

**ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM
SUPPLEMENTAL DRUG-REBATE AGREEMENT
AHCCCS AGREEMENT # _____**

1. PARTIES/PERIOD

- 1.1. This Supplemental Drug-Rebate Agreement (“Agreement”) is made and entered into this _____ day of _____, by and between the Arizona Health Care Cost Containment System (“State”), represented by the Director of Pharmacy (“DOP”), and _____ (“Manufacturer”), Labeler Code(s) _____. The parties, in consideration of the covenants, conditions, agreements, and stipulations expressed in this Agreement, do agree as follows:

2. PURPOSE

- 2.1. It is the intent of this Agreement that the State will receive Supplemental Rebates, in addition to the rebates received under Manufacturer’s CMS Agreement, pursuant to Section 1927 of the Social Security Act (42 U.S.C. §1396r-8), for the Manufacturer's Supplemental Covered Product(s) quarterly utilization in the Arizona Medicaid Program, including all Fee-For-Service and Managed Care beneficiaries, in which there is Medicaid federal financial participation. The parties also intend for this Agreement to meet the requirements of federal law at Section 1927 of the Social Security Act (42 U.S.C. §1396r-8).

3. DEFINITIONS

- 3.1. 'Average Manufacturer Price' (AMP) means the Manufacturer's price for the Covered Product(s) calculated as specified in Manufacturer's CMS Agreement.
- 3.2. 'Best Price' shall mean Best Price as set forth in the CMS Agreement, 42 U.S.C. §1396r-8, and regulations promulgated by CMS thereto, if any, as such Agreement, statute or regulations may be amended from time to time, excluding State Supplemental Rebate amounts.
- 3.3. 'Covered Product(s)' means the pharmaceutical product(s) of the Manufacturer subject to the CMS Agreement.
- 3.4. 'CMS Agreement' means the Manufacturer's drug rebate agreement with the Secretary of the United States Department of Health and Human Services, entered into pursuant to Section 1927 of the Social Security Act (42 U.S.C. §1396r-8).
- 3.5. 'CMS Basic Rebate' means, with respect to the Covered Product(s), the quarterly payment by the 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. §1396r-8(c)(3)].
- 3.6. 'CMS CPI Rebate' means, with respect to the Covered Product(s), the quarterly payment by Manufacturer pursuant to Manufacturer's CMS Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act [42 U.S.C. §1396r-8(c)(2)].
 - 3.7. 'CMS Unit Rebate Amount' means, the unit amount computed by CMS pursuant to the CMS calculation to which the Medicaid utilization information may be applied by states in invoicing the Manufacturer for the rebate payment due under the CMS Agreement and/or this Agreement.
 - 3.8. 'Manufacturer' means, for purposes of this Agreement, the non-state party to this Agreement, which may be a pharmaceutical manufacturer, labeler or other entity not prohibited by law from entering into this Agreement, as identified in Section 1.1 of this Agreement.
 - 3.9. 'Net Cost Per Unit' or 'Net Cost' means, with respect to the Supplemental Covered Product(s), the amount per National Drug Code ID number agreed upon by the parties to this Agreement and set forth in the attached Addendum A.
 - 3.10. 'Pharmacy Provider' means an entity or person reimbursed for the legend drugs they are licensed or permitted by law to dispense or administer, and who are enrolled as a State Medicaid Provider.
 - 3.11. 'CMS Rebate' means, with respect to the Covered Product(s), the quarterly payment made by the Manufacturer to states as detailed in Sections 3.5, 3.6, and 4.1 of this Agreement.
 - 3.12. 'State Utilization Data' means the data derived from reimbursement by the State and its Contractors to pharmacy providers under the Arizona Medicaid Program. State Utilization Data excludes data from covered entities identified in Title 42 U.S.C. §256b(a)(4) in accordance with Title 42 U.S.C. §256b(a)(5)(A) and 1396r-8(a)(5)(C).
 - 3.13. 'Supplemental Covered Product(s)' means the Manufacturer's Covered Product(s), as listed in the attached Addendum A, that are the subject of this Agreement and for which the Manufacturer has agreed to pay Supplemental Rebates. These are the Manufacturer's Covered Product(s) that received preferred status on the Arizona Medicaid Preferred Drug List as a result of this Agreement.
 - 3.14. 'Supplemental Rebate Amount Per Unit' means, with respect to the Supplemental Covered Product(s), the amount(s) by National Drug Code ID number, as specified in the attached Addendum A, that the Manufacturer has agreed to reimburse the State per unit of Supplemental Covered Product in accordance with the formula detailed in the attached Addendum A.
 - 3.15. 'Rebate Summary' means the report itemizing the State Utilization Data supporting the State's invoice for Supplemental Rebates. The Rebate Summary will comply in all respects with the requirements for Medicaid Utilization Information in the CMS Agreement.

- 3.16. 'Supplemental Rebate' means, with respect to the Supplemental Covered Product(s), the quarterly payment made by the Manufacturer pursuant to Section 4.2 of this Agreement.
- 3.17. 'Wholesale Acquisition Cost' or 'WAC' means the Manufacturer's U.S. Dollar wholesale acquisition price in effect on the last day of the applicable quarter on a per unit basis, as published by a third party source, such as First Databank or MediSpan, for each product and is understood to represent the Manufacturer's published price for a drug product to wholesalers. Any dispute as to the applicable WAC shall be conducted in accordance with the dispute provisions contained herein.
- 3.18. 'NDC' means the National Drug Code of a Product.
- 3.19. 'GNUP' means the Guaranteed Net Unit Price.
- 3.20. 'MCO' means Managed Care Organization.
- 3.21. "Addendum A" means an attached document labeled Addendum A that lists the supplemental rebate terms for specific drugs covered under the agreement and the effective date of the agreement.

4. MANUFACTURER'S RESPONSIBILITIES

- 4.1. Manufacturer will calculate and provide the State a CMS Rebate for the Covered Product(s), which includes the CMS Basic Rebate and CMS CPI Rebate, as appropriate. The CMS Rebate will be calculated in accordance with Manufacturer's CMS Agreement. Manufacturer's obligation for CMS Rebates will continue for the duration of the Manufacturer's CMS Agreement and is not affected by this Agreement.
- 4.2. In addition to the CMS Rebates described in Sections 3.5, 3.6, and 4.1 of this Agreement, Manufacturer will remit to the State Supplemental Rebates for the Supplemental Covered Product(s) utilization in the Arizona Medicaid Program. For drugs covered under this contract for Supplemental Rebates, the manufacturer may not provide a rebate for utilization of these contracted drugs to an AHCCCS Contracted Managed Care Organization or its Contractors. The Supplemental Rebates will be calculated on a calendar quarter based on an invoice and supporting Rebate Summary provided by the State or the State's vendor to the Manufacturer's CMS financial contact. The invoice will reflect the State's calculation of the Supplemental Rebate for the quarter which will be determined by multiplying the number of units of each of the Supplemental Covered Product(s) (by NDC#) reimbursed by the State or its Contractors, for Arizona Medicaid utilization, in the preceding quarter by its corresponding Supplemental Rebate Amount Per Unit, as listed in Addendum A attached hereto, and summing the products of said multiplication(s).

- 4.3. The Manufacturer will pay the Supplemental Rebate(s) set forth in this Agreement for utilization of the Supplemental Covered Product(s) during the time period which this Agreement remains in effect.
- 4.4. The quarters to be used for calculating the Supplemental Rebates in Section 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.
- 4.5. Manufacturer shall submit the Supplemental Rebate payment within thirty-eight (38) days of the Manufacturer's receipt of the Rebate Summary from the State.
- 4.6. Manufacturer will pay the Supplemental Rebate(s), including any applicable interest at the rate described in Section 1903 (d)(5) of the Act. Interest on the Supplemental Rebates payable under Section 4.2 of this Agreement begins accruing thirty-eight (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. If the date of mailing of the Supplemental Rebates payable under Section 4.2 of this Agreement is sixty-nine (69) days or more from the date of mailing of the invoice, the interest rate will be calculated as required under federal guidelines for rebates described in Sections 3.5, 3.6 and 4.1. If the State has not received the Supplemental Rebates payable under Section 4.2 of this Agreement, including any applicable interest, within one hundred eighty (180) days of the postmark date of the State's invoice and supporting Rebate Summary sent to Manufacturer, this Agreement will be deemed to be in default and the State may terminate this Agreement by providing the Manufacturer with written notice of termination. Said notice of termination shall cite this section of the Agreement and the termination shall not affect Manufacturer's obligation to remit Supplemental Rebates for utilization of Manufacturer's Supplemental Covered Products that occurred prior to the termination of this Agreement.
- 4.7. Manufacturer agrees to continue to pay Supplemental Rebates on the Supplemental Covered Product(s) for as long as this Agreement is in force and the State Utilization Data shows that payment was made for the Supplemental Covered Product(s), regardless of whether the Manufacturer continues to market the Supplemental Covered Product(s). Notwithstanding the above, in the event Manufacturer sells or transfers its right to sell a Supplemental Covered Product(s) and ceases to manufacture, sell, label, and market the Supplemental Covered Product(s), Manufacturer may assign its obligations under this Agreement with respect to said Supplemental Covered Product(s) to the Supplemental Covered Product(s)'s new owner. However, Manufacturer shall continue to have liability under this Agreement for the same period of time that Manufacturer has liability for CMS Rebates under Manufacturer's CMS Agreement for said assigned Supplemental Covered Product(s). Manufacturer shall provide the State with

notice of the sale of said Supplemental Covered Product(s) and any assignment of the obligations under this Agreement concurrent with Manufacturer’s notice to CMS. If the obligations under this Agreement with respect to a Supplemental Covered Product are assigned pursuant to this Section, Manufacturer shall provide the State with an update of the information contained in Section 9.3 herein with respect to the Supplemental Covered Product(s)’s new owner.

- 4.8. Unless notified otherwise, Manufacturer shall send Supplemental Rebate payments to the following address:

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| <u>Please make your checks payable to:</u> Arizona Health Care Cost Containment System (AHCCCS) | |
| <u>Post Master Address:</u> State of Arizona P.O. BOX 741573 Atlanta, GA 30374-1573 | <u>Courier Delivery Address:</u> Bank of America Lockbox Services Lockbox #741573 6000 Feldwood Road College Park, GA 30349 |

5. STATE RESPONSIBILITIES

- 5.1. Subject to the concurrence of the State Pharmacy and Therapeutics Committee, the State will classify Manufacturer’s Supplemental Covered Product(s) as “preferred” in the Arizona Medicaid Preferred Drug List. The State may determine, as a result of a therapeutic class review, that prior authorization is required for all preferred drugs in a therapeutic class. If prior authorization is required for any Supplemental Covered Product, the State will comply with all provisions of section 1927(d) of the Social Security Act applicable to Prior Authorization programs.
- 5.2. The State will provide aggregate State Utilization Data to Manufacturer on a quarterly basis. This data will be based on paid claims and encounters data (data used by AHCCCS and its Contractors’ PBM’s to reimburse pharmacy providers) under the Arizona Medicaid Program, will be consistent with any applicable Federal or State guidelines, regulations and standards for such data, and will be the basis for the State's calculation of the Supplemental Rebate(s).
- 5.3. The State and its rebate contractor will maintain data systems necessary to calculate the Supplemental Rebate(s). In the event material discrepancies are discovered, the State and its rebate contractor will promptly justify its data or make an appropriate adjustment, which may include a credit as to the amount of the Supplemental Rebates, or a refund to Manufacturer as the parties may agree.
- 5.4. The State shall maintain electronic or other claims records, for such time periods as are required by CMS to permit verification of the calculation of CMS Rebates, to permit Manufacturer to verify through an audit process the Rebate Summaries provided by the State. Any audit

conducted, pursuant to this Section 5.4, shall be conducted by independent auditors, at the Manufacturer's expense, during regular business hours and not more often than one (1) time per calendar year. The independent auditors shall provide at least thirty (30) days prior written notification of their intent to audit. The State shall make available to the independent auditors such records as are required to demonstrate the accuracy of the claims submitted to the Manufacturer under this Agreement. The independent auditors may be required to enter into confidentiality agreements with the State and the Manufacturer as necessary to comply with state and federal laws and regulations governing the privacy of individual or other health information or information that is proprietary and/or confidential. The independent auditors will not be provided access to information related to or from other manufacturers.

- 5.5. Upon implementation of this Agreement, and from time to time thereafter, the State and Manufacturer may 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 State to the Manufacturer are adequate for the purposes of this Agreement.
- 5.6. The State shall obtain CMS approval of its state Medicaid plan, including the State's establishment of its Medicaid preferred drug list/supplemental-drug rebate program under which the Supplemental Rebates contracted for herein will be paid. Manufacturer shall not be required to remit any Supplemental Rebates that have accrued and are due prior to the effective date of the CMS approval provided for in this Section. The State will provide Manufacturer, within thirty (30) days of receipt, a copy of the CMS document authorizing State's Medicaid preferred drug list/supplemental-drug rebate program.

6. DISPUTE RESOLUTION

- 6.1. In the event that in any quarter the State Utilization Data is questioned by the Manufacturer, which discrepancy the Manufacturer and the State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy to the State.
- 6.2. If the Manufacturer in good faith believes the State Utilization Data is erroneous, the Manufacturer shall pay the State that portion of the Supplemental Rebate claimed, that is not in dispute by the required date in Section 4.6. The balance in dispute, if any, will be paid by the Manufacturer to the State by the due date of the next quarterly payment after resolution of the dispute.
- 6.3. The State and the Manufacturer will use their best efforts to resolve any discrepancy within sixty (60) days of receipt of written notification. Should additional information be required to resolve disputes, the State will cooperate with the Manufacturer in obtaining the additional information.

- 6.4. In the event that the State and the Manufacturer are not able to resolve a discrepancy regarding State Utilization Data as provided for in Sections 6.1 through 6.3, the Manufacturer may request a reconsideration of the State's determination within thirty (30) days after the end of the sixty (60) day period identified in Section 6.3. The Manufacturer shall submit to the State, along with its written request, its argument in writing, along with any other materials, supporting its position.
- 6.5. In the event that the State and the Manufacturer are unable to resolve a discrepancy regarding State Utilization Data as provided for in Sections 6.1 through 6.4, the parties will utilize the same State procedure that is used to resolve disputes under the Medicaid Rebate Program, consistent with CMS' *Best Practices Guide for Dispute Resolution Under the Medicaid Drug Rebate Program*.

7. CONFIDENTIALITY PROVISIONS

- 7.1. Subject to 42 U.S.C. 1396r-8(b)(3)(D), other relevant federal and state laws, and the parties agreement herein, the parties agree that this Agreement and all information provided pursuant to this Agreement will not be disclosed and that the parties will not duplicate or use the information, except in connection with this Agreement or as may be required by statute, regulation, or judicial order. The State further agrees it will not voluntarily disclose any information provided by the Manufacturer to the State, or any agent of either party pursuant to this Agreement, including pricing information and this Agreement itself. The State will oppose any public records request or subpoena on the basis that the information and this Agreement itself constitute confidential commercial and financial information. Confidential information, including but not limited to trade secrets, Best Price information, Net Cost information, GNUP, WAC, AMP, other pricing information, utilization data and this Agreement itself will not be disclosed, or used except in connection with this Agreement or as may be required by statute, regulation, or judicial order. In the event an attempt is made to compel either party to divulge confidential and/or proprietary information related to this Agreement, said party shall notify the other party to this Agreement in a prompt manner to allow the other party to seek injunctive or other relief prohibiting the disclosure of such information.
- 7.2. The Manufacturer will hold the State Utilization Data 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 State Utilization Data to auditors who must agree to keep such information confidential.
- 7.3. Notwithstanding the non-renewal or termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect.

8. TERM OF AGREEMENT

- 8.1. This Agreement shall be effective beginning on the date notated in Addendum A, but not prior to January 1, 2015 and shall remain in effect for a period of twelve (12) months. This Agreement shall automatically renew for additional one (1) year periods unless terminated.
- 8.2. On or before ninety (90) days prior to the expiration date, either party may provide written notice of its intent not to renew this Agreement. Nothing contained herein shall prevent Manufacturer and State from mutually agreeing to the amending of this Agreement to increase the Supplemental Rebates and/or add additional Supplemental Covered Products to this Agreement.
- 8.3. Notwithstanding any non-renewal or termination of this Agreement, Supplemental Rebates shall continue to be due and payable from the Manufacturer under Section 4.2 for any Supplemental Covered Product(s) utilization for which the State and its Contractors' obligation to reimburse arose prior to the effective date of termination of this Agreement.

9. GENERAL PROVISIONS

- 9.1. This Agreement will be construed and interpreted in accordance with the laws of the State of Arizona and 42 U.S.C. §1396r-8.
- 9.2. Any notice required to be given pursuant to the terms and provisions of this Agreement shall be sent in writing to:

Arizona Health Care Cost Containment System
Attn: Suzanne Berman, RPh, Director of Pharmacy
801 E. Jefferson, MD5000
Phoenix, AZ 85034
Suzanne.Berman@azahcccs.gov

- 9.3. Notice to Manufacturer will be sent to:

_____ (Name)
_____ (Title)
_____ (Company Name)
_____ (Address)
_____ (email)

- 9.4. Nothing herein shall be construed or interpreted as limiting or otherwise affecting the State'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. Proper venue and jurisdiction for any legal action relating to this Agreement shall be in the State of Arizona.
- 9.5. 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.
- 9.6. Manufacturer may not assign this Agreement, either in whole or in part, without the written consent of the State except as provided for in Section 4.7. However, in the event of a transfer in ownership of the Manufacturer, the Agreement is automatically assigned to the new owner, subject to the terms and conditions of this Agreement. If the Agreement is assigned pursuant to this Section, Manufacturer shall provide the State with an update of the information contained in Section 9.3, *supra*.
- 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 or state 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 agreement as is possible.
- 9.8. The State and Manufacturer declare that this Agreement, including attachments and Addenda/Addendum, 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. This Agreement will not be altered except by an amendment in writing signed by both parties. No individual is authorized to alter or vary the terms or make any representation or inducement relative to it, unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the State and Manufacturer.
- 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's negligent or willful misconduct in the performance of this Agreement. State must provide the Manufacturer with prompt written notice of any claim or action alleging such liability and State must cooperate fully in the defense of such claim or action. Manufacturer is authorized to manage and defend such claim or action and no such claim or action may be compromised or settled without the prior written approval of Manufacturer unless State first relieves Manufacturer of its liability hereunder.

- 9.11. In as much as the Supplemental Rebate(s) required by this Agreement are for Arizona Medicaid Program beneficiaries, it is agreed, in accordance with Medicaid Drug Rebate Program Release #102 For State Medicaid Directors and other applicable law, that the Supplemental Rebate(s) do not establish a new 'Best Price' for purposes of Manufacturer's CMS Agreement.
- 9.12. In the event that the State requires prior authorization of Manufacturer's Supplemental Covered Product(s) consistent with Section 5.1, this Agreement remains in force. If, however, a Supplemental Covered Product(s) of the Manufacturer should require prior authorization, and the Supplemental Covered Product is disadvantaged as compared to other competitive branded products in the therapeutic class, the State shall notify the Manufacturer and the parties agree that the affected Supplemental Covered Product (by NDC) shall be removed from this Agreement upon Manufacturer's written request. Said removal shall be retroactive to the date the affected Supplemental Covered Product (by NDC) was subjected to prior authorization.

IN WITNESS THEREOF, THE PARTIES AGREED AND ACCEPTED:

| MANUFACTURER | AHCCCS |
|---------------------|---------------|
| Signature: | Signature: |
| Printed: | Printed: |
| Title: | Title: |
| Date: | Date: |