MEDICAID PROGRAM: REQUIREMENTS RELATING TO COVERED OUTPATIENT DRUGS FOR THE CATEGORICALLY NEEDY

12.a. Prescribed Drugs: Description of Service Limitation

Citation(s)		Provision(s)
	☒	(d) prescription vitamins and mineral products.
	☒	(e) nonprescription drugs. Selective non-prescription (over the counter) medications will be covered as listed on the state's website.
	☒	(f) covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer, or its designee.

The State may enter into value-based contracts with manufacturers for both FFS and MCO's. These contracts will be executed on the model agreement entitled "Value-Based Supplemental Rebate Agreement" authorized for use beginning January 1, 2025.

- Supplemental rebates received by the state for the Medicaid population (FFS & MCO) in excess of those required under the national drug rebate agreement will be shared with the federal government. The state will remit the federal portion of any cash state supplemental rebates collected on the same percentage basis as applied under the national rebate agreement.

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

VALUE-BASED SUPPLEMENTAL REBATE AGREEMENT

This Value-Based Supplemental Rebate Agreement ("Agreement") by and between the New Mexico Health Care Authority ("State") and _____ ("Manufacturer") sets forth the terms and conditions of this Agreement.

RECITALS

WHEREAS, State and Manufacturer both participate in the Medicaid Drug Rebate Program ("MDRP"), which requires Manufacturer to pay a rebate to State on covered outpatient drugs pursuant to a statutory formula;

WHEREAS, MDRP allows for supplemental rebates and there may be an existing supplemental rebate arrangement between State and Manufacturer;

WHEREAS, State and Manufacturer desire to enter into an outcome-based supplemental rebate arrangement for the payment of rebates in excess of the MDRP statutory rebate and any existing supplemental rebate;

WHEREAS, State and Manufacturer would like the flexibility of including bona fide, itemized services to support the outcome-based arrangement in accordance with Section 1927(k)(1)(B)(i)(II) of the Social Security Act, 42 U.S.C. Section 1396r-8(k)(1)(B)(i)(II), and 42 C.F.R. Section 447.502;

WHEREAS, State and Manufacturer desire that the outcome-based supplemental rebate arrangement may include the payment of a base administrative fee by the Manufacturer to the State to cover the administrative costs related to this Agreement; and

WHEREAS, State and Manufacturer would like the outcome-based supplemental rebate arrangement to encompass drugs purchased in a fee-for-service ("FFS") structure, drugs purchased in a managed care organization ("MCO") structure or both.

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

1. Definitions. As used herein, the following terms shall have the meanings set forth below:

1.1. "Average Manufacturer Price" or "AMP" shall mean the Average Manufacturer Price as defined in Section 1927(k)(1) of the Social Security Act, 42 U.S.C. Section 1396r-8(k)(1), and final regulations promulgated by the Centers for Medicare and Medicaid Services ("CMS"), as such statute or regulations may be amended from time to time. The AMP for covered product(s) shall exclude rebates paid under this Agreement.

1.2. "Base Administrative Fee" shall mean any amount paid by the Manufacturer to the State or directly to the data administrator 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 B.

1.3. "Best Price" shall mean the Best Price as defined in Section 1927(c)(1)(C) of the Social Security Act, 42 U.S.C. Section 1396r-8(c)(1)(C), and final regulations promulgated by CMS, as such statute or regulations may be amended from time to time. The Best Price for covered product(s) shall exclude rebates paid under this Agreement.

1.4. "Bona Fide Service Fee" shall mean any fee paid by Manufacturer to a third-party purchaser of covered outpatient drugs or directly to the data administrator that represents fair market value for a bona fide, itemized service and that otherwise meets the definition of "bona fide service fee" 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.

1.5. "Bona Fide Service Plan" shall mean any plan agreed upon by the Parties for Manufacturer to pay Bona Fide Service Fees to third-party purchasers or the data administrator. The value of any Bona Fide Service Fees paid under the Bona Fide Service Plan is described in Appendix A.

1.6. "Confidential Information" means any nonpublic, confidential or proprietary information of a Party, including but not limited to trade secrets, rebate pricing data, and terms of Manufacturer agreements and Medicaid member identification.

1.7. "Covered Product" shall mean the pharmaceutical product or products identified in Appendix A and subject to evaluation and a supplemental rebate under this Agreement.

1.8. "Covered Product Status" shall mean the status of Covered Product granted by the State. At a minimum, State will ensure access to Covered Product and will not disadvantage Covered Product to competitive drugs in Product Class.

1.9. "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 Manufacturer, if any. The Data Aggregator is identified or otherwise described in Appendix A.

1.10. "Evaluation Methodology" shall mean the methodology described in Appendix A for evaluating the performance of the Covered Product based on the Outcome-Based Benchmarks agreed upon by the Parties.

1.11. "Intervention Population" shall mean the group of patients whose use of Covered Product during the Utilization Period generates the Utilization Data that is evaluated by the Data Aggregator for purposes of assessing the performance of Covered Product and calculating the Outcome-Based Supplemental Rebates. The Intervention Population is described in Appendix A and may be a subset of the total Medicaid population using Covered Product during the Utilization Period.

1.12. "National Drug Code" or "NDC" shall mean a unique eleven-digit, three-segment number for identifying a pharmaceutical based on the drug's labeler, its product strength and dosage form and its packaging. The Covered Product will be identified at the NDC-9 digit level to

ensure that all package sizes are captured under this Agreement, unless the terms of Appendix A specify that the Covered Product will be identified at the NDC-11 digit level.

1.13. "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 a supplemental rebate.

1.14. "Outcome-Based Supplemental Rebate" shall mean the amount paid by Manufacturer in excess of the MDRP-mandated rebate and any other state supplemental rebate based on the process described in Section 2 and Appendix A.

1.15. "Outcome-Based Supplemental Unit Rebate Amount" shall mean the amount Manufacturer agrees to pay State under this Agreement at the unit level.

1.16. "Party" or "Parties" shall mean State and/or Manufacturer.

1.17. "Performance Data" shall mean the data generated by the Data Aggregator by applying the Outcome-Based Benchmarks and Evaluation Methodology to the Utilization Data.

1.18. "Preferred Status" shall mean advantages the State may grant to Covered Product using a preferred drug list ("PDL"), prior authorization procedures, step-edit therapy or other means as described in Appendix A to manage Product Class. The Covered Product in this Agreement may or may not be part of the PDL and subject to PDL edits.

1.19. "Product Class" shall mean a group of pharmaceutical products that are used to treat the same condition or disease state as Covered Product.

1.20. "Rebate Calculation Methodology" shall mean the methodology for calculating the Outcome-Based Supplemental Rebate described in Appendix A.

1.21. "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 Manufacturer and, if applicable, determine whether the Bona Fide Service Plan was fulfilled. The length of the Settle-Up Period is specified in Appendix B.

1.22. "Unit" shall mean the drug unit in 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 shall be the same unit as specified by the Manufacturer as part of its submission of data under the MDRP.

1.23. "Utilization" shall mean the total number of units of the Covered Product reimbursed by State during the Utilization Period and included in the assessment of Covered Product's performance according to the Evaluation Methodology.

1.24. "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 Manufacturer for the applicable Utilization Period.

1.25. "Utilization Period" shall mean the period in which Utilization Data is collected. The length of the Utilization Period is specified in Appendix A.

2. Evaluation and Settle-Up Process

2.1. Utilization. Utilization Data will be collected during the Utilization Period by the State and forwarded to the Data Aggregator.

2.2. Evaluation. The Data Aggregator shall generate Performance Data by using the Outcome-Based Benchmarks and Evaluation Methodology to evaluate the Utilization Data. The Performance Data will be compiled and summarized prior to the beginning of the Settle-Up Period.

2.3. Data-Sharing. State and Data Aggregator will share with Manufacturer periodic reports during the Utilization Period. Any patient health information ("PHI") contained in the reports provided to Manufacturer 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 care 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 Manufacturer shall provide data on:

2.3.1. Application of the Outcome-Based Benchmarks and Evaluation Methodology to the Utilization Data;

2.3.2. The quality and integrity of the Performance Data; and

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

2.4. Settle-Up. During the Settle-Up Period, the State 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 Manufacturer within sixty (60) days 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 Manufacturer any amount under the Agreement, except with respect to overpayments by Manufacturer described in Section 6.5 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 dispute resolution process described in Section 6 to address their disagreement.

2.5. CMS Approval and Best Price Contingency. **CMS approved this model agreement [enter date] and affirmed that the rebates paid under it do not affect Best Price or AMP.**

2.6. Effect of Subsequent Changes to MDRP or State Supplemental Rebates. 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 any Base Administrative Fee unless intended otherwise by the Parties as reflected in writing in Appendix B.

3. State Obligations

3.1. Covered Product Status. At a minimum, State shall ensure access to Covered Product and not disadvantage Covered Product to competitive drugs in the same Product Class.

3.1.1. Details about Covered Product Status in the FFS setting are described in Appendix A.

3.1.2. With respect to covered outpatient drugs reimbursed by MCOs, State will work with MCOs to ensure that Covered Product has Covered Product Status. If relevant, details about Covered Product Status in the MCO setting are described in Appendix A.

3.2. Preferred Status. State may also arrange for Preferred Status for Covered Product.

3.2.1. With respect to covered outpatient drugs reimbursed on a FFS basis, Covered Product may have Preferred Status. If relevant, details about Covered Product's Preferred Status in the FFS setting are described in Appendix A.

3.2.2. With respect to covered outpatient drugs reimbursed by MCOs, State will work with MCOs to ensure that Covered Product has Preferred Status. If relevant, details about Covered Product's Preferred Status in the MCO setting are described in Appendix A.

3.2.3. State may subject Covered Product to prior authorization, step-edit therapy and other management tools that it applies to other drugs within the Product Class.

3.3. Data Aggregator. State 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 manufacturer, if any. The contract between State 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 State from serving as the Data Aggregator. Data Aggregator shall perform the following tasks:

3.3.1. Gather and tabulate Utilization Data relating to the use of the Covered Product during the Utilization Period;

3.3.2. Generate Performance Data by applying the Outcome-Based Benchmarks and Evaluation Methodology to the Utilization Data;

3.3.3. Meet with and provide interim reports to the Parties regarding the collection and evaluation of the Utilization Data;

3.3.4. Make any adjustments to the collection of Utilization Data and/or Performance Data requested by the State;

3.3.5. Calculate the Outcome-Based Supplemental Rebates owed by Manufacturer, if any, by applying the Rebate Calculation Methodology to the Performance Data.

3.4. Patient Privacy. If the Data Aggregator is a third-party entity, State shall, in accordance with HIPAA, enter into a Business Associate Agreement ("BAA") with Data Aggregator and abide by all patient privacy requirements under HIPAA.

3.5. Cooperation. State will provide necessary information or otherwise cooperate with Data Aggregator so that Data Aggregator can perform its duties under Section 3.3.

3.6. Implementation of Bona Fide Service Plan. If applicable, State or the data aggregator will assist Manufacturer with implementation of Bona Fide Service Plan as described in Appendix A. The Parties shall ensure that any such 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 U.S.C. Section 1001.952(d).

3.7. Invoicing. If applicable, State or its designee will invoice Manufacturer for the Outcome-Based Supplemental Rebates within ninety (90) days after the end of the Settle-Up Period. State or its designee shall invoice Manufacturer for Outcome-Based Supplemental Rebates separately from the MDRP statutory rebate or any other state supplemental rebate, using the format set forth by CMS. State or its designee shall submit the Outcome-Based Supplemental Rebates invoice to the Manufacturer invoice contact, as identified by the Manufacturer to CMS.

4. Manufacturer Obligations

4.1. Cooperation. Manufacturer will provide necessary information or otherwise cooperate with State and Data Aggregator so they can perform their respective duties described in Section 3.

4.2. Remittance. If applicable, Manufacturer will remit payment of the Outcome-Based Supplemental Rebates within thirty-eight (38) days of postmark on the invoice from State (subject to Manufacturer's rights set forth in Section 6.2). Interest will accrue until the postmark date of Manufacturer's payment consistent with Manufacturer's rebate agreement with CMS under the MDRP. Nothing in this Agreement shall be construed to relieve Manufacturer from its obligation to pay any other rebates, including any rebates under the MDRP or a separate supplemental rebate agreement.

4.3. Implementation of Bona Fide Service Plan. Manufacturer will pay Bona Fide Service Fees to third-party entities in accordance with any Bona Fide Service Plan. Manufacturer will provide the information needed by State to evaluate the financial value of any Bona Fide Service Fees as described in Appendix A.

5. Federal Financial Participation. State will remit the appropriate share of the Outcome-Based Supplemental Rebates received from Manufacturer to CMS as required under its approved State Plan or a federal waiver.

6. Dispute Resolution

6.1. In the event that in any quarter a discrepancy in the Utilization Data is questioned by Manufacturer, the Parties, in good faith, shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the Parties will resolve their dispute in accordance with State hearing procedures as followed by the State or CMS in disputes concerning State Medicaid rebates.

6.2. If Manufacturer, in good faith, believes the Utilization Data is erroneous, the Manufacturer shall pay State that portion of the Outcome-Based Supplemental Rebates claimed that is not in dispute by the required date. The balance in dispute, including applicable interest, if any, will be paid by Manufacturer to State by the due date of the next quarterly payment after resolution of the dispute.

6.3. State and Manufacturer will use their best efforts to resolve the discrepancy within sixty (60) days of receipt of written notification. Should additional information be required to resolve disputes, State will cooperate with Manufacturer in obtaining the additional information.

6.4. In the event that State and the Manufacturer are not able to resolve a discrepancy regarding Utilization Data, Manufacturer may request a reconsideration of State's determination within thirty (30) days after the end of the 60-day period identified in Section 6.3. Manufacturer shall submit with its written request its argument in writing, along with any other materials, supporting its position to State. State shall review the written argument and materials and issue a decision in the matter.

6.5. Any overpayment or underpayment will be refunded to the other Party within thirty (30) calendar days of either the Parties' agreement of the over/underpayment amount or the State's decision of Manufacturer's written request for reconsideration.

7. Discretion to Market. Nothing in this Agreement shall be construed to prohibit Manufacturer from discontinuing production, marketing or distribution of any Covered Product or from transferring or licensing any Covered Product to a third party. It is understood that Manufacturer is liable for the payment of Outcome-Based Supplemental Rebates only for Covered Products dispensed or administered to New Mexico Medicaid recipients. If Manufacturer elects to discontinue production, marketing or distribution of any Covered Product or to transfer or license any Covered Product to a third party, Manufacturer shall make every reasonable effort to notify State prior to such actions.

8. Confidentiality Provisions

8.1. Confidentiality. Confidential Information will not be disclosed to any third person or entity not a party to this Agreement or used except in order to implement this Agreement or as may be required by law or judicial order. The term "Confidential Information" does not include information that (a) is or becomes generally available to the public other than as a result of a wrongful disclosure by the receiving Party or its employees, officers, directors, agents, advisors, volunteers, contractors, or representatives (collectively, "Agents"), (b) was actually known by the receiving Party prior to disclosure hereunder as evidenced by the receiving Party's tangible records; (c) is developed or discovered by the receiving Party independently and solely without the use of any Confidential Information disclosed

hereunder; or (d) is required to be disclosed by law or other legal requirement, provided that the disclosing Party is given prompt prior written notice of any such proposed disclosure so it has an opportunity to file appropriate legal objections. Each Party shall maintain the confidentiality of all the terms and conditions of this Agreement throughout the term hereof and for a period of not less than three (3) years following termination.

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

8.3. Ongoing Manufacturer Duty. Subject to Section 8.4 hereof, the Manufacturer will hold Utilization Data confidential. If the Manufacturer audits this information or receives further information on such data from State, that information shall also be held confidential. The Manufacturer shall have the right to disclose Utilization Data to auditors who agree to keep such information confidential.

8.4. Third Parties. Pursuant to 42 U.S.C. Section 1396r-8(b)(3)(D), and other applicable state or federal laws, the Parties agree that this Agreement and all information provided pursuant to this Agreement will not be disclosed and that the Parties will not duplicate or use the information, except in connection with this Agreement or as may be required by law or judicial order. The Parties further agree that any information provided by Manufacturer to State or Data Aggregator pursuant to this Agreement and this Agreement itself constitute trade secrets and/or confidential or proprietary commercial and financial information not subject to public disclosure. If the services of a third party are used to administer any portion of this Agreement, Sections 8.1 through 8.5 of this Agreement shall apply to the third party. In the event that either Party is required by law to disclose any provision of this Agreement or pricing information to any person, such Party shall provide advance written notice to the other Party sufficiently in advance of the proposed disclosure to allow the other Party to seek a protective order or other relief.

8.5. Survival. Notwithstanding the non-renewal or termination of this Agreement for any reason by any Party, these confidentiality provisions will remain in full force and effect as to all Parties.

9. Term and Termination

9.1. Term. The term of this Agreement shall begin on the ____ day of _____ (the "Effective Date") and shall end on _____ with options to renew for five (5) additional one-year periods. Renewal shall be at the option of the State. If the State elects not to renew, then the Manufacturer will be notified with a minimum of 30-day notice. The option to renew shall be contingent upon the needs of the OHCA, and is at the sole discretion of the OHCA. Options to renew shall be executed by mutual agreement.

9.2. Breach. If either Party commits a material breach of this Agreement, the non-breaching Party shall deliver written notice of the alleged breach to the breaching Party, with an opportunity for the breaching Party to cure the breach during the thirty (30) day period following the delivery. Failure to cure shall give the non-breaching Party the right to cancel

this Agreement at the end of the thirty (30) day period. The non-breaching Party shall give the breaching Party final written notice of the cancellation of this Agreement.

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

10. General Provisions

10.1. Record Keeping and Audit. Unless a longer period is required by law, during the term of this Agreement and for a period of seven (7) years thereafter, both Parties to the Agreement shall use reasonable efforts at all times to ensure that they maintain accurate books, files and records relevant to this Agreement. At Manufacturer's written request, State or its agent shall make such information relevant to this agreement available for inspection by Manufacturer representatives or its designated auditors during regular business hours. Upon written request, each Party shall otherwise have the right to inspect, up to once each year, all such relevant books, and records of the other Party to verify compliance with the terms of this Agreement.

10.2. Indemnification. Manufacturer shall indemnify, defend and hold harmless State and its officers, employees and agents from any claims, actions, suits, demands, costs, damages or liabilities (including reasonable attorney's fees and court costs) arising out of or connected with (1) any negligent act or omission of Manufacturer or its employees, agents or contractors, (2) any defect in the Manufacturer's Covered Product, or (3) any breach of this Agreement of any violation of any law or regulation by Manufacturer or its employees, agents or contractors.

10.3. Notices. All written notices, requests and communications, unless specifically required to be given by a specific method, may be: (i) delivered in person, obtaining a signature indicating successful delivery; (ii) sent by a recognized overnight delivery service, obtaining a signature indicating successful delivery; (iii) sent by certified mail, obtaining a signature indicating successful delivery; or (iv) sent by electronic mail, requesting confirmation of receipt and addressed as follows:

If to Manufacturer:
[NAME]
[ADDRESS]
[EMAIL]

If to State:
New Mexico Health Care Authority
ATTN: Pharmacy
P.O. Box 2348
Santa Fe, NM 87504-2348

10.4. Force Majeure. Noncompliance with any obligations hereunder due to a force majeure event, including but not limited to acts of God, laws or regulations of any government, war, terrorism, destruction of production facilities and materials, fire, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers, and any other causes beyond the reasonable control of the Parties, shall not constitute breach of contract, and a Party's performance shall be excused during such force majeure event.

10.5. Assignment. Neither Party shall have the right to assign this Agreement to a third party without the prior written consent of the other Party. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any Party of responsibility for the performance of any obligations that have accrued prior to such assignment.

10.6. No Waiver of Rights. The failure of either Party to insist upon the strict observation or performance of any provision of this Agreement or to exercise any right or remedy shall not impair or waive any such right or remedy in the future. Every right and remedy given by this Agreement to the Parties may be exercised from time to time as often as appropriate.

10.7. Entire Agreement. This Agreement contains the entire agreement and understanding of the Parties. This Agreement may not be amended except upon the written agreement of both Parties.

10.8. Governing Law and Venue. This Agreement shall be interpreted under and governed by the laws of the State of New Mexico, without regard to its conflict of laws principles. In the event of a lawsuit involving this Agreement, venue shall be in any court of competent jurisdiction in New Mexico.

10.9. Survival. The provisions of this Agreement that by their nature are intended to continue in their effect following expiration or termination of this Agreement shall survive any such expiration or termination, including, but not limited to, Sections 2, 6, 8, 10.1., 10.2, and 10.8.

10.10. Effect of Future Laws. In the event of the occurrence of a Future Law, each Party shall have the right to enter into good faith negotiations with the other in order to seek to agree on reasonable terms for maintaining the intent of the Agreement. Agreement on any such terms shall be at the sole discretion of each Party. If the Parties do not agree within sixty (60) days of a Party's written request for negotiations, either Party may terminate this Agreement with respect to the affected Covered Products upon expiration of the sixty (60) day period, with immediate effect. For purposes of this section "Future Laws" means any statutory enactment or rule promulgation, and any final legal or administrative determinations made by a court or tribunal of competent jurisdiction that materially impairs any Party's ability or obligation to carry out its obligations or receive consideration due under this Agreement, including, without limitation, any changes to calculations of AMP or Best Price or laws regarding value-based or outcome-based rebate agreements. "Future laws" shall not invalidate or otherwise affect the calculation of the Outcome-Based Supplemental Rebate or the Base Administrative Fee except in accordance with Section 2.6.

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

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

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

Manufacturer	**New Mexico Health Care Authority**
_____	_____
Name	Name
Title: _____	Title: _____
Date: _____	Date: _____

Appendix A

Covered Product – Each Covered Product subject to this Agreement is specified below. Each Covered Product is identified by its NDC-11 number. 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 (the below NDC-11s only)	Drug Name

Utilization Period – Each Utilization Period shall encompass [_____] calendar quarter(s). It shall commence on [DATE], the first day of the first calendar quarter, and conclude on the last day of the last calendar quarter.

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 State to track Covered Product's utilization, to evaluate its performance and to calculate the Outcome-Based Supplemental Rebates. The Data Aggregator selected by the State for purposes of this Agreement is identified and described below:

Data Aggregator will be Pharmacy Management Consultants (PMC).

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

Covered Product Status – The Parties agree that each Covered Product will not be disadvantaged to competing products within its 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.*]
- Covered Product Status in MCO Setting – *[To be filled in or marked as not applicable.*]

Preferred Status – State may arrange for Preferred Status for Covered Product using a PDL, prior authorization procedures, step-edit therapy or other means to manage Product Class. 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.*]
- Preferred Status in MCO Setting – *[To be filled in or marked as not applicable.*]

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

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

Appendix B

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

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

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

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

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, Manufacturer 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 may 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 applicable 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 [SPECIFY NUMBER] days thereafter. The Settle-Up Period can be extended by written agreement of the Parties.

Appendix A

Covered Product – Each Covered Product subject to this Agreement is specified below. Each Covered Product is identified by its NDC-11 number. 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 (the below NDC-11s only)	Drug Name

Utilization Period – Each Utilization Period shall encompass [_____] calendar quarter(s). It shall commence on [DATE], the first day of the first calendar quarter, and conclude on the last day of the last calendar quarter.

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 State to track Covered Product's utilization, to evaluate its performance and to calculate the Outcome-Based Supplemental Rebates. The Data Aggregator selected by the State for purposes of this Agreement is identified and described below:

Data Aggregator will be Pharmacy Management Consultants (PMC).

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

Covered Product Status – The Parties agree that each Covered Product will not be disadvantaged to competing products within its 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.*]
- Covered Product Status in MCO Setting – *[To be filled in or marked as not applicable.*]

Preferred Status – State may arrange for Preferred Status for Covered Product using a PDL, prior authorization procedures, step-edit therapy or other means to manage Product Class. 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.*]
- Preferred Status in MCO Setting – *[To be filled in or marked as not applicable.*]

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

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

Appendix B

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

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

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

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

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, Manufacturer 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 may 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 applicable 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 [SPECIFY NUMBER] days thereafter. The Settle-Up Period can be extended by written agreement of the Parties.