

**AGREEMENT BETWEEN
OKLAHOMA HEALTH CARE AUTHORITY
AND**

Based upon the following recitals the Oklahoma Health Care Authority (hereinafter referred to as OHCA) and _____, FEIN _____ (hereinafter referred to as Manufacturer), enter into this Agreement.

ARTICLE I. PURPOSE

1.0 The purpose of the Agreement is for the Manufacturer to establish supplemental rebates for utilization of the Manufacturer’s Preferred Product(s) which are reimbursed by the OHCA.

ARTICLE II. THE PARTIES

2.0 OKLAHOMA HEALTH CARE AUTHORITY

- (a) OHCA is the single state agency designated by the Oklahoma Legislature through 63 O.S. § 5009(B) to administer Oklahoma’s Medicaid Program, known as SoonerCare.
- (b) OHCA has authority to enter into this Agreement pursuant to 63 O.S. § 5006(A) 2 OHCA’s Chief Executive Officer has authority to execute this Agreement pursuant to 63 O.S § 5008(B)4 and 5
- (c) OHCA states that its mailing address for purposes of the Agreement is as follows:
Oklahoma Health Care Authority
4345 N Lincoln Blvd
Oklahoma City, Oklahoma 73105-5101
Attention: Kerri Wade
Phone Number: (405) 522-7073
E-mail: kerri.wade@okhca.org

2.1 _____

- (a) Manufacturer states that it has the experience and expertise to perform the services required under this Agreement.
- (b) Manufacturer has the authority to enter this Agreement pursuant to its organizational documents, bylaws, or properly enacted resolution of its governing authority. The person executing this Agreement for Manufacturer has authority to execute this Agreement on Manufacturer’s behalf pursuant to the Manufacturer’s organizational documents, bylaws, or properly enacted resolution of Manufacturer’s governing authority.
- (c) Manufacturer states that its mailing address for purposes of this Agreement is as follows:

ARTICLE III. DEFINITIONS

- 3.0** "Agreement" means this Supplemental Rebate Agreement, including all documents attached or incorporated by reference.
- 3.1** "AAC" shall mean the Actual Acquisition Cost as calculated by a survey of invoice prices such as the National Average Drug Acquisition Cost (NADAC)
- 3.2** "AMP" shall mean the Average Manufacturer Price as set forth in 42 U.S.C. 1396r-8, as such statute may be amended from time to time.
- 3.3** "Best Price" shall mean Best Price as set forth in 42 U.S.C. 1396r-8, as such statute may be amended from time to time, excluding Medicaid State Supplemental Rebate amounts.
- 3.4** "CMS" shall mean the Centers for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration) of the United States Department of Health and Human Services, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.
- 3.5** "CMS Agreement" means Manufacturer's drug rebate contract with the Centers for Medicare & Medicaid Services, formerly known as the Health Care Financing Administration (CMS), entered pursuant to Section 1927 of the Social Security Act (42 USC 1396r-8).
- 3.6** "CMS Basic 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)(1) or Section 1927(c)(3) of the Social Security Act [42 USC 1396r-8(c)(1) and 42 USC 1396r-8(c)(3)].
- 3.7** "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 USC 1396r-8(c)(2)].
- 3.8** "Contract Quarter" means one of the quarters ending on March 31, June 30, September 30, and December 31 of each calendar year during the term of this Agreement.
- 3.9** "DUR Board" shall mean the Oklahoma Drug Utilization Review Board as defined by Title 63, Oklahoma Statutes, Section 5030."
- 3.10** "Federal Rebate" means the sum of the CMS Basic Rebate and the CMS CPI Rebate.
- 3.11** "Guaranteed Net Unit Price (GNUP)" means the final fixed price agreed upon by the parties to the Agreement. It shall be calculated as stated in the attached Schedule A.
- 3.12** "Manufacturer's Product(s)" means only the pharmaceutical product(s) stated in Schedule A of this Agreement.
- 3.13** "Medicaid State Supplemental Rebate" means, with respect to the Covered Product(s), the quarterly payment by Manufacturer pursuant to Section 5.1 and 5.2 of this Agreement.

- 3.14** “Medicaid Supplemental Rebates Workgroup” shall mean the group of OHCA employees and contract staff members who will evaluate rebate offers.
- 3.15** “New Product” shall mean any pharmaceutical product of Manufacturer that may be launched or otherwise become available from Manufacturer after the effective date of this Agreement.
- 3.16** “Oklahoma Medicaid” means 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.
- 3.17** “Oklahoma Medicaid Preferred Drug List” means the preferred drug list established for Oklahoma Medicaid fee-for-service and SoonerCare Choice pharmacy members. This list includes drugs subject to prior authorization requirements under OHCA regulations.
- 3.18** “Oklahoma Medicaid Member” shall mean any person enrolled in Oklahoma Medicaid and eligible to receive prescription drug benefits.
- 3.19** “Pharmacy” shall mean a facility licensed in accordance with the laws of the state in which the pharmacy is located or of the State of Oklahoma, as applicable, to dispense legend drugs, and contracted with the OHCA as a provider of pharmacy services to Medicaid members.
- 3.20** “Preferred Drug List (PDL)” refers to the preferred single source brands participating in the Supplemental Rebate program and generic products within the same therapeutic class.
- 3.21** “Single Source Brand Name” means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application. (42 USC 1398r-8(k)(7)(iv))
- 3.22** “SSDC” refers to the Sovereign States Drug Consortium who administers a Medicaid supplemental rebate program that allows participating states to pool their prescription utilization numbers to obtain supplemental rebates from pharmaceutical manufacturers.
- The updated SSDC rebate agreement between the State and participating manufacturers for drugs provided to the Medicaid program, submitted to CMS on November 4, 2019 supersedes the SSDC rebate agreement approved in OK SPA 20-0002. CMS has authorized the updated agreement. The updated agreement applies to drugs dispensed effective **January 1, 2020**.
- 3.23** “State Utilization Data” means the OHCA data which reflects reimbursement through Fee-for-Service programs to pharmacy providers or medical providers under the Oklahoma Medicaid Program. Fee-for-Service utilization information is based on claims paid during a Quarter. State Utilization Data excludes data from covered entities identified in Title 42 USC 256b(g)(4) in accordance with Title 42 USC 256b(a)(4)(A) and 1396r-8(a)(5)(C). State Utilization Data shall not include any Products dispensed or administered to Medicaid Members outside of the United States.
- 3.24** “Wholesale Acquisition Cost (WAC)” shall mean wholesale acquisition cost as of the last day of a Contract Quarter published by First Data Bank, MediSpan, Red Book, or any other national pricing compendia.

ARTICLE IV. GENERAL PROVISIONS

4.0 TERM OF THE AGREEMENT

- (a) The term of this Agreement shall begin on January 1, 2020 and end on December 31, 2020.
- (b) It is understood and agreed by the parties hereto that all obligations of OHCA, including the continuance of payments, are contingent upon the availability and continued appropriation of state and federal funds, and on CMS' written authorization of the Oklahoma Medicaid Supplemental Rebate Program. In no event shall OHCA be liable for any payments in excess of such available appropriated funds.

4.1 AMENDMENTS

This Agreement contains all of the terms and conditions of the parties and supersedes all prior agreements pertaining only to supplemental rebate agreements, written or oral, between the parties (except confidentiality agreements which shall survive execution hereof). No verbal representations by either party, which contradict the terms of this Agreement, are binding. Any amendments to this Agreement must be in writing, signed by both parties, and be approved in writing by CMS.

4.2 ASSIGNMENT

The parties shall not assign or transfer any rights or obligations under this Agreement without prior written consent of the other parties.

ARTICLE V. SCOPE OF WORK

Manufacturer shall:

- 5.0** Calculate and provide OHCA a CMS Rebate for the Covered Product(s), which includes the CMS Basic Rebate and CMS CPI Rebate, as appropriate. The CMS Rebate represents the discount to be obtained by multiplying the units of the covered product(s) dispensed or administered to Oklahoma Medicaid members in the United States in the preceding quarter by the per unit rebate amount provided to OHCA by CMS. CMS will calculate the CMS Rebate amount in accordance with Manufacturer's CMS Agreement. Manufacturer's obligation for CMS Rebates will continue for the duration of the Manufacturer's CMS Agreement.
- 5.1** Remit to OHCA a Medicaid State Supplemental Rebate for the Manufacturer's Product(s) such that the supplemental rebate amount received by OHCA shall follow the calculations as set forth on Schedule A. This Medicaid State Supplemental Rebate is in addition to the CMS Rebates described in Section 4.0 of the Agreement, Manufacturer's obligation for Medicaid State Supplemental Rebates will begin on the Effective Date; provided, however, that Manufacturer shall not pay any supplemental rebates until OHCA provides Manufacturer with written confirmation of: (a) CMS's written authorization of the Oklahoma Medicaid State Supplemental Rebate Program, and (b) CMS's finding that the Medicaid State Supplemental Rebate does not establish a new 'Best Price' for purposes of Manufacturer's CMS Agreement.
- 5.2** Utilization of Manufacturer's Products by Oklahoma Medicaid Members is subject to the Medicaid State Supplemental Rebates set forth in Schedule A to this Agreement.
- 5.3** If Manufacturer discontinues the manufacture, sale or distribution of any Manufacturer Product or decides to transfer or license any Manufacturer Product to a third party, then Manufacturer shall notify OHCA, such product shall be removed from the definition of

“Manufacturer Products”, and no discount shall be payable with respect to utilization of such product occurring after notice of such discontinuance and the product will be removed from the Preferred Drug List.

OHCA shall:

5.4 In consideration of the Medicaid State Supplemental Rebates provided under this Agreement, OHCA, directly and through its respective affiliates and agents, agrees that it will:

(a) Place and maintain all Manufacturer’s Products on the Oklahoma Medicaid Preferred Drug List with the status set forth in Schedule A;

(b) Not prefer, neither directly or indirectly, any competing Single Source Brand Name product over a Manufacturer’s Product, except for reasons of medical appropriateness or consistency with Schedule A, as applicable. This does not in any way limit or restrict other mechanisms that OHCA may use to insure proper utilization of Contractor’s Products, such as quantity or days supply limits;

(c) List all Manufacturer’s Products on all Oklahoma Medicaid Preferred Drug Lists (including but not limited to printed and electronic versions of the list) with the status specified in Schedule A, as applicable; within ten (10) business days of the Effective Date of this Agreement and at intervals of six (6) months

(d) Undertake independent actions that appropriately reflect the preferred status of and any plan benefit design attributes listed in Schedule A relevant to Manufacturer’s Products, including communication on a regular basis of the preferred status of Manufacturer’s Products to Oklahoma Medicaid physicians, pharmacists, and other appropriate parties (with a copy provided to Manufacturer);

(e) Provide Manufacturer with a copy of the Oklahoma Medicaid Preferred Drug List and internet web site addresses (if any) where such listings may be found within thirty (30) days of the Effective Date of this Agreement, and immediately upon making any changes to that portion of the Oklahoma Medicaid Preferred Drug List related to a therapeutic category in which a Manufacturer Product competes;

(f) Review for Preferred Drug List acceptance new Manufacturer’s products (including any products marketed by a Manufacturer Joint Venture) within six (6) months of notification by Manufacturer that the new product has been approved by the FDA and released for marketing if the new product belongs to a therapeutic class of drugs included in the Oklahoma Medicaid Preferred Drug List;

(g) Review for Preferred Drug List acceptance new Manufacturer’s products (including any products marketed by a Manufacturer Joint Venture) in a new therapeutic class within six (6) months of notification by Manufacturer that the new product has been approved by the FDA and released for marketing, only if the new product or new therapeutic class is selected for inclusion in the Oklahoma Medicaid Preferred Drug List;

(h) Review for Preferred Drug List acceptance new FDA-approved indications for Manufacturer’s Products (including any products marketed by a Manufacturer Joint Venture) within six (6) months of notification by Manufacturer that the FDA has approved a new indication for a Manufacturer’s Product only if the new indication places the product into a class of medications based on usage, chemical structure, therapeutic similarity, disease state, or treatment included in the Oklahoma Medicaid Preferred Drug List.

5.5 OHCA shall approve the content of all communications regarding Manufacturer Products independent of the influence, control or participation of Manufacturer, except as the parties otherwise agree in writing.

- 5.6 OHCA shall submit State Utilization Data to Manufacturer on a quarterly basis. The data will be based on paid claims data for the Oklahoma Medicaid Program. OHCA shall seek Medicaid State Supplemental Rebates only with respect to utilization of Manufacturer's Products that are eligible for a CMS Basic Rebate and CMS CPI Rebate.
- 5.7 OHCA warrants that it has received CMS authorization to receive Medicaid State Supplemental Rebates as provided under this Agreement and that Manufacturer's payment of Medicaid State Supplemental Rebates under this Agreement will not affect the Best Price or AMP used by Manufacturer to determine rebates paid pursuant to 42 U.S.C. 1396r-8.
- 5.8 OHCA represents and warrants that it has obtained any and all necessary consent(s) from any and all third parties, as required by law, regulation, ethical or professional code, contract, agreement or otherwise, to provide to Manufacturer all data required pursuant to Section 6.0 hereof.
- 5.9 OHCA warrants 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, OHCA warrants 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. OHCA currently provides CMS full and unfettered access to all information held by OHCA regarding the implementation of the Oklahoma Medicaid Program, and shall continue to do so throughout the implementation of the Medicaid State Supplemental Rebate and Oklahoma Preferred Drug List.

ARTICLE VI. LAWS APPLICABLE

- 6.0 The parties to this Agreement acknowledge and expect that changes may occur over the term of this Agreement regarding (i) federal Medicaid statutes and regulations, (ii) state Medicaid statutes and rules, and (iii) state statutes and rules governing practice of health-care professions. The parties shall be mutually bound by such changes.
- 6.1 As applicable the Manufacturer shall comply and certifies compliance with:
- (a) the Age Discrimination in Employment Act, 29 U.S.C. § 621 et seq.;
 - (b) the Rehabilitation Act, 29 U.S.C. § 701 et seq.;
 - (c) the Drug-Free Workplace Act, 41 U.S.C. § 701 et seq.;
 - (d) Subchapters XIX and XXI of the Social Security Act, 42 U.S.C. § 1396 et seq.;
 - (e) Title VI and VII of the Civil Rights Act, 42 U.S.C. §2000det seq. and §2000e et seq.;
 - (f) the Age Discrimination in Federally Assisted Programs, 42 U.S.C. § 6101 et seq.;
 - (g) Equal Opportunity for Individuals with Disabilities, 42 U.S.C. § 12101 et seq.;
 - (h) the Oklahoma Worker's Compensation Act, 85 O.S. § 1 et seq.;
 - (i) the Fair Labor Standards Act, 29 U.S.C. § 201 et seq.;
 - (j) the Equal Pay Act, 29 U.S.C. §206 d;
 - (k) the Vietnam Era Veterans Re-adjustment Act, 38 U.S.C §4212;
 - (l) 31 U.S.C. § 1352 and 45 C.F.R. § 93.100 et seq., which (1) prohibit use of federal funds paid under this Agreement to lobby Congress or any federal official to enhance or

protect the monies paid under this Agreement and (2) require disclosures to be made if other monies are used for such lobbying;

- (m) Presidential Executive Orders 11141, 11246 and 11375, which together require certain federal Manufacturers and subManufacturers to institute affirmative action plans to ensure absence of discrimination for employment because of race, color, religion, sex, or national origin;
- (n) 45 C.F.R. §76.105 and §76.110 concerning debarment, suspension and other responsibility matters;
- (o) 74 O.S. § 85.44(B) and (C) and 45 C.F.R. § 74.34 with regard to equipment (as defined by 2 C.F.R §220, §225, or §230 depending on the type of entity of the Manufacturer) purchased with monies received from OHCA pursuant to this Agreement; and
- (p) the Anti-Kickback Act of 1986; 41 U.S.C §8701 – 8707, which prohibits any person from providing or attempting to provide or offering to provide any kickback;
- (q) Federal False Claims Act, 31 U.S.C §3729-3733 and the Administrative Remedies for False Claims and Statements, 31 U.S.C. §3801; and
- (r) Oklahoma Taxpayer and Citizen Protection Act of 2007, 25 O.S. §1313 and participates in the Status Verification System. The Status Verifications System is defined at 25 O.S. §1312 and includes, but is not limited to, the free Employment Verification Program (E-Verify) available at www.dhs.gov/E-Verify.

6.2 The explicit inclusion of some statutory and regulatory duties in this Agreement shall not exclude other statutory or regulatory duties.

6.3 All questions pertaining to validity, interpretation, and administration of this Agreements shall be determined in accordance with the laws of the State of Oklahoma, regardless of where any service is performed. The Manufacturer further acknowledges that nothing contained in the Agreement shall be construed as a waiver of the immunity from liability, which would otherwise be available to the State of Oklahoma under the principles of sovereign immunity. In particular, the Manufacturer agrees that the sole and exclusive means for the presentation of any claim against the State arising out of this Agreement, shall be in accordance with all applicable Oklahoma statutes. The Manufacturer further covenants not to initiate legal proceedings in a State or Federal court in addition to, or in lieu of, any proceedings available under Oklahoma statutes.

6.4 The venue for civil actions arising from this Agreement shall be Oklahoma County, Oklahoma. For the purpose of Federal jurisdiction, in any action in which the State of Oklahoma is a party, venue shall be United States District Court for the Western District of Oklahoma.

6.5 If any portion of this Agreement is found to be in violation of State or Federal Statutes, that portion shall be stricken from this Agreement, and the remainder of the Agreement shall remain in full force and effect.

6.6 Any action against OHCA, including but not limited to, actions either for break of Agreement or for enforcement of its provisions, or both, shall be commenced within the period provided for in Title 12 O.S. §95. All defenses in law or equity shall be reserved to OHCA.

ARTICLE VII. AUDIT & INSPECTION

7.0 Manufacturer shall keep such records as are necessary to disclose fully the extent of service provided under this Agreement, and shall furnish records and information regarding any

claim for providing such service to OHCA, the (State Auditor & Inspector), CPD (Office of Management and Enterprise Services – Central Purchasing Division), the GAO (General Accounting Office), MFCU (Oklahoma Attorney General’s Medicaid Fraud Control Unit), and the U.S. Secretary of the Department of Health and Human Services (hereinafter referred to as Secretary) for seven years from the date of service. The Manufacturer shall not destroy or dispose of records, which are under audit, review or investigation when the seven-year limitation is met. Manufacturer shall maintain such records until informed in writing by the auditing, reviewing, or investigating agency that the audit, review or investigation is complete.

- 7.1 Authorized representatives of OHCA, SA&I, CPD, GAO, MFCU, and the Secretary shall have the right to make physical inspection of the Manufacturer’s location or facility and to examine records relating to financial statements or claims submitted by Manufacturer under this Agreement and to audit the Manufacturer’s financial records.
- 7.2 Pursuant to 74 O.S. § 85.41, OHCA, SA&I, CPD, GAO, and MFCU shall have the right to examine the Manufacturer’s books, records, documents, accounting procedures, practices, or any other items relevant to this Agreement. OHCA shall allow for the inspection of public records in accordance with the provisions of the Oklahoma Open Records Act.

ARTICLE VIII. CONFIDENTIALITY

- 8.0 OHCA agrees that under 42 U.S.C, § 1396r-8 (b)(3)(D) and 51 Okla. Stat. § 24A.13 that certain information will be shared with OHCA to comply with the federal approval of this agreement. Under federal law both “best price” and “average manufacturer price” may be given so that compliance with federal legislation may be achieved. OHCA agrees to comply with federal law cited above so that information disclosed to reach this agreement may not be disclosed. Further to the extent a Court determines that such information involves a “trade secret” as defined in 78 Okla. Stat. § 86 (4) OHCA agrees not to release the information that would lead to the release of this proprietary information.
- 8.1 To the extent that OHCA utilizes the services of a third-party to develop and maintain the Preferred Drug List and/or administer any portion of this Agreement, all provisions of Section 10.0 shall apply to the third-party, and OHCA shall have the third-party sign a written agreement ensuring the third-party’s compliance with all aspects of this Section 10.0 before disclosing any information to the third-party. This Section 10.0 shall survive termination or expiration of this Agreement.
- 8.2 The parties agree not to disclose, to each other or to any third party, any information protected as confidential information under state or federal law, including but not limited to information revealing the identity of Medicaid Members.
- 8.3 Manufacturer agrees that SoonerCare member information is confidential and is not to be released to the general public under 42 U.S.C. § 1396a(a)(7), 42 C.F.R. § 431:300-306 and 63 O.S. § 5018. Manufacturer agrees not to release the information governed by these SoonerCare member requirements to any other state agency or public citizen without the approval of OHCA.

- 8.4 Manufacturer agrees that SoonerCare member and provider information cannot be remarketed, summarized, distributed, or sold to any other organization without the express written approval of OHCA.
- 8.5 Manufacturer agrees to comply with the Federal Privacy Regulations and the Federal Security Regulations as contained in 45 C.F.R §§160 – 164 that are applicable to such party as mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and 42 U.S.C. §§1320d et. seq..
- 8.6 Manufacturer must report a known breach of confidentiality, privacy, or security, as defined under HIPAA, to OHCA Privacy and Confidentiality Officer within 48 hours of knowledge of an unauthorized act. Failure to perform may constitute immediate termination of Agreement.
- 8.7 Manufacturer must report potential known violations of 21 O.S. §1953 to OHCA Legal Division within 48 hours of knowledge of an unauthorized act. In general, this criminal statute makes it a crime to willfully and without authorization gain access to, alter, modify, disrupt, or threaten a computer system.
- 8.8 Manufacturer shall provide encrypted e-mail communication when PHI is transmitted to OHCA. No direct connection of Virtual Private Network (VPN) to OHCA will be used for this purpose nor will OHCA use individual e-mail certificates for its staff. Such encrypted e-mail will require a X.509 certificate that can be collected by the existing OHCA e-mail encryption system, so that e-mails can be decrypted automatically by OHCA. OHCA shall provide no additional hardware/software to the Manufacturer for this purpose nor accept any Manufacturer provided hardware/software.

ARTICLE IX. PAYMENTS/REIMBURSEMENTS

Manufacturer shall:

- 9.0 Make payment of Medicaid State Supplemental Rebates due under Article IV herein within 30 days after receipt by Manufacturer of complete and accurate State Utilization Data as set forth above and provided the conditions of Section 4.0 (b) have been met. If the Medicaid State Supplemental Rebate due is not paid within 90 days after receipt of complete and accurate State Utilization Data, Manufacturer shall be considered to be in default of this Agreement and all Manufacturer Products shall be removed from the Oklahoma Medicaid Preferred Drug List.
- 9.1 Provide OHCA at the time of each discount payment reconciliation statements. OHCA is aware of this process with respect to reporting CMS Basic Rebates and CMS CPI Rebates under the terms of the CMS Agreement and agrees to use the reconciliation statements to accurately report to CMS the CMS Basic Rebates, CMS CPI Rebates, and Medicaid State Supplemental Rebates for each Manufacturer's Product for which a discount has been paid under this Agreement, to the extent required under applicable federal or state law.

OHCA shall:

- 9.2 Deliver to Manufacturer, in a mutually acceptable electronic format, State Utilization Data and State Utilization Data to Manufacturer in the same manner within 60 days following the close of each Contract Quarter. Submit at the same time the State Utilization Data for the CMS Rebate under Oklahoma Medicaid. Manufacturer is not required to pay Medicaid State Supplemental Rebates with respect to utilization that occurred during a Contract Quarter for

which complete and accurate State Utilization Data is received by Manufacturer more than 180 days following the close of that Contract Quarter.

- 9.3** Return immediately to Manufacturer all Medicaid State Supplemental Rebates paid under the Agreement and remove all Manufacturer's Products from the Oklahoma Medicaid Preferred Drug List if CMS's authorization of the Oklahoma Medicaid State Supplemental Rebate Program is found to be invalid.
- 9.4** Payment of Medicaid State Supplemental Rebates is contingent upon the conditions set forth in Article V where applicable. No Medicaid State Supplemental Rebates shall be paid to OHCA when OHCA is in default of any of its obligations under this Agreement.

Both Parties shall:

- 9.5** Pay the other party to reflect such adjustment if any error is discovered in the data submitted or Medicaid State Supplemental Rebates paid under this Agreement, including the submission of data with respect to members or utilization not subject to Medicaid State Supplemental Rebates under this Agreement, the Medicaid State Supplemental Rebates due hereunder shall be appropriately adjusted to reflect the error. If Manufacturer has made an overpayment which is then verified by OHCA, Manufacturer may, at its sole discretion, deduct the amount of the overpayment from future discount payments due pursuant to this Agreement. Time limits for error adjustment shall be equal to those limits set forth by CMS regulations for the CMS Rebate.

ARTICLE X. DISPUTES

- 10.0** Parties shall resolve any disputes relating to the Agreement in accordance with generally applicable procedures followed by OHCA or CMS in disputes concerning rebates paid pursuant to 42 U.S.C. 1396r-8.

ARTICLE XI. TERMINATION

- 11.0** Either party may terminate at the end of the calendar quarter for cause with a thirty (30) day written notice to the other party. Either party may terminate at the end of the calendar quarter without cause with a sixty (60) day written notice to the other party, however OHCA may not terminate the Agreement pursuant to Section 4.0b solely for the purpose of negotiating Medicaid Supplemental Rebates that are greater than those provided for under the Agreement or because Manufacturer denies a request from OHCA for Medicaid Supplemental Rebates that are greater than those provided for under the Agreement. If the Agreement is terminated, the OHCA shall be liable only for payment for services delivered and accepted.
- 11.1** In the event funding of the Medicaid Program from the State, Federal or other sources is withdrawn, reduced, or limited in any way after the effective date of this Agreement and prior to the anticipated Agreement expiration date, this Agreement may be terminated immediately by OHCA.
- 11.2** This Agreement may be immediately terminated upon the occurrence of any one of the following events: (1) 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 remuneration. For the purposes of this Section 10.2, “authorized governmental authority” shall mean any officer or agency of the Federal Government (e.g., Office of the Inspector General, Department of Justice, Department of Health and Human Services) or the State of Oklahoma (e.g., Oklahoma 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 (2) a determination by CMS or any other legal entity that the Medicaid State Supplemental Rebates paid or payable by Manufacturer under this Agreement will affect or be included in Best Price calculations for determining rebates paid pursuant to 42 U.S.C. 1396r-8.

11.3 Upon termination of this Agreement, all Manufacturer’s Products will be removed from the Oklahoma Medicaid Preferred Drug List and shall require prior authorization.

ARTICLE XII. HOLD HARMLESS

12.0 The parties intend that each shall be responsible for its own intentional act and negligent acts or omissions to act. The OHCA shall be responsible for the acts and omissions to act of its officer and employees while acting within the scope of their employment according to the Governmental Tort Claims Act, 51 Okla. Stat. §151, et seq. The Manufacturer shall be responsible for any damages or personal injury caused by the negligent acts or omissions to act by its officers, employees, or agents. The Manufacturer agrees to hold harmless the OHCA of any claims, demands and liabilities resulting from any act or omission on the part of the Manufacturer and/or its agents, servants, and employees in the performance of the Agreement. It is the express intention of the parties hereto that this Agreement shall not be construed as, or given the effect of, creating a joint venture, partnership or affiliation or association that would otherwise render the parties liable as partners, agents, employer-employee or otherwise create any joint and several liability.

ARTICLE XIII. WAIVER OF BREACH

13.0 Failure of either party to complain of any act or omission on the part of the other party shall not be deemed a waiver of any breach or default of any term or condition of this Agreement. No waiver by either party of any breach or default of any term or condition of this Agreement shall be deemed a waiver of any other or subsequent breach or default.

ARTICLE XIV. FORCE MAJEURE

14.0 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, 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 this Agreement.

ARTICLE XV. NOTICES

15.0 Whenever notice is required to be given to the other party, it shall be made in writing and all notices under this Agreement shall refer to the F.E.I.N. on the first page of this Agreement. Notices shall be addressed and sent to the attention of the designated contact individual

identified in Article II of this Agreement. Either party may change its address for the receipt of notices by notice given in accordance with this subsection.

15.1 Notices shall be delivered by certified mail or by overnight courier service. Delivery of notices shall be deemed to have occurred if a signed receipt is obtained, either when delivered by hand or after mailing by certified mail. For notices given by certified mail, return receipt requested shall be sufficient. Notices delivered in hand shall not be sufficient unless acknowledged in writing by the addressee.

EXECUTED:

Manufacturer:

Authorized Agent Signature

Typed Name and Title

Date

Manufacturer:

2nd Authorized Agent Signature (if needed)

Typed Name and Title

Date

Oklahoma Health Care Authority:

OHCA Authorized Signature

Melody Anthony – State Medicaid Director

Typed Name and Title

Date

Attachments to this Agreement include:

Schedule A – Covered Products

Oklahoma Supplemental Rebate Agreement

Schedule A

Covered Products and Rebate Formula

The following products will not be disadvantaged in any way to other single source, branded agents in the same class. The following products to which the Supplemental Rebate Agreement shall apply are the following:

9 Digit NDC	Product Description	Offer Tier ¹	Formula ²	Contracted Rate	Comments	Excluded NDCs

¹Offer Tier – The offer tier represents the number of preferred branded agents in the drug category.

- **Tier 1** - The Contracted Product will be the only preferred brand product in the drug category.
- **Tier 2** - The Contracted Product will be one of no more than two preferred brand products in the drug category.
- **Tier 3** - The Contracted Product will be one of no more than three preferred brand products in the drug category.
- **Tier 4** - The Contracted Product will be preferred as one of many in the drug category.

²Formulas – WAC as of last day of the quarter.

- **Guaranteed Net Unit Price (GNUP)** - Calculation shall be $WAC - Federal\ URA - Contracted\ Rate = Supplemental\ Rebate\ Amount\ per\ Unit$
- **Percentage of WAC** - Calculation shall be $WAC * Contracted\ Rate = Supplemental\ Rebate\ Amount\ per\ Unit$. Contracted Rate should be expressed as a decimal if using this formula.