

AMOUNT, DURATION AND SCOPE OF
SERVICES PROVIDED

Revised:

July 1, 2016

CATEGORICALLY NEEDY

12. Prescribed drugs, dentures and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist (Continued)

a. Prescribed Drugs (continued)

(4) The state is in compliance with section 1927 of the Social Security Act. The state will cover drugs of Federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data.

The state will be negotiating supplemental rebates in the Medicaid program in addition to the Federal rebates provided for in Title XIX. Rebate agreements between the state and pharmaceutical manufacturer(s) will be separate from the Federal rebates.

A rebate agreement between the state and a participating drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on **May 24, 2016**, and entitled, State of Arkansas Supplemental Rebate Agreement, has been authorized by CMS. Any additional versions of rebate agreements negotiated between the state and manufacturer(s) after **May 24, 2016**, will be submitted to CMS for authorization.

Supplemental rebates received by the State in excess of those required under the National Drug Rebate Agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.

All drugs covered by the program, irrespective of a supplemental rebate agreement, will comply with the provisions of the national drug rebate agreement.

The supplemental rebate program does not establish a drug formulary within the meaning of 1927(d)(4) of the Social Security Act.

The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification, in accordance with Section 1927(b)(3)(D) of the Social Security Act.

(5) Pursuant to 42 U.S.C. Section 1396r-8 the state is establishing a preferred drug list with prior authorization for drugs not included on the preferred drug list. Prior authorization will be provided within a 24-hour turn-around from receipt of request and a 72-hour supply of drugs in emergency situations.

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ARKANSAS SUPPLEMENTAL REBATE AGREEMENT

This Supplemental Rebate Agreement (“Agreement”) by and between the State of Arkansas Department of Human Services (“State”) and _____ (“Manufacturer”), sets forth the terms and conditions of this Agreement.

RECITALS

WHEREAS, the State has the authority to enter into agreements with pharmaceutical Manufacturers to collect supplemental rebates for the benefit of the State’s Medicaid recipients providing such agreements are approved by the Centers for Medicare and Medicaid Services (CMS); and

WHEREAS, Manufacturer is willing to provide supplemental rebates to the State based on the actual dispensing of Manufacturer’s Covered Products under the State’s Medicaid program or Managed Medicaid utilization under prescribed conditions as set forth in Attachment “C”

NOW THEREFORE, in consideration of the foregoing and of the representations, warranties and covenants set forth below, the parties, intending to be legally bound, agree as follows:

1. **Definitions.** As used herein, the following terms shall have the meanings set forth below:
 - 1.1. **“Agreement”** shall mean this Supplemental Rebate Agreement, including all documents attached or incorporated by reference.
 - 1.2. **“Average Manufacturer Price (“AMP”)”** means, The Average Manufacturer Price as defined in 42 U.S.C. 1396r-8 and final regulations promulgated by CMS thereto, if any, as such statute or regulations may be amended from time to time and shall exclude rebates paid under CMS authorized Supplemental Rebate Agreements.
 - 1.3. **“Best Price”** shall mean the Best Price as defined in 42 U.S.C. 1396r-8 and final regulations promulgated by CMS thereto, if any, as such statute or regulations may be amended from time to time and shall exclude rebates paid under CMS authorized Supplemental Rebate Agreements.“. “Centers for Medicare & Medicaid Services” or “CMS” shall mean the agency within the Federal Department of Health and Human Services that is charged with overseeing the Medicaid programs administered by states
 - 1.4. **“Product Category”** shall mean a pharmaceutical product that is therapeutically interchangeable to one or more Covered Products of Manufacturer.
 - 1.5. **“CMS Agreement”** means the Manufacturer’s drug rebate contract with the Centers for Medicare & Medicaid Services (or ‘CMS’), formerly known as the Health Care Financing Administration, entered pursuant to Section 1927 of the Social Security Act [42 U.S.C. § 1396r-8].
 - 1.6. **“CMS Basic Rebate”** means, with respect to the Supplemental Covered Product(s), the quarterly payment by Manufacturer pursuant to Manufacturer’s CMS Agreement, made in accordance with Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act [42 U.S.C. §1396r-8(c)(1) and 42 U.S.C. § 1396r8(c)(3)].
 - 1.7. **“CMS Additional Rebate”** means, with respect to the Supplemental Covered Product(s), the quarterly additional payment by Manufacturer pursuant to

Manufacturer's CMS Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act (pertaining to the additional rebate calculated for single source and innovator multiple source drugs), as may be applicable [42 U.S.C. §1396r-8(c)(2)].

- 1.8. **“CMS Rebate”** means, with respect to the Supplemental Covered Product(s), the quarterly payment by Manufacturer
- 1.9. **“Covered Product” OR “Supplemental Covered Product”** shall mean a pharmaceutical product or products identified in Attachment A of this Agreement, which is attached hereto and incorporated herein by reference
- 1.10. **“Covered Outpatient Drug”** will have the meaning as set forth in 42 U.S.C. 1396r-8(k)(2),(k)(3) and (k)(4) and regulations promulgated by CMS thereto, if any, as such statute or regulations may be amended from time to time.
- 1.11. **“Consumer Price Index-Urban” or “CPI-U”** shall have the same meaning as in the Federal Rebate Agreement.
- 1.12. **“Federal Rebate”** shall mean any monetary payment remitted by Labeler pursuant to the Federal Rebate Agreement and made in accordance with 42 U.S.C. 1396r-8.
- 1.13. **“Federal Rebate Agreement”** shall mean the contractual agreement between Labeler and the Federal Secretary of Health and Human Services entered pursuant to 42 U.S.C. 1396r-8.
- 1.14. **“Generic Equivalent”** shall mean a pharmaceutical product that has been designated by the U.S. Food and Drug Administration as therapeutically equivalent to the Covered Product for the purposes of this definition, the concept of therapeutic equivalence applies only to products containing the same active ingredient(s) and does not encompass a comparison of different therapeutic agents used for the same condition.
- 1.15. **“Guaranteed Net Unit Price” or “Net Unit Price” or “Discount Per Unit”** means, with respect to Covered Product(s), the amount per unit or for each NDC set forth in Attachment A and used in the Supplemental Rebate Calculation, Attachment B.
- 1.16. **“Manufacturer” or “Labeler”** shall have the meaning set forth in 42 U.S.C. 1396r-8(k)(5), shall also mean the entity holding legal title to or possession of the NDC(s) for the Covered Product(s) and shall include Labeler identified above.
- 1.17. **“Medicaid MCO”** means a Medicaid managed care organization that is responsible for coverage of Covered Outpatient Drugs for Medicaid Recipients who are enrolled with the managed care entity, as further described in 42 U.S.C. § 1396b(m), as may be amended from time to time.
- 1.18. **“Medicaid Recipient”** shall mean any person enrolled in the State Medicaid Program and eligible to receive prescription drug benefits under a fee for service or Medicaid MCO arrangement.

- 1.19. “National Drug Code” or “NDC”** shall mean the unique nine (9) or eleven (11) character code assigned to drug products composed of three distinct sub-codes to include the labeler code, product code, and package size as requested at the time of bid solicitation.
- 1.20. “Participating Medicaid MCO”** means a Medicaid MCO that the State has determined is eligible for Supplemental Rebates consistent with the State Medicaid Plan and the State’s contract with the Medicaid MCO. In order to qualify as a Participating Medicaid MCO, the Medicaid MCO must have aligned its formulary and/or preferred drug list, as applicable, with the State’s PDL, assuring access to Covered Product(s) is no more restrictive than the State PDL requirements applicable to the Supplemental Covered Product.
- 1.21. “Preferred Drug List” or “PDL”** shall mean a document listing various pharmaceutical products designated as preferred drugs by the State Medicaid Program in consultation with the State’s Drug Review Committee (DRC) pursuant to the state’s relevant enabling legislation, as applicable.
- 1.22. “Prior Authorization”** shall mean a process by which the State Medicaid Program approves prior to reimbursing various pharmaceutical products for the purpose of guiding the prescribing, dispensing, and acquisition of pharmaceutical products covered by the State Medicaid Program.
- 1.23. “Quarter”** shall mean one of the four three-month periods by which the calendar year is divided, that calendar year beginning January 1 and ending on the following December 31.
- 1.24. “State Medicaid Program”** shall mean the joint federal and state medical assistance program as established and defined pursuant to Title 42 U.S.C. 1396, et seq., that provides reimbursement for or coverage of prescription drug products to Medicaid Recipients.
- 1.25. “State Utilization Data” or “State Utilization”** shall mean the information provided on the total number of units of each dosage form and strength, as identified by National Drug Code (NDC) for each of Labeler’s Covered Products reimbursed by Arkansas during a Quarter where Covered Product was listed as preferred on the Arkansas Preferred Drug List. In addition, State Utilization Data shall include the units invoiced hereunder with respect to such Medicaid MCO utilization, in addition to the applicable state fee-for-service Medicaid utilization, provided conditions as set forth in Attachment C are met. In no case may the State Supplemental Rebate amount be a negative amount.
- 1.26. “State Supplemental Rebate” or “Supplemental Rebate”** shall mean any monetary payment remitted by Labeler, pursuant to this Agreement, that supplements the Federal Rebate.
- 1.27. “Supplemental Rebate Amount”** means, with respect to the Covered Product(s), the amount(s) specified in Attachment A, and Supplemental Rebate Calculation, Attachment B, that the Manufacturer has agreed to reimburse Arkansas per unit of drug in accordance with the formula detailed in the above Attachments.

- 1.28. “Supplemental Rebate Per Unit” or “SRPU”** is calculated for each NDC of a Covered Product according to the formula in Attachment B
- 1.29. “Supplemental Rebate Invoice”** shall mean the report that itemizes and aggregates, by NDC number, the claims reimbursed by Arkansas for each Covered Product during a Quarter and any cover letter that accompanies said report. The Supplemental Rebate Invoice shall comply with the requirements for Medicaid Utilization Information as set forth in the Federal Rebate Agreement
- 1.30. “Unit”** shall mean the drug unit in the lowest identifiable amount on which the rebate is calculated (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.
- 1.31. “USC”** shall mean the United States Code. All references to this agreement to USC chapters or sections shall include any successor, amended, or replacement statute.
- 1.32. “Unit Rebate Amount” or “URA”** shall mean the computed unit amount to which the State Utilization Data is applied for the Federal Rebate or Supplemental Rebate payment due. For the purposes of this Agreement, unit rebate amount shall be synonymous with the terms Rebate Per Unit (RPU) and Rebate Amount Per Unit and encompass said terms.
- 1.33. “Unit Rebate Off-Set Amount” or “UROA”** shall mean the unit amount calculated by CMS pursuant to 42 U.S.C. 1396r-8 and final regulations promulgated by CMS thereto, if any, as such statute or regulations may be amended from time to time.
- 1.34. “Wholesale Acquisition Cost” or “WAC”** shall mean the manufacturer’s list price for the Covered Product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, that was in effect on the last day of the subject Quarter as published in a national drug data file, such as First Data Bank, Medi-Span or other publications of drug pricing data.

2. State Obligations

- 2.1. Preferred Drug List.** To be eligible for the State Supplemental Rebates specified in Attachment B:
- 2.1.1.** Covered Product(s) will accrue Supplemental Rebates when listed as preferred on the State Preferred Drug List and when not disadvantaged to other preferred drugs on the State PDL unless described in Attachment A. At the sole discretion of the State, and without notice to Labeler, Covered Product can be moved from preferred to non-preferred status on the State’s PDL. Rebate accrual begins and ends on the effective date noted on the State’s PDL
- 2.1.2.** State shall place Covered Product(s) in an advantaged position relative to non-preferred drugs regarding Preferred Drug List status; this shall not in any way limit or restrict other mechanisms that the State may use to ensure proper utilization of Manufacturer’s products, such as quantity limits or day supply limits, or other clinical Prior Authorization criteria applied to the Covered Product;

2.2. Preferred Drug List Documentation and Publication. State shall communicate the inclusion of Covered Product on the Preferred Drug List to State Medicaid Program providers through a notification process, which may include, but not be limited to, issuance of written notification to Medicaid providers, inclusion on the Department of Human Services website, or remittance advice messages. The PDL communication will include an effective date of said changes.

2.3. Invoicing. State or its designee shall invoice State Supplemental Rebates separately from the Federal Rebates, on a Quarterly basis, utilizing an invoice format substantially similar to that of the Federal Rebate invoice that provides at a minimum for each Covered Product reimbursed by the State during the Quarter. The State, at its option, may compute the total Supplemental Rebate anticipated but it shall remain the responsibility of Labeler to correctly calculate the Supplemental Rebate amount based on the applicable methodology set out in Attachment B. The State or its designee shall submit the Supplemental Rebate invoice to the Labeler's invoice contact, as identified by Labeler to CMS.

2.4. Approval of Generic Equivalent.

2.4.1. If during the term of this Agreement, a Generic Equivalent of the Covered Product should become available, the State, at its sole discretion, may allow the applicable Covered Product to remain preferred on the Arkansas PDL. Additionally, and without notice to Labeler, Covered Product can be moved from preferred to non-preferred status on the State's PDL. Rebate accrual begins and ends on the effective date noted on the State's PDL.

3. Manufacturer Obligations

3.1. State Supplemental Rebate Payment. Manufacturer agrees to provide a State Supplemental Rebate for each of its Covered Products that is paid for by the State as a Covered Outpatient Drug for each calendar Quarter that Covered Products are included in the Preferred Drug List. Manufacturer shall pay to State the State Supplemental Rebate amount in accordance with the formula set forth in Attachment B. Nothing in this Agreement shall be construed to relieve Manufacturer from its obligation to make payments according to its CMS Agreement for utilization by State Medicaid Recipients and if applicable, those Medicaid Recipients enrolled in Participating Medicaid MCOs in accordance with Attachment C. State shall remit the appropriate share of the State Supplemental Rebate payments made under this Agreement to CMS as required under its approved state plan. While the State or its designee, may compute the total Supplemental Rebate anticipated, it shall remain the responsibility of Labeler to correctly calculate the Supplemental Rebate amount owed to the State based on the applicable methodology set out in Attachment B. Manufacturer will also calculate and provide the State a CMS Rebate for the Supplemental Covered Product(s), which includes the CMS Basic Rebate and CMS Additional Rebate, as appropriate, in accordance with the terms of the CMS Agreement. Manufacturer's obligation for CMS Rebates will continue for the duration of the Manufacturer's CMS Agreement.

3.2. Payment and Interest Timeframe. Manufacturer shall pay to State the State Supplemental Rebate amount to which State is entitled in accordance with the formula set forth in Attachment B, within thirty-eight (38) days of Manufacturer's receipt of such submission pursuant to Section 2.3. Manufacturer will pay the State Supplemental

Rebates, including any applicable interest in accordance with Section 1903 (d)(5) of the Act. Interest on the State Supplemental Rebates begins accruing 38 calendar days from the postmark date of the State's invoice and supporting Rebate Summary sent to the Manufacturer and interest will continue to accrue until the postmark date of the Manufacturer's payment. Interest will accrue using the same methodology as in the CMS Agreement.

3.3. Dispute Resolution

3.3.1. In the event that in any quarter a discrepancy in the State Medicaid Program's Utilization data is questioned by the Manufacturer, which the Manufacturer and the State Medicaid Program in good faith are unable to resolve, the affected parties shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the parties will resolve their dispute in accordance with generally applicable procedures followed by the State Medicaid Program or CMS in disputes concerning CMS Rebates. Notwithstanding anything to the contrary herein, any dispute relating to eligibility of the State MCO utilization for State Supplemental Rebates hereunder shall be resolved exclusively between the Manufacturer and the State.

3.3.2. If the Manufacturer, in good faith, believes the State Medicaid Program's State Utilization data is erroneous, the Manufacturer shall pay the State Medicaid Program that portion of the rebate claimed, that is not in dispute by the required date. The balance in dispute, including applicable interest, if any, will be paid by the Manufacturer to the State Medicaid Program by the due date of the next quarterly payment after resolution of the dispute.

3.3.3. The State Medicaid Program and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of written notification. Should additional information be required to resolve disputes, the State Medicaid Program and its designee will cooperate with the Manufacturer in obtaining the additional information.

3.3.4. In the event that the State Medicaid Program and the Manufacturer are not able to resolve a discrepancy regarding State Utilization data, as provided for in Sections 3.3.1 through 3.3.3, the Manufacturer may request a reconsideration of the State Medicaid Program's determination within 30 days after the end of the 60 day period identified in Section 3.3.3. The Manufacturer shall submit with its written request its argument in writing, along with any other materials, supporting its position to the State Medicaid Program and its designee. The State Medicaid Program shall review the written argument and materials and issue a decision in the matter.

3.4. Discretion to Market. Nothing in this Agreement shall be construed to prohibit Manufacturer from discontinuing production, marketing or distribution of any Covered Product or from transferring or licensing any Covered Product to a third party. It is understood that Manufacturer is liable for the payment of State Supplemental Rebates only for Covered Products (as identified by the 11-digit NDC code) and dispensed or administered to Medicaid Recipients or those Medicaid Recipients enrolled in Participating Medicaid MCOs. If Manufacturer elects to discontinue production,

marketing or distribution of any Covered Product or to transfer or license any Covered Product to a third party, Manufacturer shall make every reasonable effort to notify State prior to such actions.

4. Term and Termination

4.1. **Effective Date.**

4.1.1. The Manufacturer's obligation for State Supplemental Rebates will begin _____ [DATE] and will continue through the Rebate Billing Period that ends _____ [DATE].

4.1.2. At the sole discretion of the State, State may solicit Manufacturer for an enhanced GNUP on its Supplemental Covered Products.

4.1.3. **Breach.** If either party commits a material breach of this Agreement, the non-breaching party shall deliver written notice mailed by certified mail, return receipt requested, of the alleged breach to the breaching party, with an opportunity for the breaching party to cure the breach during the thirty (30) day period following the delivery. Failure to cure shall give the non-breaching party the right to cancel this Agreement at the end of the thirty (30) day period. The non-breaching party shall give the breaching party final written notice of the cancellation of this Agreement.

4.1.4. **Termination.** The State may terminate its participation in this Agreement by giving Manufacturer written notice at least (90) days prior to the annual anniversary date of this Agreement, in which case termination shall become effective on the annual anniversary date of the date of effective date of this Agreement. The termination of this Agreement by the State shall not affect the Manufacturer's or State's obligations under this Agreement. Manufacturer may terminate this Agreement and all Addenda by giving the State written notice at least ninety (90) days prior to the annual anniversary date of this Agreement, in which case termination shall become effective on the anniversary date of this Agreement. Manufacturer's right of termination is limited to the right to terminate the entire Agreement. In addition, this Agreement shall be co-terminous with the CMS Rebate agreement, in the event that such agreement is terminated for any reason.

4.2. **Accrued Obligations/Remedies.** The expiration or termination of this Agreement shall not affect any rights or obligations of the parties that have accrued prior to the effective date of such termination. The fact that either party exercises any right of termination it may have under this Agreement shall not prevent such party from pursuing any other remedy it may be entitled to in law or equity. Any remedy provided herein shall not be deemed an exclusive remedy unless expressly provided for as such.

4.3. **Execution, Amendment, and Waiver.** This Agreement shall be binding only upon signature by both parties. This Agreement, or any provision, may be altered, amended, or waived by a written amendment executed by both parties as authorized by CMS.

5. Miscellaneous

5.1. **Record Keeping and Audit.** During the term of this Agreement and for a period of five (5) years thereafter, both parties to the Agreement shall use reasonable efforts at all

times to ensure that they maintain accurate books, files and records relevant to this Agreement. At Manufacturer's written request, State or its agent shall make such information available for inspection by Manufacturer representatives or its designated auditors during regular business hours. Upon written request, each party shall otherwise have the right to inspect, up to once each year, all such relevant books, and records of the other party to verify compliance with the terms of this Agreement.

5.2. Indemnification. Manufacturer shall be responsible for and shall indemnify and hold State harmless from all claims resulting from the acts or omissions of Manufacturer and any Subcontractor of the Manufacturer in its performance of this Agreement.

5.3. Confidentiality. Except as otherwise may be required to be disclosed by law and in accordance with the CMS Agreement between the Secretary of Health and Human Services and the drug manufacturers, information disclosed by Manufacturer in connection with this Agreement will not be disclosed by the State. The State finds that the provisions of Attachment A to this Agreement comprise files that if disclosed would give advantage to competitors or bidders. Each party shall maintain the confidentiality of all the terms and conditions of this Agreement throughout the term hereof and for a period of five (5) years thereafter.

5.3.1. Patient Information. State, its agents, employees and contractors shall not provide to Manufacturer any patient identifiable information or protected health information or any other information prohibited or regulated by laws or regulations governing confidentiality of medical or other information.

5.4. Notices. Except for any notice of alleged breach under Subsection 4.1.1, All written notices, requests and communications, unless specifically required to be given by a specific method, may be: (i) delivered in person, obtaining a signature indicating successful delivery; (ii) sent by a recognized overnight delivery service, obtaining a signature indicating successful delivery; or (iii) sent by certified mail, obtaining a signature indicating successful delivery, to the address set forth below. Notwithstanding the forgoing, notices other than those pertaining to contract termination, amendment, and assignment, which may include, but not be limited to State Supplemental Rebate invoices, shall not be subject to the formal "notice" requirements, and may be transmitted by State or its designee to the Manufacturer via US Mail or electronic means, which may include, without limitation, facsimile or electronic mail, and any electronic communication shall be considered received as of the date/time of such electronic transmission by the sender:

State

Attn: _____

Manufacturer

Attn: _____

- 5.5. Force Majeure.** Noncompliance with any obligations hereunder due to force majeure, such as acts of God, laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, earthquake or 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.
- 5.6. Assignment.** Neither party shall have the right to assign this Agreement to a third party without the prior written consent of the other party, which consent shall not be unreasonably withheld. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any party of responsibility for the performance of any obligations that have accrued prior to such assignment.
- 5.7. No Waiver of Rights.** The failure of either party to insist upon the strict observation or performance of any provision of this Agreement or to exercise any right or remedy shall not impair or waive any such right or remedy in the future. Every right and remedy given by this Agreement to the parties may be exercised from time to time as often as appropriate.
- 5.8. Entire Agreement.** This Agreement contains the entire agreement and understanding of the parties. This Agreement may not be amended except upon the written agreement of both parties.
- 5.9. Governing Law.** The laws of the State of Arkansas shall govern this Agreement. In the event of a lawsuit involving this Agreement, venue shall be proper only in Pulaski County, Arkansas.
- 5.10. Effect of Future Laws.** For purposes of this section “Future Laws” means any enactment or rule promulgation, and any final legal or administrative determinations made by a court or tribunal of competent jurisdiction that materially impairs any party’s ability or obligation to carry out its obligations or receive consideration due under this Agreement. “Future laws” does not include changes to the federal Medicaid rebate program unless those changes expressly govern state supplemental rebate agreements. In the event of the occurrence of a Future Law, each party shall have the right to enter into good faith negotiations with the other in order to seek to agree on reasonable terms for maintaining the intent of the Agreement. Agreement on any such terms shall be at the sole discretion of each party. If the parties do not agree within sixty (60) days of a party’s written request for negotiations, either party may terminate this Agreement with respect to the affected Covered Products upon expiration of the sixty (60) day period, with immediate effect.

5.11. Compliance with Law. In connection with its respective obligations under this Agreement, each party shall comply with all applicable federal, state and local laws and regulations, including without limitation any disclosure or consent requirements.

5.12. Authority. State and Manufacturer each represent and warrant to the other that the person signing below has all requisite legal power and authority to execute this Agreement on behalf of each party and each party shall thereby be bound.

5.13. Best Price Contingency. The effectiveness of this Agreement shall be contingent on Manufacturer's Best Price and AMP not being affected by State Supplemental Rebates.

5.14. CMS Approval Contingency. The effectiveness of this Agreement shall be contingent on receipt of CMS approval by State, as evidenced by the CMS authorization of supplemental rebate agreement, attached hereto as Attachment D and incorporated by reference.

IN WITNESS WHEREOF, this Agreement has been executed by the parties set forth below:

Manufacturer

**State of Arkansas Department of
Human Services Division of Medical
Services**

Name

Name

Title: _____

Title: _____

Date: _____

Date: _____

NET COST

**ATTACHMENT A
Covered Products**

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

LABEL NAME	NDC	POSITION	CALC TYPE	DISCOUNT PER UNIT

The Discount Per Unit is determined based on the following variables:

The product position (1 of 1, 1 of 2 etc.) of a Supplemental Covered Product will be determined as compared to the PDL status of the other products listed within its Product Category.

Positioning: For [Insert Supplemental Covered Product Name] and associated NDCs, the following terms shall apply:

- Position 1: [Insert detailed description of positioning offer from Manufacturer]
- Position 2: [Insert detailed description of positioning offer from Manufacturer]
- Position 3: [Insert detailed description of positioning offer from Manufacturer]

ATTACHMENT B

Calculation of State Supplemental Rebate Payment

The State Supplemental Rebate per unit (SRPU) for each Covered Product shall be calculated each quarter as follows:

1. **WAC Based GNUMP: (SRPU) = WAC per Unit minus CMS Unit Rebate Amount minus Discount Per Unit.**

Or

2. **Alternative Calculation Type ['CALCULATION TYPE']** (if different than WAC Based GNUMP defined above): SRPU = [FORMULA]

(SRPU) will be greater than or equal to zero.

State Supplemental Rebate amount due = State Supplemental Rebate amount per Unit times State Utilization.

The "Discount Per Unit" is determined based on the following variables:

The product position (1 of 1, 1 of 2 etc.) of a Supplemental Covered Product will be determined as compared to the PDL status of products listed within its Product Category. Manufacturer will pay State Supplemental Rebates on Supplemental Covered Products associated with their Product's(s') position held from the first day in which the PDL was in effect or Supplemental Covered Product was listed on the PDL as a preferred drug. In addition, should the number of Supplemental Covered Products change during the applicable quarter, for the purpose of invoicing, the preferred count shall be determined by the number of Supplemental Covered Products during the majority of the preferred period. By way of example; In 1st quarter, Supplemental Covered Products A and B are preferred and invoiced at the Discount Per Unit corresponding with the 1 of 2 position. In the 2nd quarter, Supplemental Covered Product C is added to the PDL during the first 30 days of the quarter. Upon invoicing, Supplemental Covered Products A, B and C will all be invoiced at the 1 of 3 position (Supplemental Covered Product A and B invoiced for 90 days and Supplemental Covered Product C invoiced for 60 days). Conversely, in 3rd quarter, Supplemental Covered Product C is removed from the PDL during the first 30 days of the quarter. Upon invoicing, Supplemental Covered Products A and B will be invoiced at the 1 of 2 position while Supplemental Covered Product C is invoiced at the 1 of 3 position (Supplemental Covered Product A and B invoiced for 90 days and Supplemental Covered Product C invoiced for 30 days).

ATTACHMENT C

Attestation of Inclusion/Exclusion of Medicaid MCOs

The State of Arkansas hereby represents and warrants the following with respect to Participating Medicaid MCOs (**must check one**):

Effective for utilization dispensed to Participating Medicaid MCO members on or after _____ [DATE*], the State will include utilization of Participating Medicaid MCO(s) for Supplemental Rebates under this Agreement for:

all preferred Supplemental Covered Products, OR

limited to the following Supplemental Covered Product(s) or Product Category(ies):

1. _____
2. _____

I certify on behalf of the State that the State Medicaid Plan permits the inclusion of Participating Medicaid MCO utilization in Supplemental Rebates, and that the State’s contracts with MCOs do not prohibit such inclusion. I further certify on behalf of the State that the State has reasonably determined that: (i) the utilization of any Participating Medicaid MCO submitted hereunder is eligible for CMS Rebates under 42 U.S.C. § 1396r-8 and (ii) each Participating Medicaid MCO shall align their respective formulary(ies) and/or preferred drug list(s), as applicable, assuring access to preferred Supplemental Covered Product is no more restrictive than the State PDL requirements for any period with respect to which the State will invoice for Supplemental Rebates for utilization under this Agreement. It is the intent and expectation of the Medicaid Program that Supplemental Rebates hereunder shall be excluded from Manufacturer’s calculation of Best Price or AMP. ***If this option is checked, the State must have documented the above determination via applicable regulation, law, contract, or other formal state agency issuance and the State must attach hereto: (1) a copy of such documentation, as well as (2) a copy of the applicable State Medicaid Plan (and/or amendment thereto) permitting the election of this option.***

The State will exclude utilization from all of its Medicaid MCO(s) under this Agreement.

The State has no Participating Medicaid MCOs.

MANUFACTURER CONSENT SHALL NOT BE REQUIRED FOR THE STATE TO AMEND THIS ATTACHMENT C.

So Certified:

State: _____

By: _____

Title: _____

Date: _____

**Effective date for including MCO utilization shall not predate the date this Attachment C is executed by the State.*

ATTACHMENT D
CMS Authorization of Supplemental Rebate Agreement

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-01-16
Baltimore, Maryland 21244-1850



Center for Medicaid and State Operation

NOV 23 2004

Mr. Mike R. Jeffus
Director, Division of Medical Services
P.O. Box 1437, Slot S295
Little Rock, Arkansas 72203-1437

RECEIVED

NOV 30 2004

**PROGRAM PLANNING
& DEVELOPMENT**


Dear Mr. Jeffus:

We have reviewed Arkansas's State Plan Amendment (SPA) 04-04 submitted to the Dallas Regional Office on August 31, 2004. This SPA provides for the use of a new single-state Medicaid supplemental rebate agreement (SRA) and an evidence-based preferred drug list (PDL). We have determined that the SPA, PDL and SRA are consistent with the objectives of the Medicaid program. Based on the information provided, we are pleased to inform you that Arkansas SPA 04-04 is approved, effective October 15, 2004.

Approval of SPA 04-04 extends only to the SRA that was submitted to CMS on November 16, 2004, which is specifically referenced in the SPA. If changes are subsequently made to that drug rebate agreement, a new SPA and the revised agreement should be submitted to CMS for review and approval.

A copy of the CMS-179 form, as well as the pages approved for incorporation into the Arkansas state plan, will be forwarded by the Dallas Regional Office. If you have any questions regarding this amendment, please contact Claire Hardwick at (410) 786-6777.

Sincerely,


Larry Reed
Co-Leader
Pharmacy Team

cc: Andrew Frederickson, ARA, Dallas Regional Office
Michael Jones, Dallas Regional Office
JP Peters, Dallas Regional Office