For the purposes of this Section, 8.3, "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 USC 1396r-8.

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

9. GENERAL PROVISIONS

9.1 This Agreement will be governed and construed in accordance with Title 42 USC Section 1396r-8; Title 42 of the Code of Federal Regulations; and all other applicable federal law and regulations.

9.2 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:

Iowa Medicaid Enterprise
Attn: Susan Parker, Pharmacy Consultant
100 Army Post Road
Des Moines IA 50315-6241

Notice to the Manufacturer will be sent to:

_____
Name

_____
Title

_____
Company Name

_____
Address

_____

9.3 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.

9.4 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.

9.5 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.

9.6 In the event of a transfer in ownership of the Manufacturer, the Agreement is automatically assigned to the new owner subject to the conditions of this Agreement.

9.7 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.

9.8 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.

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

- 9.2 Notice Provision
- 9.12 Effective Dates
- 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 appropriate State control agencies. Any modification of the formula to include non-Medicaid population groups must be authorized by CMS.

9.10 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, 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.

9.11 This Agreement is not assignable by _____ (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 _____ (MANUFACTURER), which will not unreasonably be withheld.

9.12 This Agreement shall be effective from _____ (MONTH, DAY, YEAR) through _____ (MONTH, DAY, YEAR).

9.13 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 8.3(b) of this Agreement, and on CMS's valid authorization of the Iowa Supplemental Rebate Program of which this Agreement forms a part.

9.14 If during the duration of this Agreement a generic equivalent of any Covered Product should become available, the Department will allow the Covered Product to remain on the Preferred Drug List and/or Recommended 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.

9.15 It is the Department's belief that the business arrangement contemplated by this Agreement is not subject to the provisions of 42 USC 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 USC 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 throughout the implementation of the State Supplemental Rebate and Iowa Medicaid Preferred and Recommended Drug Lists.

9.16 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 contract.

As evidence of their Agreement to the foregoing terms and conditions, the parties have signed below.

_____	_____
Signature	Signature
Eugene I. Gessow	_____
Name (Print)	Name (Print)
Director	_____
Title	Title
Iowa Department of Human Services	_____
Company	Company
_____	_____
Date	Date

ATTACHMENT A

Covered Products

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

Manufacturer	NDC	Product Description	Formula

ATTACHMENT B

Rebate Formula

Manufacturer	NDC (11 digits required)	Product Description	WAC	CMS Rebate	Tier[1]	Formula[2]	Contracted GNP

[1] **Tiers (Preferred Brand Levels)**

Preferred Brand Levels, referred to as Tiers in the offer entry system, represent how the Member States will use an offer in a given tier. Manufacturers may submit an offer in any combination of or all of the 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.

[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-CMS Rebate-Guaranteed Net Price=Supplemental Rebate Amount per Unit