

**MEDI-CAL VALUE-BASED SUPPLEMENTAL  
DRUG REBATE AGREEMENT**

This Agreement is made and entered into this \_\_\_\_ day of \_\_\_\_\_ 20\_\_\_\_, by and between the State of California (State), represented by the Department of Health Care Services (Department), and **(ENTER FULL, LEGAL NAME OF COMPANY)** (Contractor), Labeler Code **00000**. The Parties, in consideration of the covenants, conditions, agreements, and stipulations expressed in this Agreement, do agree as follows:

**ARTICLE I - PREAMBLE**

- 1.1 It is the intent of this Agreement that, pursuant to Welfare and Institutions Code Sections 14105.31 and 14105.33, the Department will receive a Rebate for Contractor's Covered Product(s), including a State Supplemental Rebate, and that the Department will **(add/retain)** Contractor's Covered Product(s) **(to/on)** the Medi-Cal List of Contract Drugs. The Parties also intend for this Agreement to meet the requirements of Federal law at Title 42 United States Code Section 1396r8.

**ARTICLE II - DEFINITIONS**

- 2.1 'Actual Acquisition Cost' (AAC) shall mean the highest cost of the drug, pursuant to Welfare and Institutions Code, Section 14105.45, during the calendar quarter that corresponds to the calendar quarter for which the Medi-Cal Utilization Data for the Covered Product(s) is reported to Contractor by the Department in the applicable Rebate Summary.
- 2.2 'Base Administrative Fee' shall mean the amount paid by the Contractor to the State to cover the administrative costs related to performance of this Agreement. The fee may be in the form of a one-time fee, a per claim fee, a percentage-based fee, or some other arrangement as determined by the Parties and described in Appendix A.
- 2.3 'Bona Fide Service Fee' shall mean a fee paid by Contractor to a third-party purchaser of outpatient drugs or products that may or do qualify as Covered Product(s), where such fee represents the fair market value for a bona fide, itemized service and that otherwise meets the

definition of “bona fide service fee,” as codified at 42 C.F.R. Section 447.502. Examples include fees associated with administrative service agreements and patient care programs, such as medication compliance and patient education programs.

- 2.4 ‘Bona Fide Service Plan’ shall mean a plan agreed upon by the Parties for Contractor to pay Bona Fide Service Fees to third-party purchasers. The value of the Bona Fide Service Fees paid under the Bona Fide Service Plan is described in Appendix A.
- 2.5 ‘CMS Agreement’ shall mean the Contractor's drug rebate contract with the Centers for Medicare and Medicaid Services (CMS), entered pursuant to Section 1927 of the Social Security Act (42 USC 1396r-8).
- 2.6 ‘CMS Basic Rebate’ shall mean, with respect to the Covered Product(s), the quarterly payment by Contractor pursuant to Contractor'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)).
- 2.7 ‘CMS CPI Rebate’ shall mean, with respect to the Covered Product(s), the quarterly payment by Contractor pursuant to Contractor's CMS Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act (42 USC 1396r-8(c)(2)).
- 2.8 ‘Covered Product(s)’ shall mean the pharmaceutical product(s) **[CHEMICAL NAME (REGISTERED TRADEMARK NAME), DOSAGE FORM, STRENGTH]**.
- 2.9 ‘Data Aggregator’ shall mean a State entity or contractor (such as a consulting company, research institution, State designee or other organization under contract with the State) that tracks Covered Product’s utilization, evaluates its performance, and calculates the Outcome-Based Supplemental Rebates owed by Contractor, if any. The Data Aggregator is identified or otherwise described in Appendix A.
- 2.10 ‘Evaluation Methodology’ shall mean the methodology described in Appendix A for evaluating the performance of the Covered Product(s) based on the Outcome-Based Benchmarks agreed upon by the Parties.

- 2.11 'Intervention Population' shall mean the group of patients whose use of Covered Product(s) during the Utilization Period generates the Utilization Data that is evaluated for purposes of assessing the performance of Covered Product and calculating the Outcome-Based Supplemental Rebates. The Intervention Population is described in Appendix A.
- 2.12 'Medi-Cal List of Contract Drugs' shall mean the list of drugs covered by the Medi-Cal program pursuant to Welfare and Institutions Code Section 41405.35.
- 2.13 'Medi-Cal Net Cost' shall mean the prescription drug ingredient reimbursement by National Drug Code (NDC) for the Covered Product(s) paid by the Department to Medi-Cal providers during a calendar quarter calculated as the AAC of the drug, minus the sum of all Rebates paid by Contractor to the Department for the Covered Product(s) for the same calendar quarter pursuant to Article VI, Section 4.1 and 4.2 of this Agreement. In the event of any change to the calculation used by the Department to determine drug ingredient reimbursement paid by the Department to Medi-Cal providers, the Parties may elect to renegotiate the terms of this Agreement pursuant to Section 6.8.
- 2.14 'Medi-Cal Utilization Data' has the same meaning as 'utilization data' as described in Welfare and Institutions Code section 14105.33.
- 2.15 'Outcome-Based Benchmarks' shall mean the measurable benchmarks, thresholds and/or outcomes described in Appendix A used to evaluate the Covered Product's performance for purposes of calculating an 'Outcome-Based Supplemental Rebate.'
- 2.16 'Outcome-Based Supplemental Rebate' shall mean the amount paid by Contractor in excess of the sum of the following rebates: the CMS Basic Rebate, the CMS CPI Rebate, and the State Supplemental Rebate based on the process described in Appendix A.
- 2.17 'Outcome-Based Supplemental Unit Rebate Amount' shall mean the amount the Contractor agrees to pay the State under this Agreement at the unit level.

- 2.18 'Outcome-Based Utilization Data' shall mean the data collected by the Data Aggregator necessary to evaluate the Covered Product's performance and to calculate the Outcome-Based Supplemental Rebates owed by Contractor for the applicable Utilization Period.
- 2.19 'Parties' – shall mean the State of California (State), represented by the Department of Health Care Services, and **(ENTER FULL, LEGAL NAME OF COMPANY)**, Labeler Code **00000**.
- 2.20 'Performance Data' shall mean the data that will be generated by applying the Outcome-Based Benchmark and Evaluation Methodology to the 'Outcome-Based Utilization Data.'
- 2.21 'Rebate' shall mean, with respect to the Covered Product(s), the quarterly payment by Contractor pursuant to Article IV, Sections 4.1 and 4.2 of this Agreement.
- 2.22 'Rebate Calculation Methodology' shall mean the methodology for calculating the Outcome-Based Supplemental Rebate described in Appendix A.
- 2.23 'Rebate Summary' shall mean the report itemizing the Medi-Cal Utilization Data supporting the Department's invoice for Rebates. The Rebate Summary will comply in all respects with requirements for Medicaid Utilization Information in the CMS Agreement.
- 2.24 'Settle-Up Period' shall mean the period in which the Parties and Data Aggregator evaluate the Performance Data, calculate the Outcome-Based Supplemental Rebates owed by Contractor and, if applicable, determine whether the Bona Fide Service Plan was fulfilled. The length of the Settle-Up Period is specified in Appendix B.
- 2.25 'State Supplemental Rebate' shall mean, with respect to the Covered Product(s), the quarterly payment by Contractor pursuant to Article IV, Section 4.2 of this Agreement.
- 2.26 'Utilization' shall mean the total number of units of the Covered Product reimbursed by the State during the Utilization Period and included in the assessment of Covered Product's performance according to the Evaluation Methodology.

- 2.27 ‘Utilization Period’ shall mean the period in which Outcome-Based Utilization Data is collected. The length of the Utilization Period is specified in Appendix A.
- 2.28 ‘Unit’ shall refer to the drug unit, be the lowest identifiable amount on which the Outcome-Based Supplemental Rebate is calculated (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams), and be the same unit as specified by the Contractor as part of its submission of data under the Medicaid Drug Rebate Program (MDRP).

### **ARTICLE III – EVALUATION AND SETTLE-UP PROCESS**

- 3.1 Outcome-based Utilization Data will be collected during the Utilization Period by the State and forwarded to the Data Aggregator if applicable.
- 3.2 The Data Aggregator shall generate Performance Data by using the Outcome-Based Benchmarks and Evaluation Methodology to evaluate the Outcome-Based Utilization Data. The Performance Data will be compiled and summarized prior to the beginning of the Settle-Up Period.
- 3.3 The Department and Data Aggregator will share with Contractor periodic reports during the Utilization Period. The Parties agree that any data exchanged containing Personal Information, as defined in California Civil Code Section 1798.3, shall comply with all applicable requirements of the California Information Practices Act (California Civil Code Sections 1798 -1798.78). Any patient health information (“PHI”) contained in the reports provided to Contractor shall be de-identified in accordance with the Health Insurance Portability and Accountability Act (“HIPAA”). The Parties may use a unique alpha-numeric code as a case identifier to track the service rendered to any individual patient during the Utilization Period. The alpha-numeric code shall not be derived from “Individually Identifiable Health Information,” as specified and defined in HIPAA. The reports provided to Contractor shall provide data on:
- 3.3.1 Application of the Outcome-Based Benchmarks and Evaluation Methodology to the Outcome-Based Utilization Data;
- 3.3.2 The quality and integrity of the Performance Data; and

3.3.3 Preliminary calculation of the Outcome-Based Supplemental Rebates owed by Contractor, if any, based on application of the Rebate Calculation Methodology to the Performance Data.

3.4 During the Settle-Up Period, the Department and Data Aggregator shall calculate all Outcome-Based Supplemental Rebates owed using the Rebate Calculation Methodology in Appendix B. A report of these calculations and the Outcome-Based Supplemental Rebates shall be shared with the Contractor within (**insert specific time period**) of the Settle-Up period commencing. In no case may the Outcome-Based Supplemental Rebate amount be a negative amount such that State would be obligated to pay Contractor any amount under the Agreement, except with respect to overpayments by Contractor described in Section 4.10 below. If the Parties cannot agree on the amount owed or any other aspect of the utilization, evaluation and settle-up procedures described above, they will use the CMS dispute resolution process.

3.5 The effectiveness of this Agreement shall be contingent on receipt of approval by CMS and contingent on receipt of FMAP. It shall also be contingent on Contractor's Best Price and AMP not being affected by the Medicaid Outcome-Based Supplemental Rebate nor the Bona Fide Service Fees payable under this Agreement.

3.6 Any changes to any rebates required under the MDRP or any other state supplemental rebates (other than the Outcome-Based Supplemental Rebate) shall not invalidate or otherwise affect the calculation of Outcome-Based Supplemental Rebate or the Base Administrative Fee unless intended otherwise by the Parties as reflected in writing in Appendix B.

#### **ARTICLE IV - CONTRACTOR'S RESPONSIBILITIES**

4.1 Contractor will provide the Department a Rebate for the Covered Product(s), which includes the CMS Basic Rebate and CMS CPI Rebate, as appropriate. The CMS rebates represent the discount obtained by multiplying the units of the Covered Product(s) reimbursed by the Department in the preceding quarter by the per unit rebate amount provided to the Department by CMS. CMS will

calculate the rebate amount in accordance with Contractor's CMS Agreement. Contractor's obligation for Rebates will continue for the duration of the Contractor's CMS Agreement.

- 4.2 In addition to the Rebates described in Section 4.1 of this Agreement, Contractor will remit to the Department a State Supplemental Rebate for the Covered Product(s) such that the Medi-Cal Net Cost of the Covered Product(s) will be (\$x.xx) per (specify unit – gm, ml, tablet, etc) or a lower Medi-Cal Net Cost which may be generated by Contractor's CMS Agreement. Contractor's obligation for State Supplemental Rebates will begin with the rebate billing period for **first, second, third, fourth** quarter **year** which begins **DATE GENERALLY SHOULD BE THE START OF A CALENDAR QUARTER**, and will continue through the quarter that ends **DATE GENERALLY COINCIDES WITH THE END DATE OF THE CONTRACT IN SECTION 6.9**. If CMS establishes and the Department implements Federal Upper Limit prices, or if the Department establishes and implements Maximum Allowable Ingredient Cost prices on any strengths of the Covered Product(s), Contractor shall pay no State Supplemental Rebate for those strengths of the Covered Product(s) commencing with the beginning of the quarter in which the Federal Upper Limit price or Maximum Allowable Ingredient Cost price is implemented.
- 4.3 The quarters to be used for calculating the Rebates in Section 4.1 and 4.2 of this Agreement will be those ending on March 31, June 30, September 30, and December 31 of each calendar year during the term of this Agreement.
- 4.4 Contractor will assist the Department in developing annual estimates of aggregate Rebates for the Department's budgetary purposes.
- 4.5 Contractor will pay the Rebates, including any applicable interest on late Rebate payments, in accordance with Welfare and Institutions Code Sections 14105.31 and 14105.33(k) - (u), and Federal laws, regulations, and/or guidelines. Interest on Rebates payable under Section 4.1 of this Agreement begins accruing 38 calendar days from the postmark date or electronic notification date of the Department's invoice and supporting utilization data sent to the Contractor, and interest will continue to accrue until the postmark date of the Contractor's payment. For State Supplemental Rebates payable under Section 4.2 of this Agreement, interest is only applicable to invoices for **first, second, third, fourth** calendar quarter **year**, and thereafter, and if the date of mailing of the Rebate payable under Section 4.2 of this Agreement is 69 days or more from the date of mailing of

the invoice, the interest rate will be calculated as required under Federal guidelines, but will be increased by ten percentage points. For Rebates invoiced for **first, second, third, fourth** calendar quarter **year**, and thereafter, if the Department has not received the Rebates payable under Section 4.1 or 4.2 of this Agreement, including interest, within 180 days of the postmark date of the Department's invoice and supporting utilization data sent to the Contractor, this Agreement will be deemed to be in default and will be terminated in accordance with Section 6.11 of this Agreement.

- 4.6 With each quarterly remittance, Contractor will submit a Form CMS-304 (Reconciliation of State Invoice), consistent with Federal requirements, and a separate Form CMS-304 for the State Supplemental Rebate. In the event that in any quarter any material discrepancy is discovered by Contractor, which Contractor in good faith is unable to resolve, Contractor will provide written notice of the discrepancy to the Department. The Department and Contractor will use their best efforts to resolve the discrepancy within 90 days of receipt by the Department of the notification.
- 4.7 If Contractor in good faith believes the amount claimed in the Rebate Summary is erroneous, Contractor may pay the Department only that portion of the amount claimed which is not disputed. Upon resolution of the dispute, any balance will be paid by Contractor promptly; any overpayment will be credited by the Department against the next payment due, if any.
- 4.8 Contractor agrees to continue to pay a Rebate on the Covered Product(s) for as long as this Agreement is in force, and Medi-Cal Utilization Data shows that payment was made for that drug, regardless of whether the Contractor continues to market that drug.
- 4.9 In addition to the Rebates described in Section 4.1 and 4.2 of this Agreement, the Contractor will remit to the Department an 'Outcome-Based Supplemental Unit Rebate Amount' based on the 'Performance Data' and 'Evaluation Methodology' as described in Appendix A.
- 4.10 The Contractor will remit any Outcome-Based Supplemental Rebates owed based on the calculation methodology in Appendix A. A report of these calculations and the Outcome-Based Supplemental Rebates amounts shall be shared with the Contractor within (**insert specific time period same as section 3.4**) of the Settle-Up period commencing. In no case may the Outcome-Based Supplemental Rebate amount be a negative amount such that State would be obligated to



pay Contractor any amount under the Agreement, except with respect to overpayments by Contractor.

- 4.11 The Contractor will remit payment of the Outcome-Based Supplemental Rebates within thirty-eight (38) days of postmark on the invoice from the Department. Interest will accrue until the postmark date of Contractor's payment consistent with Contractor's rebate agreement with CMS under the MDRP. Nothing in this Agreement shall be construed to relieve Contractor from its obligation to pay any other rebates, including any rebates under the MDRP or a separate supplemental rebate included in this agreement.
- 4.12 The Contractor will pay Bona Fide Service Fees to third-party entities in accordance with the Bona Fide Service Plan. Contractor will provide the information needed by State to evaluate the financial value of the Bona Fide Service Fees as described in Appendix A.
- 4.13 Unless notified otherwise, Contractor will send Rebate payments to the following address:
- Department of Health Care Services  
Accounting Section  
1501 Capitol Avenue, Suite 2048, MS 1101  
Sacramento, CA 95814

## **ARTICLE V - DEPARTMENT RESPONSIBILITIES**

- 5.1 The Department will **(add/retain)** the Covered Product(s) **(to/on)** the Medi-Cal List of Contract Drugs. **(ENTER HERE A STATEMENT REGARDING EXCLUSIVITY OR CODE I RESTRICTIONS, IF APPLICABLE).**
- 5.2 The Department will provide Medi-Cal Utilization Data to Contractor on a quarterly basis. This data will be based on paid claims data (data used to reimburse providers) under the Medi-Cal program, will be consistent with any applicable Federal or State guidelines, regulations and standards for such data, and will be the basis for the Department's calculation of the Rebate.

- 5.3 The Department shall contract with or otherwise arrange for a Data Aggregator to track Covered Product's utilization, evaluate its performance, and calculate the Outcome-Based Supplemental Rebates owed by Contractor, if any. The contract between the Department and a third-party Data Aggregator shall comply with the requirements of State and Federal anti-kickback laws, including the Federal Anti-Kickback Statute at Section 1128B of the Social Security Act, 42 U.S.C. Section 1320a-7b, to the extent those laws are applicable. Nothing in this provision shall prevent the Department from serving as the Data Aggregator. Data Aggregator shall perform the following tasks:
- 5.3.1 Gather and tabulate Outcome-Based Utilization Data relating to the use of the Covered Product during the Utilization Period;
  - 5.3.2 Generate Performance Data by applying the Outcome-Based Benchmarks and Evaluation Methodology to the Outcome-Based Utilization Data;
  - 5.3.3 Meet with and provide interim reports to the Parties regarding the collection and evaluation of the Outcome-Based Utilization Data;
  - 5.3.4 Make any adjustments to the collection of Outcome-Based Utilization Data and /or Performance Data requested by the Department;
  - 5.3.5 Calculate the Outcome-Based Supplemental Rebates owed by Contractor, if any, by applying the Rebate Calculation Methodology to the performance Data.
- 5.4 If the Data Aggregator is a third-party entity, the Department shall, in accordance with HIPAA, enter into a Business Associate Agreement (BAA) with Data Aggregator and abide by all patient privacy requirements under HIPAA.
- 5.5 The Department will provide necessary information or otherwise cooperate with Data Aggregator so that Data Aggregator can perform its duties under Section 5.3.
- 5.6 If applicable, the Department will assist Contractor with implementation of Bona Fide Service Plan as described in Appendix A. The Parties shall ensure that the Bona Fide Service Plan complies with State or Federal anti-kickback laws, such as those appearing in Section 1128B of the Social Security Act, 42 U.S.C. Section 1320a-7b and any applicable safe harbor, including but not limited to the safe harbor for personal services and management contracts codified at 42 CFR Section 1001.952(d).

- 5.7 If applicable, the Department or its designee will invoice Contractor for the Outcome-Based Supplemental Rebates within ninety (90) days after the end of the Settle-Up Period. The Department or its designee shall invoice Contractor for Outcome-Based Supplemental Rebates separately from the MDRP statutory rebate or any other State supplemental rebate, using the format set forth by CMS. The Department or its designee shall submit the Outcome-Based Supplemental Rebates invoice to the Contractor invoice contact, as identified by the Contractor to CMS
- 5.8 The Department will maintain those data systems and audits as are necessary to ensure the accuracy of the data used to calculate the Rebate. In the event material discrepancies are discovered, the Department will promptly justify its data or make an appropriate adjustment which may include a credit as to the amount of the Rebate to Contractor as the parties may agree.
- 5.9 Upon implementation of this Agreement, and from time to time thereafter, the Parties will meet to discuss any data or data system improvements which are necessary or desirable to ensure that the data and any information provided by the Parties are adequate for the purposes of this Agreement.
- 5.10 The Department will provide Contractor with a copy of the independent auditor's report of the Electronic Data Processing Application Systems Audit of the Department's fiscal intermediary for Medi-Cal Utilization Data. In the event material discrepancies are discovered by the auditor, the Department will promptly justify its data or make an appropriate adjustment.

## **ARTICLE VI - GENERAL PROVISIONS**

- 6.1 This Agreement will be governed and construed in accordance with: (a) Part 3, Division 9 of the Welfare and Institutions Code; Division 3 of Title 22 of the California Code of Regulations; and all other applicable State law and regulations; and (b) Title 42 United States Code Section 1396; Title 42 of the Code of Federal Regulations; and all other applicable Federal law and regulations.
- 6.2 Any notice required to be given pursuant to the terms and provisions of this Agreement will be in writing and will be sent by certified mail, return receipt requested. Notice to the Department will be sent to:

California Department of Health Care Services  
Pharmacy Benefits Division  
1501 Capitol Avenue, Suite 71.6089, MS 4604  
Sacramento, CA 95814

Notice to Contractor will be sent to:

\_\_\_\_\_(NAME)  
\_\_\_\_\_(TITLE)  
\_\_\_\_\_(COMPANY NAME)  
\_\_\_\_\_(ADDRESS)

- 6.3 Pursuant to 42 USC 1396r-8(b)(3)(D), the parties agree that confidential information will not be disclosed. Pursuant to Welfare and Institutions Code Section 14105.33(h) and Evidence Code Section 1060, the parties agree that the terms of this Agreement are confidential and exempt from disclosure under the California Public Records Act at Division 10 of Title 1 of the Government Code (commencing with Section 7920.000). Each party will treat trade secrets and other confidential information as confidential, will preserve the confidentiality and will not duplicate, disclose or use the information, except in connection with this Agreement or as may be required by judicial order. Notwithstanding the termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect.
- 6.4 Contractor and the agents and employees of Contractor in the performance of this Agreement, will act in an independent capacity and not as officers or employees or agents of the State of California.
- 6.5 This Agreement is not assignable either in whole or in part without the written consent of the Department, which will not unreasonably be withheld.

- 6.6 Nothing in this Agreement will be construed so as to require the commission of any act contrary to law. If any provision of this Agreement is found to be invalid or illegal by a court of law, or inconsistent with Federal requirements, this Agreement will be construed in all respects as if any invalid, unenforceable, or inconsistent provision were eliminated, and without any effect on any other provision. The parties agree to negotiate replacement provisions, to afford the parties as much of the benefit of their original bargain as is possible.
- 6.7 The Department and Contractor declare that this Agreement, including attachments, contains a total integration of all rights and obligations of both Parties. There are no extrinsic conditions or 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.
- 6.8 The introductory paragraph and sections 1.1, 2.2, 3.4, 4.2, 4.5, 4.10, 5.1, 6.2, 6.9, Appendix A, and Appendix B of this Agreement will not be altered except by an amendment in writing signed by both Parties and approved by the appropriate State control agencies. All other numbered sections of this Agreement will not be altered except by an amendment in writing signed by both parties and approved by the appropriate State control agencies and authorized by the Centers for Medicare and Medicaid Services. No person 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 Contractor and approved by the appropriate State control agencies.
- 6.9 This Agreement will be in effect from date of execution through **(Insert Date)**.
- 6.10 The Department intends to implement this contract through a single administrator, called the "Contracting Officer". The Contracting Officer will be appointed by the Director of the Department. The Contracting Officer will make all determinations and take all actions as are appropriate under this contract on behalf of the Department, subject to the limitations of California law.

- 6.11 This Agreement may be terminated by either Party by giving written notice to the other Party at least 90 days prior to the effective date of the termination. Termination of this Agreement will result in Contractor's Covered Product(s) being available to Medi-Cal beneficiaries only through prior authorization.
- 6.12 Neither Party contemplates any circumstances under which indemnification of the other Party would arise. Nevertheless, should such circumstances arise, Contractor 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 Contractor in the performance of this Agreement.
- 6.13 Inasmuch as the State Supplemental Rebate required by this Agreement is only for Medi-Cal beneficiaries, the State Supplemental Rebate does not establish a new 'Best Price' for purposes of Contractor's CMS Agreement.
- 6.14 In the event that the Department determines, as a result of a therapeutic category review, that a Covered Product of the Contractor included on the Medi-Cal list of contract drugs as a consequence of this Agreement should be removed from the list of contract drugs and require prior approval, the Parties agree that the terms of Section 6.11 shall apply.

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

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Lisa Ghotbi, Pharm. D.

Chief, Pharmacy Benefits Division

Department of Health Care Services,

for the State of California

Dated: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_ (NAME)

\_\_\_\_\_ (TITLE)

\_\_\_\_\_ (COMPANY NAME)

Dated: \_\_\_\_\_

## Appendix A

**Covered Product** – The Covered Product subject to this Agreement is specified below. The Covered Product is identified by its NDC-9 number to ensure that all package sizes are captured under this Agreement, In the event the Agreement covers multiple products with different NDCs and/or labeler names, the information pertaining to each product is also specified below:

MANUFACTURER/LABELER NAME	NDC	Drug Name

**Utilization Period** – The Utilization Period will begin on first, second, third, fourth quarter year which begins date. It shall conclude through the quarter that ends date.

**Outcome-Based Benchmarks** – The Parties agree to the following Outcome-Based Benchmarks for evaluating the Utilization Data:

*[To be filled in or marked as not applicable.]*

**Intervention Population** – The Parties agree to define the Intervention Population on which the Outcome-Based Benchmarks shall be measured as follows:

*[To be filled in or marked as not applicable.]*

**Evaluation Methodology** – The Parties agree to the following Evaluation Methodology for evaluating the performance of the Covered Product during the Utilization Period:

*[To be filled in or marked as not applicable.]*

**Data Aggregator** – The Data Aggregator is authorized by the Department to track Covered Product's utilization, to evaluate its performance and to calculate the Outcome-Based Supplemental Rebates. The

Data Aggregator selected by the Department for purposes of this Agreement is identified and described below:

[To be filled in or marked as not applicable.]

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In the event the Department desires to change or replace the Data Aggregator, it shall give Contractor 30 days written notice prior to implementation. Nothing in this Agreement prevents the Department from serving as the Data Aggregator and performing the tasks described in Section 3.3.

**Covered Product Status** – The Parties agree that Covered Product will not be disadvantaged to Competitive Drugs within Product Class. The Covered Product Status in the FFS and/or MCO setting is described below:

- Covered Product Status in FFS Setting – [To be filled in or marked as not applicable.]

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- Covered Product Status in MCO Setting – [To be filled in or marked as not applicable.]

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**Preferred Status** – The Department may arrange for Preferred Status for Covered Product by listing the drug in a Preferred Drug List section of the Contract Drugs List (CDL), prior authorization procedures, step therapy requirements, or other means to manage Product Class, including requirements related to clinical appropriateness. The Preferred Status for Covered Product in the FFS and/or MCO setting is described below, if applicable:

- Preferred Status in FFS Setting – [To be filled in or marked as not applicable.]

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- Preferred Status in MCO Setting – [To be filled in or marked as not applicable.]

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**Bona Fide Service Plan** – The Parties agree to the following Bona Fide Service Plan, including the specific services Contractor shall provide under the Bona Fide Service Plan, the financial value of those services:

[To be filled in or marked as not applicable.]

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## Appendix B

**Base Administrative Fee** – The amount paid by the Contractor to cover the administrative costs related to this Agreement.

*[To be filled in or marked as not applicable.]*

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**Payment for Outcome-Based Benchmarks** – The amount paid by the Contractor based on the Outcome-Based Benchmarks calculated as per Appendix A:

*[To be filled in or marked as not applicable.]*

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**Outcome-Based Supplemental Unit Rebate Amount** – For each Unit of the Covered Product identified and evaluated by Data Aggregator for the Intervention Population during Utilization Period in question, Contractor agrees to pay an Outcome-Based Supplemental Rebate beyond the rebate owed under the MDRP or any other State supplemental rebate. The Outcome-Based Supplemental Unit Rebate Amount will vary as a result of the Outcome-Based Benchmarks and/or Evaluation Methodology described in Appendix A. The different amounts will be determined as follows:

LABEL NAME	NDC	CALCULATION TYPE	DISCOUNT PER UNIT	Outcome measure
PRODUCT A	99999-9999	{Specify WAC, GNUP, AMP other}	%, \$, other	Note 1 below
PRODUCT A	99999-9999	{Specify WAC, GNUP, AMP other}	%, \$, other	Note 2 below
PRODUCT A	99999-9999	{Specify WAC, GNUP, AMP other}	%, \$, other	Note 3 below

Calculation Type is *[customize one of the options below and/or insert new description]*

- [a percentage discount of WAC, based on the WAC as shown in pricing compendia for the last day of the Utilization Period.]
- [is WAC based GNUP where Supplemental Rebate amount per Unit = [WAC minus Federal RPU minus Discount Per Unit].
- [insert other description as applicable]

**Outcome measure note 1:** [above target]

**Outcome measure note 2:** [target]

**Outcome measure note 3:** [below target]

**Rebate Calculation Methodology** – The Outcome-Based Supplemental Rebates shall be calculated by multiplying the Outcome-Based Supplemental Unit Rebate Amount by the Covered Product’s Utilization during the Utilization Period.

**Settle-Up Period** – The Settle-Up Period shall commence after the close of the Utilization Period and shall terminate at the conclusion of the quarter that ends **date**. The Settle-Up Period can be extended by written agreement of the Parties.