

# STATE OF COLORADO CONTRACT

## COVER AND SIGNATURE PAGE

**State Agency**

Colorado Department of Health Care Policy and Financing (HCPF)

**Manufacturer**

Insert Manufacturer's Full Legal Name, including "Inc.", "LLC", etc.

**Contract Number**

Insert CMS number or Other Contract Number

**Contract Performance Beginning Date**

Month Day, Year

**Initial Contract Expiration Date**

Month Day, Year

**Contract Authority**

Authority to enter into this Contract exists in C.R.S. §§25.5-1-101, *et. seq.*

**Contract Purpose**

This Agreement establishes a State Supplemental Rebate for the Manufacturer's preferred drugs under Colorado Medicaid, in addition to rebates provided under the federal Medicaid Drug Rebate Program pursuant to 42 U.S.C. § 1396r-8.

**Exhibits and Order of Precedence**

The following Exhibits and attachments are included with this Contract:

1. Exhibit A – Preferred Products

**Principal Representatives**

For the State:

Greg Miller  
Department of Health Care Policy and Financing  
303 E 17<sup>th</sup> Ave  
Suite 1100  
Denver, Colorado, 80203  
greg.miller@state.co.us

For Manufacturer:

Name  
Company Name  
Address Line 1  
Address Line 2  
City, State ZIP  
Email

THE PARTIES HERETO HAVE EXECUTED THIS CONTRACT

Each person signing this Contract represents and warrants that he or she is duly authorized to execute this Contract and to bind the Party authorizing his or her signature.

**MANUFACTURER**

INSERT: Legal Name of Manufacturer

**STATE OF COLORADO**

Jared S. Polis, Governor  
Department of Health Care Policy and Financing  
Gretchen Hammer, Executive Director

Date: \_\_\_\_\_

Date: \_\_\_\_\_

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## CONTRACT PROVISIONS

### 1. PARTIES

This Contract is entered into by and between Manufacturer named on the Cover Page for this Contract (“Manufacturer”), and the STATE OF COLORADO acting by and through the State agency named on the Cover Page for this Contract (the “State,” the “Department,” or “HCPF”). Manufacturer and the State agree to the terms and conditions in this Contract.

### 2. TERM AND EFFECTIVE DATE

#### A. Effective Date

This Contract shall not be valid or enforceable until the Effective Date.

#### B. Initial Term

The Parties’ respective performances under this Contract shall commence on the Contract Performance Beginning Date shown on the Cover Page for this Contract and shall terminate on the Initial Contract Expiration Date shown on the Cover Page for this Contract (the “Initial Term”) unless sooner terminated or further extended in accordance with the terms of this Contract.

#### C. Early Termination by the Department

The Department may terminate this Contract without cause by providing 60 days’ notice to Manufacturer. The Department may terminate this Contract without notice to Manufacturer if the Department determines that immediate termination is required to protect the interests of the State, Manufacturer is debarred or suspended by the State or federal government, or a court of competent jurisdiction or any governmental authority with jurisdiction over the subject matter of this Contract determines this arrangements or transactions under this Contract violate any state or federal law.

### 3. DEFINITIONS

The following terms shall be construed and interpreted as follows:

- A. **“AMP”** means the Average Manufacturer Price as defined in 42 U.S.C. §1396r-8(k)(1) and final regulations promulgated by CMS, if any, as such statute or regulations may be amended from time to time.
- B. **“BEST PRICE”** means the best price as defined in 42 U.S.C. §1396r-8(c)(1)(C) and final regulations promulgated by CMS, if any, as such statute or regulations may be amended from time to time.
- C. **“Breach of Contract”** means the failure of a Party to perform any of its obligations in accordance with this Contract, in whole or in part or in a timely or satisfactory manner. The institution of proceedings under any bankruptcy, insolvency, reorganization or similar law, by or against Manufacturer, or the appointment of a receiver or similar officer for Manufacturer or any of its property, which is not vacated or fully stayed within 30 days after the institution of such proceeding, shall also constitute a breach. If Manufacturer is debarred or suspended under §24-109-105, C.R.S. at any time during the term of this Contract, then such debarment or suspension shall constitute a breach.
- D. **“Business Day”** means any day in which the State is open and conducting business, but shall not include Saturday, Sunday or any day on which the State observes one of the holidays listed in §24-11-101(1), C.R.S. Any measure of time referencing days means calendar days unless specifically designated as Business Days.
- E. **“CMS”** means the Centers for Medicare and Medicaid Services or any successor agency responsible for the administration of Medicaid.
- F. **“Contract”** means this agreement, including all attached Exhibits, all documents incorporated by reference, all referenced statutes, rules and cited authorities, and any future modifications thereto.
- G. **“Effective Date”** means the date on which this Contract is approved and signed by the last Party.
- H. **“Exhibits”** means the exhibits and attachments included with this Contract as shown on the Cover Page for this Contract.
- I. **“Medicaid Utilization Data”** means drug utilization data provided by the Department for each National Drug Code (NDC) included on the PDL that shows, at a minimum, the number of units paid for each Preferred Product by NDC.
- J. **“National Drug Code” or “NDC”** means the national drug code as defined in 42 C.F.R. §447.502
- K. **“National Rebate Agreement”** means the federal rebate agreement developed and entered into by CMS and a manufacturer pursuant to 42 U.S.C. §1396r-8.
- L. **“Party”** means the State or Manufacturer, and **“Parties”** means both the State and Manufacturer.
- M. **“PDL”** means the Department’s Preferred Drug List.
- N. **“Preferred Product”** means a drug that is designated as preferred on the PDL.

- O. **“Rebate Payment Due Date”** means 38 calendar days after the date the Department delivers the Department’s invoice and Medicaid Utilization Data for a quarter to Manufacturer.
- P. **“State Records”** means any and all State data, information, and records, regardless of physical form.
- Q. **“State Supplemental Rebate”** means the rebate amount owed by Manufacturer to the Department for Preferred Product utilization as specified in Exhibit A.
- R. **“Unit”** means the lowest dispensable amount of a product (e.g., each, milliliter (mL), gram (g)).
- S. **“WAC”** means Wholesale Acquisition Cost as defined in 42 C.F.R. §447.502.

Any other term used in this Contract that is defined in an Exhibit shall be construed and interpreted as defined in that Exhibit.

#### 4. OBLIGATIONS OF THE DEPARTMENT

##### A. PDL

The Department shall maintain and publish a PDL that lists all Preferred Products.

- i. The Department shall not discourage or disadvantage a Preferred Product relative to any other drug product in its therapeutic class except as specifically described in this Contract.
- ii. The Department shall not subject Preferred Products to clinical edits, prior authorization, step therapy, or similar utilization management controls that are more restrictive than the FDA-approved Prescribing Information for those Preferred Products unless those controls are applied equally to all products in a therapeutic class or is specifically described otherwise in Exhibit A.

##### B. Submission of Medicaid Utilization Data and Invoice

The Department shall submit Medicaid Utilization Data and an invoice to Manufacturer showing the State Supplemental Rebate due from Manufacturer on a quarterly basis.

##### C. Records Maintenance

The Department shall maintain all electronic claims records necessary for Manufacturer to verify the Medicaid Utilization Data provided by the Department and the resulting State Supplemental Rebates.

#### 5. PAYMENTS BY MANUFACTURER

##### A. Payment of State Supplemental Rebates

Manufacturer shall pay the Department a Supplemental Rebate Per Unit shown on the Department’s invoice based on the formula in Exhibit A for the FFS utilization of Preferred Products, on a quarterly basis, including any prior quarter adjustments. MCO claims will not be included in the utilization data used to create invoices for the manufacturers.

Manufacturer shall pay each State Supplemental Rebate by the Rebate Payment Due Date, unless the State Supplemental Rebate is subject to a good faith dispute as described in this Contract. If a portion of a State Supplemental Rebate is subject to a good faith dispute under this Contract, then Manufacturer shall pay all portions of the State Supplemental Rebate not subject to the dispute by the Rebate Payment Due Date. Manufacturer shall pay

the State Supplemental Rebates in the same manner as described in the National Rebate Agreement.

B. Interest Payments

Any State Supplemental Rebate paid after the Rebate Payment Due Date as described in §5.A above shall accrue interest calculated in accordance with federal guidelines.

C. Best Price Contingency

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

**6. CONFIDENTIAL INFORMATION**

A. Confidentiality of State Records

Manufacturer shall keep confidential, and cause all Subcontractors to keep confidential, all State Records, unless those State Records are publicly available. Manufacturer shall not, without prior written approval of the State, use, publish, copy, disclose to any third party, or permit the use by any third party of any State Records, except as otherwise stated in this Contract, permitted by law, or approved in writing by the State.

B. Safeguarding Personal Identifiable Information (PII)

If Manufacturer or any of its Subcontractors will or may receive PII under this Contract, Manufacturer shall provide for the security of such PII, in a manner and form acceptable to the State, including, without limitation, State non-disclosure requirements, use of appropriate technology, security practices, computer access security, data access security, data storage encryption, data transmission encryption, security inspections, and audits. Manufacturer shall be a "Third-Party Service Provider" as defined in §24-73-103(1)(i), C.R.S. and shall maintain security procedures and practices consistent with §§24-73-101 *et seq.*, C.R.S. In addition, as set forth in §§24-74-102, *et. seq.*, C.R.S., Manufacturer, including, but not limited to, Manufacturer's employees, agents and Subcontractors, agrees not to share any PII with any third parties for the purpose of investigating for, participating in, cooperating with, or assisting with Federal immigration enforcement.

C. Confidentiality of Manufacturer Information

The Department will keep all information disclosed by Manufacturer in connect with this Contract confidential and shall not disclose that information except as permitted in 42 U.S.C. § 1396r-8(b)(3)(D) or otherwise required by law. The Department may only disclose this information to other consultants, contractors, and agents who need to know the information and only if those individuals or organizations agree to confidentiality requirements at least as strict as those described in this Contract, including confidentiality provisions contained in a contract between the Department and those consultants, contractors, and agents. If the Department is required by law to disclose information described in this section, the Department shall provide notice to Manufacturer of such request prior to the disclosure to allow Manufacturer to seek a protective order or other relief.

## 7. CONFLICTS OF INTEREST

### A. Actual Conflicts of Interest

Manufacturer shall not engage in any business or activities, or maintain any relationships that conflict in any way with the full performance of the obligations of Manufacturer under this Contract. Such a conflict of interest would arise when a Manufacturer's or Subcontractor's employee, officer or agent were to offer or provide any tangible personal benefit to an employee of the State, or any member of the employee's immediate family or employee's partner, related to the award of, entry into or management or oversight of this Contract.

### B. Apparent Conflicts of Interest

Manufacturer acknowledges that, with respect to this Contract, even the appearance of a conflict of interest shall be harmful to the State's interests. Absent the State's prior written approval, Manufacturer shall refrain from any practices, activities or relationships that reasonably appear to be in conflict with the full performance of Manufacturer's obligations under this Contract.

### C. Disclosure to the State

If a conflict or the appearance of a conflict arises, or if Manufacturer is uncertain whether a conflict or the appearance of a conflict has arisen, Manufacturer shall submit to the State a disclosure statement setting forth the relevant details for the State's consideration. Failure to promptly submit a disclosure statement or to follow the State's direction in regard to the actual or apparent conflict constitutes a Breach of Contract.

### D. Acknowledgement

Manufacturer acknowledges that all State employees are subject to the ethical principles described in §24-18-105, C.R.S. Manufacturer further acknowledges that State employees may be subject to the requirements of §24-18-105, C.R.S. with regard to this Contract.

## 8. DISPUTE RESOLUTION

### A. Initial Resolution

Except as herein specifically provided otherwise, disputes concerning the performance of this Contract which cannot be resolved by the designated Contract representatives shall be referred in writing to a senior departmental management staff member designated by the State and a senior manager designated by Manufacturer for resolution.

### B. Final Resolution

If the initial resolution described in §8.A fails to resolve the dispute within 10 Business Days, Manufacturer and the Department shall follow the dispute resolution process described in the National Rebate Agreement.

## 9. NOTICES AND REPRESENTATIVES

Each individual identified as a Principal Representative on the Cover Page for this Contract shall be the principal representative of the designating Party. All notices required or permitted to be given under this Contract shall be in writing, and shall be delivered **(A)** by hand with receipt required, **(B)** by certified or registered mail to such Party's principal representative at the address set forth on the Cover Page for this Contract, or **(C)** as an email with read receipt requested to the principal representative at the email address, if any, set forth on the Cover Page for this Contract.

If a Party delivers a notice to another through email and the email is undeliverable, then, unless the Party has been provided with an alternate email contact, the Party delivering the notice shall deliver the notice by hand with receipt required or by certified or registered mail to such Party's principal representative at the address set forth on the Cover Page for this Contract. Either Party may change its principal representative or principal representative contact information or may designate specific other individuals to receive certain types of notices in addition to or in lieu of a principal representative by notice submitted in accordance with this section without a formal amendment to this Contract. Unless otherwise provided in this Contract, notices shall be effective upon delivery of the written notice.

## 10. GENERAL PROVISIONS

### A. Assignment

Manufacturer's rights and obligations under this Contract are personal and may not be transferred or assigned without the prior, written consent of the State. Any attempt at assignment or transfer without such consent shall be void. Any assignment or transfer of Manufacturer's rights and obligations approved by the State shall be subject to the provisions of this Contract.

### B. Binding Effect

Except as otherwise provided in §10.A, all provisions of this Contract, including the benefits and burdens, shall extend to and be binding upon the Parties' respective successors and assigns.

### C. Authority

Each Party represents and warrants to the other that the execution and delivery of this Contract and the performance of such Party's obligations have been duly authorized.

### D. Captions and References

The captions and headings in this Contract are for convenience of reference only, and shall not be used to interpret, define, or limit its provisions. All references in this Contract to sections (whether spelled out or using the § symbol), subsections, exhibits or other attachments, are references to sections, subsections, exhibits or other attachments contained herein or incorporated as a part hereof, unless otherwise noted.

### E. Counterparts

This Contract may be executed in multiple, identical, original counterparts, each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same agreement.

### F. Entire Understanding

This Contract represents the complete integration of all understandings between the Parties related to the Work, and all prior representations and understandings related to the Work, oral or written, are merged into this Contract. Prior or contemporaneous additions, deletions, or other changes to this Contract shall not have any force or effect whatsoever, unless embodied herein.

### G. Digital Signatures

If any signatory signs this Contract using a digital signature in accordance with the Colorado State Controller Contract, Grant and Purchase Order Policies regarding the use of

digital signatures issued under the State Fiscal Rules, then any agreement or consent to use digital signatures within the electronic system through which that signatory signed shall be incorporated into this Contract by reference.

H. Modification

Except as otherwise provided in this Contract, any modification to this Contract shall only be effective if agreed to in a formal amendment to this Contract, properly executed and approved in accordance with applicable Colorado State law, federal laws, and State Fiscal Rules.

I. Statutes, Regulations, Fiscal Rules, and Other Authority

Any reference in this Contract to a statute, regulation, State Fiscal Rule, fiscal policy or other authority shall be interpreted to refer to such authority then current, as may have been changed or amended since the Effective Date of this Contract.

J. Severability

The invalidity or unenforceability of any provision of this Contract shall not affect the validity or enforceability of any other provision of this Contract, which shall remain in full force and effect, provided that the Parties can continue to perform their obligations under this Contract in accordance with the intent of this Contract.

K. Survival of Certain Contract Terms

Any provision of this Contract that imposes an obligation on a Party after termination or expiration of this Contract shall survive the termination or expiration of this Contract and shall be enforceable by the other Party.

L. Third Party Beneficiaries

Except for the Parties' respective successors and assigns described in § 10.A, this Contract does not and is not intended to confer any rights or remedies upon any person or entity other than the Parties. Enforcement of this Contract and all rights and obligations hereunder are reserved solely to the Parties. Any services or benefits which third parties receive as a result of this Contract are incidental to this Contract, and do not create any rights for such third parties.

M. Waiver

A Party's failure or delay in exercising any right, power, or privilege under this Contract, whether explicit or by lack of enforcement, shall not operate as a waiver, nor shall any single or partial exercise of any right, power, or privilege preclude any other or further exercise of such right, power, or privilege.

N. Indemnification

i. General Indemnification

Manufacturer shall indemnify, save, and hold harmless the State, its employees, agents and assignees (the "Indemnified Parties"), against any and all costs, expenses, claims, damages, liabilities, court awards and other amounts (including attorneys' fees and related costs) incurred by any of the Indemnified Parties in relation to any act or omission by Manufacturer, or its employees, agents, Subcontractors, or assignees in connection with this Contract.

ii. Confidential Information Indemnification

Disclosure or use of State Records by Manufacturer in violation of §6 may be cause for legal action by third parties against Manufacturer, the State, or their respective agents. Manufacturer shall indemnify, save, and hold harmless the Indemnified Parties, against any and all claims, damages, liabilities, losses, costs, expenses (including attorneys' fees and costs) incurred by the State in relation to any act or omission by Manufacturer, or its employees, agents, assigns, or Subcontractors in violation of §6.

**11. COLORADO SPECIAL PROVISIONS (COLORADO FISCAL RULE 3-3)**

**A. GOVERNMENTAL IMMUNITY.**

Liability for claims for injuries to persons or property arising from the negligence of the State, its departments, boards, commissions committees, bureaus, offices, employees and officials shall be controlled and limited by the provisions of the Colorado Governmental Immunity Act, §24-10-101, et seq., C.R.S.; the Federal Tort Claims Act, 28 U.S.C. Pt. VI, Ch. 171 and 28 U.S.C. 1346(b), and the State's risk management statutes, §§24-30-1501, et seq. C.R.S. No term or condition of this Contract shall be construed or interpreted as a waiver, express or implied, of any of the immunities, rights, benefits, protections, or other provisions, contained in these statutes.

**B. COMPLIANCE WITH LAW.**

Manufacturer shall comply with all applicable federal and State laws, rules, and regulations in effect or hereafter established, including, without limitation, laws applicable to discrimination and unfair employment practices.

**C. CHOICE OF LAW, JURISDICTION, AND VENUE.**

Colorado law, and rules and regulations issued pursuant thereto, shall be applied in the interpretation, execution, and enforcement of this Contract. Any provision included or incorporated herein by reference which conflicts with said laws, rules, and regulations shall be null and void. All suits or actions related to this Contract shall be filed and proceedings held in the State of Colorado and exclusive venue shall be in the City and County of Denver.

**D. PROHIBITED TERMS.**

Any term included in this Contract that requires the State to indemnify or hold Manufacturer harmless; requires the State to agree to binding arbitration; limits Manufacturer's liability for damages resulting from death, bodily injury, or damage to tangible property; or that conflicts with this provision in any way shall be void ab initio. Nothing in this Contract shall be construed as a waiver of any provision of §24-106-109, C.R.S.

**E. EMPLOYEE FINANCIAL INTEREST/CONFLICT OF INTEREST. §§24-18-201 and 24-50-507, C.R.S.**

The signatories aver that to their knowledge, no employee of the State has any personal or beneficial interest whatsoever in the service or property described in this Contract. Manufacturer has no interest and shall not acquire any interest, direct or indirect, that would conflict in any manner or degree with the performance of Manufacturer's services and Manufacturer shall not employ any person having such known interests.

**EXHIBIT A, PREFERRED PRODUCTS**

Manufacturer	NDC	Product Description	Tier	Guaranteed Net Unit Price (GNUP)	Comments

Tier Definitions:

- A. Tier 1: The Contracted Product will be the only preferred brand product in the PDL category
- B. Tier 2: The Contracted Product will be one of no more than two preferred brand products in the PDL category.
- C. Tier 3: The Contracted Product will be one of no more than three preferred brand products in the PDL category.
- D. Tier 4: The Contracted Product will be preferred without limitation on the number of preferred products in the PDL.

Calculation of Supplemental Rebate Per Unit

- A. Supplemental Rebate Per Unit = WAC per unit (as of the last day of the quarter) – CMS Rebate per unit – Guaranteed Net Unit Price (GNUP)