

MISSISSIPPI MEDICAID SUPPLEMENTAL DRUG REBATE AGREEMENT

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

Pharmaceutical Manufacturer ("Manufacturer")	State of Mississippi Division of Medicaid ("DOM")
Manufacturer Name Labeler Codes:	State of Mississippi Division of Medicaid
Manufacturer Primary Billing Address:	DOM Primary Billing Address:
Manufacturer Primary Contact Person:	DOM Primary Contact Person:
Manufacturer Primary Contact Telephone:	DOM Primary Contact Telephone:
Manufacturer Primary Contact e-mail:	DOM Primary Contact e-mail:
Address for Notices required by Agreement ("Manufacturer Notice Address"):	Address for Notices required by Agreement: ("DOM Notice Address"):
Termination Date: ("Termination Date")	Effective Date ("Effective Date")

In consideration of the mutual covenants in this Agreement, including Attachment A 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:	DOM, by:
Signature:	Signature:
Printed Name:	Printed Name:
Title:	Title:
Date:	Date:

General Supplemental Rebate Terms

1. **PURPOSE**

1.1 DOM and Manufacturer have entered into this Agreement for the purpose of establishing a State Supplemental Rebate for utilization of Manufacturer's Preferred Product(s) by Mississippi Medicaid recipients, which will be in addition to rebates received under the National Medicaid 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.

2. **DEFINITIONS**

2.1 **AMP** shall mean the Average Manufacturer Price as set forth in Section 1927(k)(1) of the Act as implemented by 42 C.F.R. 447.504.

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

2.3 **CMS** shall mean the Centers for Medicare & Medicaid Services of the United States Department of Health and Human Services or any successor or renamed agency having authority to administer the Medicaid program.

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

2.5 **Covered Outpatient Drug** shall 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.

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

2.7 **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 CCO 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 CCO 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).

- 2.8 **National Drug Code (NDC)** shall have the meaning as set forth in 42 C.F.R. § 447.502.
- 2.9 **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.
- 2.10 **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 the NDRA.
- 2.11 **Participating Medicaid CCO** means a Medicaid CCO that is contracted with the DOM to supply a prescription drug benefit to Mississippi Medicaid Recipients. In order to qualify as a Participating Medicaid CCO, the Medicaid CCO must have aligned its formulary and/or Preferred Drug List, as applicable, with the DOM Fee-for-Service Program Preferred Drug List, assuring access to a Preferred Product is no more restrictive than the DOM Fee-for-Service Program Preferred Drug List requirements applicable to the Preferred Product.
- 2.12 **Pharmacy and Therapeutics Committee or P&T Committee** shall mean the committee established for the purpose of providing Preferred Drug List recommendations to DOM.
- 2.13 **Preferred Drug List or PDL** shall mean the list of preferred drugs adopted by the DOM and Participating Medicaid CCOs.
- 2.14 **Quarter** means calendar quarter unless otherwise specified.
- 2.15 **State Supplemental Rebate** shall mean the quarterly amount invoiced by DOM as calculated in accordance with the Contracted Products Attachment A. 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.
- 2.16 **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.
- 2.17 **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.

3. MANUFACTURER'S RESPONSIBILITIES

- 3.1 Manufacturer will provide DOM with the National Rebate for the Contracted Product(s) in accordance with the Manufacturer's National Drug Rebate Agreement.
- 3.2 In addition to the National Rebates, the Manufacturer will remit to the DOM a State Supplemental Rebate for Covered Product(s) included on the PDL. The Manufacturer shall pay to the DOM the State Supplemental Rebate amount in accordance with the formula set forth in Attachment A. This State Supplemental Rebate is in addition to the National Rebates.
- 3.3 Absent a dispute raised pursuant to the Dispute Resolution section of this Agreement, Manufacturer shall pay the State Supplemental Rebate amount to DOM for each Quarter no later than the Rebate Payment Due Date. 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.
- 3.4 Manufacturer will pay the State Supplemental Rebate, including any applicable interest. Interest on the State Supplemental Rebates payable under Section 4.2 of this Agreement begins accruing 38 calendar days from the postmark date of the State Supplemental Rebate invoice sent to Manufacturer and will continue to accrue until the postmark date of Manufacturer's payment. Interest on State Supplemental Rebates is calculated in the same manner as interest on the National Rebate:
- (a). Obtain yield rates of weekly auction of 13-Week Treasury bills under Investment Rate% or in the DDR.
 - (b). Determine the date range for which interest is owed beginning with the 38th day from the invoice postmark date.
 - (c). Total the yield rates of each weekly auction for the period during which interest applies.
 - (d). Divide that total by the number of yield rates (i.e., number of weeks) to determine the average interest rate.
 - (e). Multiply the average interest rate by the amount of unpaid rebate to determine amount of interest due.
 - (f). Divide the amount of interest by 365 days to determine the daily interest amount due.
 - (g). Multiply the daily interest amount by the number of days for which interest is owed. This amount represents the total interest owed.
- 3.5 Nothing in this Agreement shall be construed as prohibiting 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 DOM of such action as soon as commercially reasonable. Upon such notification, DOM has the right to remove the Contracted Product from the definition of Contracted Products without cause. Manufacturer will continue to be responsible for all State Supplemental Rebates until such notification is given.

- 3.6 Unless notified otherwise, Manufacturer will send State Supplemental Rebate payments by certified mail, return receipt requested, to the DOM Primary Billing Address identified on the first page of this Agreement.

4. DOM RESPONSIBILITIES

- 4.1 DOM shall maintain and publish a list of Preferred Products that 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 A of this Agreement. DOM may apply clinical edits, prior authorization, step therapy or similar utilization management controls to a Preferred Product that are consistent with, but not more restrictive than, the FDA-approved Prescribing Information as of the Effective Date of this Agreement. DOM may also apply other clinical edits, prior authorization, step therapy or similar utilization management controls if applied equally to all products in the therapeutic class.
- 4.2 DOM will report to Manufacturer the Medicaid Utilization information within ninety (90) days of the last day of each Quarter. This reporting shall be done in a manner consistent with the National Medicaid Drug Rebate program.
- 4.3 DOM 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, DOM 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.
- 4.4 DOM shall maintain electronic claims records for the most recent four Quarters that will permit Manufacturer to verify through an audit process the Medicaid Utilization information provided by DOM. DOM and Manufacturer will develop mutually-beneficial audit procedures, should such an audit be required to resolve disputes regarding Medicaid Utilization information.
- 4.5 DOM warrants that it received CMS authorization to receive State Supplemental Rebates as provided under this Agreement.

5. DISPUTE RESOLUTION

- 5.1 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 DOM and CMS in disputes concerning National Rebates.
- 5.2 In the event that in any Quarter a discrepancy in calculation of that quarter's State Supplemental Rebate is noted by Manufacturer, which Manufacturer and DOM in good faith are unable to resolve, Manufacturer will provide written notice of the discrepancy, by NDC number, to DOM by the Rebate Payment Due Date.
- 5.3 If Manufacturer in good faith believes that DOM's calculation of the State Supplemental Rebate is erroneous, Manufacturer shall pay to DOM 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 Section 3.4 of this Agreement, will be paid by Manufacturer by the due date of the next quarterly payment after resolution of the dispute.
- 5.4 DOM 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 DOM's calculation of the State Supplemental Rebate or Manufacturer's calculations and payment figures. Should an audit of provider records be required to resolve disputes, DOM will cooperate with Manufacturer and provide relevant provider information upon Manufacturer's request.

6. CONFIDENTIALITY PROVISIONS

- 6.1 Pursuant to 42 U.S.C. § 1396r-8(b)(3)(D) and this Agreement, information disclosed by Manufacturer in connection with this Agreement is confidential and, notwithstanding other laws, will not be disclosed by the Secretary or the State Medicaid Agency in a form which reveals Manufacturer, or rebates offered by 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 DOM utilizes the services of a third-party to develop and maintain the PDL, or to administer any part of this Agreement, all provisions of this section shall apply to the third-party, and DOM 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 DOM is required by law to disclose any provision of this Agreement or pricing information to any person other than as provided above, DOM shall provide advance written notice to Manufacturer sufficiently in advance of the proposed disclosure to allow 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 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 or until all obligations set forth in this Agreement are fulfilled, whichever occurs last.
- 7.2 This Agreement may be terminated by DOM, in whole or as to any Contracted Product(s) or NDC(s) without cause as of the end of a Quarter upon sixty (60) days written notice to Manufacturer.
- 7.3 This Agreement may be terminated by either party 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, Division of Medicaid Justice) or the State of Mississippi (e.g., Mississippi 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(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.
- 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 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, 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 DOM will be sent to the DOM Notice Address identified on the first page of this Agreement. Notice to 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 Mississippi and agrees that this Agreement shall be construed and interpreted in accordance with Mississippi law without giving effect to the conflicts of the law's 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 DOM'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 Manufacturer in the performance of this Agreement will act in an independent capacity and not as officers, employees or agents of the State of Mississippi.
- 8.6 In the event of a transfer in ownership of 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 DOM and 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 DOM:

- Effective Dates
- Contracted Products Attachment A

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.

- 8.10 Neither party contemplates any circumstances under which indemnification of the other party would arise. Nevertheless, should such circumstances arise, 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 Manufacturer in the performance of this Agreement.
- 8.11 This Agreement is not assignable by Manufacturer either in whole or in part without the written consent of DOM, which will not unreasonably be withheld. This Agreement is not assignable by DOM either in whole or in part without the written consent of Manufacturer, which will not unreasonably be withheld.
- 8.12 It is DOM'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 DOM'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. DOM currently provides CMS full and unfettered access to all information held by DOM regarding the implementation of the Mississippi Medicaid Program, and shall continue to do so.
- 8.13 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 A

Manufacturer	NDC	Product Description	Tier ¹	Formula ²	Contracted Rate	Comments	Excluded NDCs if applicable

¹Tier

The Tier represents the number of brand drugs that may be preferred in the Contracted Product PDL category.

- Tier 1 - The Contracted Product will be the only preferred brand product in the PDLcategory.
- 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 PDLcategory.
- Tier 4 - The Contracted Product will be preferred (offer places no limitation on the number of preferred brand products in the PDL category).

²Formula

- Formula 1: Percentage of WAC.
Formula for Supplemental Rebate calculation: $WAC * Contracted\ Rate = Supplemental\ Rebate\ Amount\ per\ Unit$
- Formula 2: Guaranteed Net Price.
Formula for Supplemental Rebate calculation: $WAC - National\ URA - Contracted\ Rate = Supplemental\ Rebate\ Amount\ per\ Unit$

CONFIDENTIAL

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Atlanta Regional Office
61 Forsyth St., Suite 4T20
Atlanta, Georgia 30303-8909



CENTER FOR MEDICAID AND CHIP SERVICES

Disabled and Elderly Health Program Group

November 21, 2017

Mr. David J. Dzielak, PhD
Executive Director
Mississippi Division of Medicaid
550 High Street, Suite 1000
Jackson, MS 39201

Dear Mr. Dzielak:

We have reviewed Mississippi State Plan Amendment (SPA) 17-0013, received in the Atlanta Regional Office on November 3, 2017. This amendment proposes to revise the current Supplemental Drug Rebate Agreement (SDRA) to be consistent with the Covered Outpatient Drug final rule with comment period (CMS-2345-FC) and to revise references to various federal laws and definitions that have been changed.

Based on the information provided, we are pleased to inform you that, consistent with the regulations at 42 CFR 430.20, SPA 17-0013 is approved with an effective date of January 1, 2018. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into the Mississippi state plan will be forwarded by the Atlanta Regional Office.

If you have any questions regarding this amendment, please contact Mickey Morgan at (410) 786-4048 or mickey.morgan@cms.hhs.gov.

Sincerely,

//s//

Meagan T. Khau
Deputy Director
Division of Pharmacy