DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 150 S. Independence Mall West Suite 216, The Public Ledger Building Philadelphia, Pennsylvania 19106-3499



Region III/Division of Medicaid and Children's Health Operations

SWIFT # 040120144019

JUL 16 2014

Claudia Schlosberg, J.D.
Acting Senior Deputy Director/State Medicaid Director
Department of Health Care Finance
441 4th Street, N.W., 9th Floor
Washington, D.C.

Dear Ms. Schlosberg:

The Centers for Medicare & Medicaid Services (CMS) has completed its review of Washington, D.C.'s State Plan Amendment (SPA) 14-02. SPA 14-02 proposed a revision of the National Medicaid Pooling Initiative (NMPI) supplemental rebate agreement that enables the District to continue to receive supplemental rebates from participating pharmaceutical manufacturers.

This SPA is acceptable. Therefore, we are approving SPA 14-02 with an effective date of January 1, 2014. Enclosed is a copy of the CMS Summary Page (CMS-179 form) and the approved State Plan pages.

We appreciate the cooperation and effort provided by your staff throughout this process. If you have further questions about this SPA, please contact Kia Banton of my staff at 215-861-4252 or by email at Kia.Banton@cms.hhs.gov.

Sincerely

Associate Regional Administrator

Enclosures

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL	1. TRANSMITTAL NUMBER: 14-02	2. STATE District of Columbia						
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	3. PROGRAM IDENTIFICATION: Title XIX of the Social Security Act							
TO: Regional Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services	4. PROPOSED EFFECTIVE DATE January 1, 2014							
5. TYPE OF PLAN MATERIAL (Check One):								
□ NEW STATE PLAN □ AMENDMENT TO BE CON	ISIDERED AS NEW PLAN							
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AME	NDMENT (Separate Transmittal for each	amendment)						
6. FEDERAL STATUTE/REGULATION CITATION Section 1927(a)(1) and 1927(a)(4) of the Social Security Act	7. FEDERAL BUDGET IMPACT a. FFY 14 \$0 b. FFY 15 \$0							
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)							
Supplement 1 to Attachment 3.1-A p. 19 Supplement 1 to Attachment 3.1-B p. 18	Supplement 1 to Attachment 3.1-A Supplement 1 to Attachment 3.1-B							
10. SUBJECT OF AMENDMENT: Pharmacy Supplemental Rebate Agreement Program								
11. GOVERNOR'S REVIEW (Check One) GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL	☑ OTHER, AS SPECIFIED: Resolution Number: 20-0682							
12. SIGNATURE OF STATE AGENCY OFFICIAL	16. RETURN TO							
13. TYPED NAME Linda Elam, Ph.D., M.P.H. 14. TITLE Senior Deputy Director/Medicaid Director 15. DATE SUBMITTED March 26, 2014	Linda Elam, Ph.D., M.P.H. Senior Deputy Director/Medicaid Director Department of Health Care Finance 441 4 th Street, NW, 9 th Floor, South Washington, DC 20002							
FOR REGIONAL OFF	ICE USE ONLY							
17. DATE RECEIVED MAR 2 6 2014	18. DATE APPROVED JUN 1	8, 2014						
PLAN APPROVED - ONE COPY ATTACHED								
19. EFFECTIVE DATE OF APPROVED MATERIAL JAN 0 1 2014	20 SIGNATURE OF REGIONAL OFFI	QIAL 2						
21. TYPED NAME Francis Mc Cullong	Associate Regional Adylin	ustrator						
23. REMARKS								

authorization. The District has established a preferred drug list with prior authorization for drugs not included on the preferred drug list. The prior authorization process complies with the requirements of Section 1927 of the Social Security Act and provides for a 24-hour turnaround by either telephone or other telecommunications device from receipt of request and provides for a 72 hour supply of drugs in emergency circumstances. The preferred drug list meets the formulary requirements that are specified in Section 1927 (d)(4) of the Act.

- 5) The drugs or classes of drugs listed in 42 USC 1396r-8(d)(2) are excluded from coverage unless specifically placed, either individually or by drug class, on the Medicaid Drug List or by prior authorization based on FDA-approved indications or a medically accepted indication documented in official compendia or peer-reviewed medical literature. The following drugs are excluded from coverage through the Outpatient Pharmacy Program:
 - a. A drug for which the FDA has issued a "less than effective (LTE) rating or a drug "identical, related, or similar" to an LTE drug;
 - b. A drug that has reached the termination drug established by the drug manufacturer; and
 - c. A drug for which the drug manufacturer has not entered into or has not complied with a rebate agreement in accordance with 42 USC 1396 r-8 (a) unless there has been a review and determination by DHCF that it shall be in the best interest of Medicaid recipients to make payments for the non-rebated drug.
- 6) Supplemental Rebate Program:

The District is in compliance with section 1927 of the Social Security Act. The District has the following policies for the Supplemental Rebate Program for the Medicaid population:

- a. The "Supplemental Drug Rebate Agreement" between the participating states, Magellan Medicaid Administration, and the participating manufacturers, has been submitted to CMS and authorized by CMS effective October 1, 2013.
- b. CMS has authorized the District of Columbia to enter into the National Medicaid Pooling Initiative (NMPI) for outpatient drugs provided to Medicaid beneficiaries. The Supplemental Drug Rebate Agreement authorizes the District to enter into new or renewal agreements with pharmaceutical manufacturers for outpatient drugs provided to Medicaid beneficiaries.
- Supplemental rebates received by the District in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national drug rebate agreement.
- d. Manufacturers who do not participate in the supplemental rebate program will continue to have their drugs made available to Medicaid participants through either the preferred drug list or the prior authorization process

Approval Date: JUN 1 8 2014 Effective Date: 1/1/2014

TN No. <u>14-02</u> Supercedes TN No. <u>05-03</u> receipt of request and provides for a 72 hour supply of drugs in emergency circumstances. The preferred drug list meets the formulary requirements that are specified in Section 1927 (d)(4) of the Act.

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 - a. A drug for which the FDA has issued a "less than effective (LTE) rating or a drug "identical, related, or similar" to an LTE drug;
 - b. A drug that has reached the termination drug established by the drug manufacturer;
 - c. A drug for which the drug manufacturer has not entered into or has not complied with a rebate agreement in accordance with 42 USC 1396 r-8 (a) unless there has been a review and determination by DHCF that it shall be in the best interest of Medicaid recipients to make payments for the non-rebated drug.

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- c. Supplemental rebates received by the District in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national drug rebate agreement.
- d. Manufacturers who do not participate in the supplemental rebate program will continue to have their drugs made available to Medicaid participants through either the preferred drug list or the prior authorization process

Approval Date JUN 18 2014

NATIONAL MEDICAID POOLING INITIATIVE ("NMPI") SUPPLEMENTAL DRUG REBATE AGREEMENT

PARTIES/PERIOD

1.1	This NMPI Supplemental Drug Rebate Agreement ("Agreement") is made and entered					
into	, by and between the State of Michigan ("State"), represented by the					
Department of Community Health ("State"), Magellan Medicaid Administration, Inc. ("Magellan						
Medica	aid Administration"),("Manufacturer"), and such other					
states	that subsequently join into this Agreement upon the terms hereafter set forth					
("Partio	cipating State(s) "). The parties, in consideration of the covenants, conditions,					
agreements, and stipulations expressed in this Agreement, do agree as follows:						

PURPOSE

2.1 It is the intent of this Agreement that (i) states that have entered into agreements for Magellan Medicaid Administration to provide pharmacy benefit administration services ("PBA Services") to the state Medicaid and other non-Medicaid programs approved by CMS in the Medicaid state plan(s) ("MMA Clients") that do not affect Best Price, including the Participating States, will receive State Supplemental Rebates, in addition to the rebates received under the CMS Rebate Agreement, pursuant to Section 1927 of the Social Security Act (42 U.S.C. § 1396r-8), for the Manufacturer's Supplemental Covered Product(s) quarterly utilization in the Participating States' Medicaid Programs in which there is Medicaid federal financial participation. It is also the intent of this Agreement that State Supplemental Rebates will be paid for utilization of the Manufacturer's Supplemental Covered Product(s) in other state funded programs that have been approved for inclusion by the Secretary of Health and Human Services ("HHS"). The parties also intend for this Agreement to meet the requirements of federal law at Section 1927 of the Social Security Act (42 U.S.C. §1396r-8).

DEFINITIONS

3.1 'Average Manufacturer Price' or 'AMP' shall mean the Average Manufacturer Price as set forth in 42 U.S.C. §1396r-8, and final regulations promulgated by CMS thereto, if any, as such statute or regulations may be amended from time to time.

- 3.2 'Best Price' shall mean Best Price as set forth in 42 U.S.C. §1396r-8, and final regulations promulgated by CMS thereto, if any, as such statute or regulations may be amended from time to time.
- 3.3 'Covered Outpatient Drug' will have the meaning as set forth in 42 U.S.C. § 1396r-8(k)(2),(k)(3) and (k)(4) and regulations promulgated by CMS thereto, if any, as such statute or regulations may be amended from time to time.
- 'CMS Agreement' means the Manufacturer's drug rebate contract with the Centers for Medicare & Medicaid Services (or 'CMS'), formerly known as the Health Care Financing Administration, entered pursuant to Section 1927 of the Social Security Act [42 U.S.C. § 1396r-8].
- 3.5 'CMS Basic Rebate' means, with respect to the Supplemental Covered Product(s), the quarterly payment by Manufacturer pursuant to Manufacturer's CMS Agreement, made in accordance with Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act [42 U.S.C. §1396r-8(c)(1) and 42 U.S.C. § 1396r8(c)(3)].
- 'CMS Additional Rebate' means, with respect to the Supplemental Covered Product(s), the quarterly additional payment by Manufacturer pursuant to Manufacturer's CMS Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act (pertaining to the additional rebate calculated for single source and innovator multiple source drugs), as may be applicable [42 U.S.C. §1396r-8(c)(2)].
- 3.7 'CMS Rebate' means, with respect to the Supplemental Covered Product(s), the quarterly payment by Manufacturer pursuant to Section 4.1 of this Agreement.
- 3.8 'CMS Unit Rebate Amount' means, the unit amount computed by CMS to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.

- 'Magellan Medicaid Administration Client(s)' or 'MMA Clients' means those states (including the State) that have entered or subsequently enter into agreements with Magellan Medicaid Administration for the provision of PBA Services to the states' Medicaid, Participating Medicaid MCO, or other non-Medicaid programs approved by CMS in the Medicaid state plan(s), subject to the supervision and oversight of such States.
- 3.10 'Manufacturer' means, for purposes of this Agreement, the party identified as such in Section 1.1 of this Agreement, which may be a pharmaceutical manufacturer, labeler or other entity not prohibited by law from entering into this Agreement.
- 3.11 'Medicaid MCO' means a Medicaid managed care organization that is responsible for coverage of Covered Outpatient Drugs for Medicaid Recipients who are enrolled with the managed care entity, as further described in 42 U.S.C. § 1396b(m)(2)(viii), as may be amended from time to time.
- 3.12 'Participating Medicaid MCO' means a Medicaid MCO that a Participating State has determined is eligible for Supplemental Rebates consistent with the applicable Participating State Medicaid Plan and the applicable Participating State's contract with the Medicaid MCO. In order to qualify as a "Participating Medicaid MCO', the Medicaid MCO must have aligned its formulary and/or preferred drug list, as applicable, with the PDL, assuring access to Supplemental Covered Product is no more restrictive than the Participating State PDL requirements applicable to the Supplemental Covered Product.
- 3.13 'Participating State(s)' means the (i) States named in Section 1.1 hereof, and (ii) other states that, subsequent to the execution of this Agreement by the States, elect to participate under this Agreement and have all necessary authorizations and approvals from CMS to do so. Unless otherwise authorized by CMS on a state -by -state basis, Participating States shall be limited to ones that have a CMS authorized contract under which Magellan Medicaid Administration has been engaged to provide PBA services to that State. For each new Participating State, a unilateral agreement ("National Medicaid Pooling Initiative ("NMPI") Medicaid Program Participation Agreement ("Participation Agreement") in the form attached hereto as Attachment A, shall be executed by the new Participating State and Magellan

Medicaid Administration and sent to the Manufacturer prior to the Participation Commencement Date. A Catalogue of NMPI Participating State Medicaid Programs, which may be amended from time to time without consent of Manufacturer, is attached hereto as Attachment B.

- 3.14 'Participating States' Discount Per Unit' or 'Discount' means the amount(s) agreed upon by the parties to this Agreement in the attached "Supplemental Rebate Matrix, Schedule 2". 'Discount' will vary in accordance with Schedule 2 and is dependent upon the number of Supplemental Covered Product(s) in a Preferred Drug List's product category. Per the attached "Supplemental Rebate Matrix, Schedule 2", Discount will be a factor in the equation that is determinative of the Supplemental Rebate Amount.
- 3.15 'Participation Commencement Date' is the latter of the date: (i) a Manufacturer's Supplemental Covered Product is effective upon public dissemination of a Participating State's Preferred Drug List via website for providers and prescribers, (ii) the Participation Agreement is fully executed and a copy provided to the Manufacturer, or (iii) the effective date of CMS approval of the Participating State's applicable state plan amendment. It is the date when the Participating State(s)' entitlement to the State Supplemental Rebate(s) from the Manufacturer accrues.
- 3.16 'Preferred Drug List' or 'PDL' shall mean the list of drugs adopted by a Participating State Medicaid program in consultation with the respective state's pharmacy and therapeutics committee pursuant to that Participating State's relevant enabling legislation, as applicable.
- 3.17 'Rebate Summary' means the individual Participating States' reports itemizing the State Utilization data supporting each Participating State's invoice for Rebates. The Rebate Summary will comply in all respects with requirements for Medicaid Utilization Information in the CMS Agreement.
- 3.18 'State Supplemental Rebate' means, with respect to the Supplemental Covered Product(s), the quarterly payment by Manufacturer pursuant to Section 4.2 of this Agreement.

- 3.19 'State Utilization' means the total number of Units of each dosage form and strength of the Supplemental Covered Product(s) reimbursed during a quarter under a Participating State Medicaid program as well as under any state-funded, HHS-approved program(s) listed in Attachment A-1. These data are based on claims paid by the Participating State program during a calendar quarter, except the data shall not include drugs dispensed prior to January 1, 1991. With respect to any program(s) listed in Attachment A-1, "State Utilization" shall not include any claims paid by such program(s) during any period of time that such program(s) were not HHSapproved for inclusion with Medicaid supplemental rebates. Where a Participating State has elected to seek Supplemental Rebate Amounts for Medicaid MCO utilization as permitted under this Agreement and the Participating State Medicaid Plan, the term "State Utilization" shall also include the total number of Units of each dosage form and strength of the Supplemental Covered Product(s) for which the Participating Medicaid MCOs were responsible for covering during a quarter, except it shall in no event include drugs dispensed prior to the date the Participating State elects to include such Medicaid MCO utilization under Attachment A-2, and provides all required documentation supporting such election to Magellan Medicaid Administration.
- 3.20 'Supplemental Covered Product' means the Covered Outpatient Drug (s) of the Manufacturer, as detailed in the attached Supplemental Rebate Matrix, Schedule 2, upon which a State Supplemental Rebate will be paid pursuant to this Agreement.
- 3.21 'Supplemental Covered Product Category' or 'Product Category' means a defined group of pharmaceutical products considered to compete with one another in the market and that are also thought to be therapeutic alternatives in many situations. Magellan Medicaid Administration has determined and defined the Product Categories in which manufacturers will bid. The Product Categories, set forth on the "Product Categories, Schedule 1" hereto, may be changed as deemed appropriate by Participating States or MMA.
- 3.22 'Supplemental Rebate Amount' means, with respect to the Supplemental Covered Product(s), the amount(s) specified in the attached Supplemental Bid Matrix, Schedule 2, and Supplemental Rebate Calculation, Schedule 3, that the Manufacturer has agreed to reimburse Participating States per unit of drug in accordance with the formula detailed in the above

Schedules. Where a Participating State has elected to include Medicaid MCO utilization as permitted under this Agreement and the Participating State Medicaid Plan, the term "Supplemental Rebate Amount" shall include the rebates invoiced hereunder with respect to such Medicaid MCO utilization, in addition to the applicable state fee-for-service Medicaid utilization and utilization under any state-funded, HHS-approved program(s) listed in Attachment A-1.

- 3.23 'Unit' means drug unit in the lowest identifiable amount (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 the submission of data under 42 U.S.C. § 1396r-8.
- 3.24 'Wholesale Acquisition Cost' or 'WAC' means the Manufacturer's U.S. Dollar wholesale acquisition price in effect on the last day of a quarter on a unit basis as published by a third party source, such as First Databank or MediSpan, or its successor publication for each Supplemental Covered Product.

MANUFACTURER'S RESPONSIBILITIES

- 4.1 Manufacturer will calculate and provide each Participating State a CMS Rebate for the Supplemental Covered Product(s), which includes the CMS Basic Rebate and CMS Additional Rebate, as appropriate, in accordance with the terms of the CMS Agreement. Manufacturer's obligation for CMS Rebates will continue for the duration of the Manufacturer's CMS Agreement.
- 4.2 In addition to the CMS Rebates described in Section 4.1 of this Agreement, Manufacturer will remit to each Participating State a State Supplemental Rebate for the Supplemental Covered Product(s) that are in each Participating States' Preferred Drug List Program. The State Supplemental Rebates will be calculated on a calendar quarter basis and provided via invoices to the Manufacturer's CMS financial contact. The State Supplemental Rebates for the quarter will be determined by applying the applicable State Supplemental Rebate to the State Utilization data for each Supplemental Covered Product in the preceding quarter. The Manufacturer's obligation for State Supplemental Rebates will continue for the

duration of this Agreement. The Supplemental Rebate calculation is described in "Supplemental Rebate Calculation, Schedule 3".

- 4.3 The Manufacturer's obligation for State Supplemental Rebates will begin

 [DATE] and will continue through the Rebate Billing Period that ends

 [DATE], subject to each Participating States' actual Participation

 Commencement Date as described in Section 3.15, supra. Notwithstanding the above, the Participating States reserve the right to solicit annually more favorable State Supplemental Rebates from Manufacturer by giving written notice thereof no less than ninety (90) days prior to the yearly anniversary of the effective date of this Agreement.
- The quarters to be used for calculating the Rebates in Sections 4.2-4.3 of this Agreement will be those ending on March 31, June 30, September 30, and December 31 of each calendar year during the term of this Agreement.
- 4.5 The participating Manufacturer will be required to submit each Participating State's State or Participating Medicaid MCO Supplemental Rebate payment within 38 days of the Manufacturer's receipt of the Participating State's Rebate Summary.
- Manufacturer will pay the State Supplemental Rebates, including any applicable interest in accordance with Section 1903 (d)(5) of the Act. Interest on the State Supplemental Rebates payable under Section 4.2 of this Agreement begins accruing 38 calendar days from the postmark date of each Participating State's invoice and supporting Rebate Summary sent to the Manufacturer and interest will continue to accrue until the postmark date of the Manufacturer's payment. For the rebate programs invoiced under this Agreement, if the date of mailing of a State Supplemental 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 for rebates described in Section 4.1 but will be increased by ten percentage points or the maximum allowed by that Participating State's state law. If a Participating State has not received the State Supplemental Rebates payable under Section 4.2 of this Agreement, including interest, within 180 days of the postmark date of said Participating State's invoice and supporting Rebate Summary sent to the Manufacturer, such Participating State may deem the

Manufacturer to be in default and Participating State may, at their sole discretion, immediately move some or all Supplemental Covered Products to non-preferred status without further notice.

- 4.7 Manufacturer agrees to continue to pay State Supplemental Rebates on the Supplemental Covered Product(s) for as long as this Agreement or any of its Addenda are in force, and State Utilization data shows that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. Manufacturer's obligation to pay State Supplemental Rebates on the Supplemental Covered Product(s) shall terminate twelve (12) months following the last expiration date of the last lot of Supplemental Covered Product sold by the Manufacturer. Notwithstanding the above, in the event Manufacturer's Supplemental Covered Product(s) is/are sold to another manufacturer, the original Manufacturer shall have no liability for rebates on utilization beyond those required by the Medicaid program. Manufacturer shall provide the State and Magellan Medicaid Administration with notice of the sale of said Supplemental Covered Product(s) concurrent with Manufacturer's notice to CMS.
- 4.8 Unless notified otherwise, Manufacturer will send Rebate payments by certified mail, return receipt requested, to the address provided to Manufacturer in each individual Participation Agreement.

PARTICIPATING STATE(S)' RESPONSIBILITIES

Each Participating State will consider the Manufacturer's Supplemental Covered Product(s) for inclusion in the Participating State's Preferred Drug List Program. Each individual Participating State reserves the right to select the products that will be in its Preferred Drug List Program and will only receive State Supplemental Rebates for Manufacturer's Supplemental Covered Products that are actually included in its Preferred Drug List Program effective on or after the applicable Participation Commencement Date. Manufacturer shall pay Participating States' State Supplemental Rebates based upon Participating State(s)' utilization of Manufacturer's Supplemental Covered Product(s), as reflected in Participating State Utilization data. Notwithstanding the forgoing, Manufacturer shall not be obligated to pay State Supplemental Rebates to a Participating State for a Supplemental Covered Product for any

period during which such Participating State subjected that Supplemental Covered Product to a prior authorization requirement, unless: (i) such Supplemental Covered Product has been assigned to a Product Category and all products in the Product Category are subject to prior authorization requirements; (ii) or Manufacturer has explicitly agreed to the terms of such controls as to such Supplemental Covered Product in writing as part of its State Supplemental Rebate terms, as set forth in the Supplemental Rebate Matrix, Schedule 2. If a Participating State determines that prior authorization is required for any Supplemental Covered Product, then the Participating State will comply with any provisions of Section 1927(d) of the Social Security Act applicable to prior authorization programs.

- 5.2 To the extent permitted by CMS and applicable law, any Participating State added hereunder may elect, but shall not be required, to include Participating State Utilization data from Participating Medicaid MCOs in their Supplemental Rebate invoices, provided that the Participating State provide to Magellan Medicaid Administration an executed and complete copy of Attachment A-2 indicating such election, as well as a copy of the applicable Participating State Medicaid Plan (and/or amendment thereto) permitting such election.
- 5.3 The State and/or Magellan Medicaid Administration shall notify the Manufacturer monthly of adoption and publication of a new or revised Preferred Drug List, whenever a Participating State adds one of Manufacturer's Supplemental Covered Products to its Preferred Drug List.
- 5.4 Each Participating State will provide aggregate State Utilization data to the Manufacturer on a quarterly basis. These data will be consistent with any applicable Federal or State guidelines, regulations and standards for such data, and will be the basis for the Participating State's calculation of the State Supplemental Rebate.
- 5.5 Each Participating State will maintain those data systems used to calculate the State Supplemental Rebates. In the event material discrepancies are discovered, the Participating State will promptly justify its data or make an appropriate adjustment, which may include a credit as to the amount of the State Supplemental Rebates, or a refund to Manufacturer as the parties may agree.

- 5.6 Each Participating State shall maintain electronic claims records for the most recent four quarters that will permit Manufacturer to verify through an audit process the Rebate Summaries provided by the Participating State with respect to its fee-for-service Medicaid utilizations, subject to applicable law and state audit guidelines.
- 5.7 Magellan Medicaid Administration, as the pharmacy benefit administrator, may assist the Participating States in fulfilling its responsibilities hereunder and is a party to this Agreement solely in its capacity as agent for, and subject to the supervision and oversight of, the Participating State(s).
- 5.8 The State and each Participating State shall obtain CMS approval of its state Medicaid plan of which this Agreement forms a part. Manufacturer shall not be obligated to remit any Supplemental Rebates that have accrued and are due under this Agreement until after the affected State or Participating State has obtained CMS approval of its Supplemental Rebate Program of which this Agreement forms a part.

DISPUTE RESOLUTION

- In the event that in any quarter a discrepancy in a Participating State's State Utilization data is questioned by the Manufacturer, which the Manufacturer and the Participating State in good faith are unable to resolve, the affected parties shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the parties will resolve their dispute in accordance with generally applicable procedures followed by the affected Participating State or CMS in disputes concerning CMS Rebates. Notwithstanding anything to the contrary herein, any dispute relating to eligibility of Participating MCO utilization for State Supplemental Rebates hereunder shall be resolved exclusively between the Manufacturer and the Participating State.
- 6.2 If the Manufacturer, in good faith, believes the Participating State's State Utilization data is erroneous, the Manufacturer shall pay the Participating State that portion of the rebate claimed, that is not in dispute by the required date. The balance in dispute, including applicable interest, if any, will be paid by the Manufacturer to the Participating State by the due date of the next quarterly payment after resolution of the dispute.
- 6.3 The Participating State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of written notification. Should additional information be

required to resolve disputes, the Participating State and Magellan Medicaid Administration will cooperate with the Manufacturer in obtaining the additional information.

In the event that the Participating State and the Manufacturer are not able to resolve a discrepancy regarding State Utilization data, as provided for in Sections 6.1 through 6.3, the Manufacturer may request a reconsideration of the Participating State's determination within 30 days after the end of the 60 day period identified in Section 6.3. The Manufacturer shall submit with its written request its argument in writing, along with any other materials, supporting its position to the Participating State and Magellan Medicaid Administration. The Participating State shall review the written argument and materials and issue a decision in the matter.

CONFIDENTIALITY PROVISIONS

- 7.1 The parties agree that confidential information will not be released to any person or entity not a party to this contract. Confidential information, including but not limited to trade secrets, rebate pricing data, and terms of manufacturer agreements, will not be disclosed or used except in order to implement this Agreement or as may be required by law or judicial order. In the event Participating State terminates its PBA Services agreement with Magellan Medicaid Administration, Magellan Medicaid Administration shall not be obligated to transition confidential information to a third party competitor of Magellan Medicaid Administration, except as may be required by law, for a period of not less than three (3) years following such termination.
- 7.2 Subject to Section 7.3 hereof, the Manufacturer will hold Participating States' State Utilization data confidential. If the Manufacturer audits this information or receives further information on such data from Magellan Medicaid Administration or a Participating State, that information shall also be held confidential. The Manufacturer shall have the right to disclose Participating State(s)'s State Utilization data to auditors who agree to keep such information confidential.
- 7.3 Pursuant to 42 USC 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 the State, Magellan Medicaid

Administration, or the Participating State(s) 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. Furthermore, the parties agree that any Manufacturer information received by Magellan Medicaid Administration pursuant to this Agreement and distributed by Magellan Medicaid Administration to the State and/or Participating States shall constitute trade secrets and/or confidential or proprietary commercial and financial information of the Manufacturer not subject to public disclosure, except as otherwise provided for herein. If the services of a third party are used to administer any portion of this Agreement, Sections 7.1 through 7.4 of this Agreement shall apply to the third party. In the event a Participating State cannot give satisfactory assurance that rebate pricing data provided under this Agreement will be exempt from public disclosure under applicable state law, then Magellan Medicaid Administration, without assuming responsibility for any wrongful disclosure by a Participating State, shall limit the amount of such data made available to the Participating State by not disclosing to the Participating State any NDC-level pricing information. For purposes hereof "satisfactory assurance" shall be deemed given when the Participating State enters the statutory cite of the applicable exemption on its Participation Agreement. 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.

7.4 Notwithstanding the non-renewal or termination of this Supplemental Rebate Agreement for any reason by any party, these confidentiality provisions will remain in full force and effect to all parties.

NON-RENEWAL or TERMINATION

- 8.1 This Agreement shall be effective as of ______ [DATE] and shall have the term indicated in Section 4.3, *supra*.
- 8.2 In the event of nonrenewal or termination with respect to the State or one or more Participating States, this Agreement shall remain in effect with respect to the remaining parties.

- 8.3 State or any Participating State may terminate its participation in this Agreement by giving Manufacturer and Magellan Medicaid Administration written notice at least (90) days prior to the anniversary date of this Agreement, in which case termination shall become effective as to the terminating State or Participating State on the anniversary date of the date of execution of this Agreement. The termination of this Agreement by State or Participating States shall not affect the Manufacturer's, Magellan Medicaid Administration's or State's or Participating States' obligations under this Agreement. Manufacturer may terminate this Agreement and all Addenda by giving all Participating States and Magellan Medicaid Administration written notice at least ninety (90) days prior to the anniversary date of this Agreement, in which case termination shall become effective on the anniversary date of the date of execution of this Agreement. Manufacturer's right of termination is limited to the right to terminate the entire Agreement. Manufacturer may not terminate specific Addendum/Addenda of less than all Participating State(s). In addition, this Agreement shall be co-terminous with the CMS Rebate agreement, in the event that such agreement is terminated for any reason.
- 8.4 Termination by MMA Client of its PBA Services agreement with Magellan Medicaid Administration shall, as of the same termination effective date, terminate this Agreement as to that Participating State. In the event of such termination by Participating State, MMA will provide Manufacturer with an updated Catalogue of NMPI Participating State Medicaid Programs (Attachment B) to this Agreement. Accordingly, in the event of such termination, Magellan Medicaid Administration shall have no additional obligation to administer the terms of this Agreement as to such Participating State as of the effective date of such termination; unless Magellan Medicaid Administration and the terminating Participating State agree in writing upon mutually acceptable terms for run-out invoicing and processing State Supplemental Rebates accrued prior to termination. In addition, State Supplemental Rebates shall cease to accrue with respect to a Participating State as of the effective date that a Participating Medicaid Program terminates its PBA Services Agreement with Magellan Medicaid Administration.
- 8.5 Notwithstanding any non-renewal or termination of this Agreement, State Supplemental Rebates will still be due and payable from the Manufacturer under Section 4.2 for

any Supplemental Covered Products for which Participating State(s)' obligation to reimburse arose prior to the effective date of termination of this Agreement.

8.6 On at least an annual basis, or at the sole discretion of Magellan Medicaid Administration, Manufacturer shall have the opportunity to enhance the Discount of its Supplemental Covered Products to increase the likelihood of product(s) utilization and/or inclusion in the Participating States Preferred Drug List Programs.

GENERAL PROVISIONS

- 9.1 This Agreement will be governed and construed in accordance with 42 U.S.C. § 1396r-8 and all other applicable federal and state law and regulations.
- All written notices, requests and communications, unless specifically required to be 9.2 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; or (iii) sent by certified mail, obtaining a signature indicating successful delivery, to the address set forth below. Notwithstanding the forgoing, notices other than those pertaining to contract termination, amendment, assignment, and breach, which may include, but not be limited to State Supplemental Rebate invoices, shall not by subject to the formal "notice" requirements, and may be transmitted by Magellan Medicaid Administration and/or the applicable Participating State to the Manufacturer via US Mail or electronic means, which may include, without limitation, facsimile or electronic mail, and any electronic communication shall be considered received as of the date/time of such electronic transmission by the sender. Notice dates for web invoices, if any, shall be determined in accordance with CMS Rebate invoicing guidance (Medicaid Drug Rebate Program Release No. 80 (Jan. 5, 2010)). Notice to individual Participating States will be sent to the addressees specified in each individual Participating State's Participation Agreement.

Notice to the State shall be sent to:

State of Michigan

Department of Community Health Medical Services Administration

Attn: Director, Bureau of Medicaid Program Operations and Quality Assurance

400 S. Pine Street

Lansing, MI 48933

Notice to Magellan Medicaid Administration shall be sent to:

Magellan Medicaid Administration, Inc.

Attn: Chief Financial Officer

With a copy to: Legal Department

11013 W. Broad StreetSuite 500

Glen Allen, VA 23060-5937

Notice to Manufacturer shall be sent to:

- 9.3 The Manufacturer agrees to be bound by the laws of the United States of America and with respect to each Participating State, the law of that Participating State. Proper venue in any legal action shall be the venue of the Participating State that is party to the proceeding. Any action brought by Manufacturer must be brought separately against individual Participating States or Magellan Medicaid Administration, unless all affected Participating States and Magellan Medicaid Administration consent to joinder of the actions.
- 9.4 Nothing herein shall be construed or interpreted as limiting or otherwise affecting Magellan Medicaid Administration or Participating State(s) ability to pursue its rights arising out

of the terms and conditions of the Agreement in the event that a dispute between the parties is not otherwise resolved.

- 9.5 Manufacturer and the agents and employees of Manufacturer in the performance of this Agreement, will act in an independent capacity and not as officers, employees or agents of Magellan Medicaid Administration or any Participating State.
- 9.6 Manufacturer may not assign this Agreement, either in whole or in part, without written notice to Magellan Medicaid Administration, as agent for Participating States, at the address shown in Section 9.2. However, in the event of a transfer in ownership of the Manufacturer, the Agreement is automatically assigned to the new owner subject to the conditions in this Agreement. If the Agreement is assigned pursuant to this Section, Manufacturer shall provide Magellan Medicaid Administration, as agent for Participating States, with an update of the information contained in Section 9.2, and any assignee shall be fully responsible for compliance with all terms and conditions of this Agreement applicable to Manufacturer.
- 9.7 Nothing in this Agreement will be construed so as to require the commission of any act contrary to law. If any provision of this Agreement is found to be invalid or illegal by a court of law, or inconsistent with federal 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.
- 9.8 Magellan Medicaid Administration, Participating State(s) and Manufacturer declare that this Agreement, including attachments, schedules and addenda, contains a total integration of all rights and obligations of the parties. There are no extrinsic conditions, collateral agreements or undertakings of any kind. In regarding this Agreement as the full and final expression of their contract, it is the express intention of the parties that any and all prior or contemporaneous agreements, promises, negotiations or representations, either oral or written, relating to the subject matter and period of time governed by this Agreement which are not expressly set forth herein are to have no force, effect, or legal consequences of any kind.

- 9.9 This Agreement will not be altered except by (i) an amendment in writing signed by all the parties, other than (ii) in the case of the addition of a new Participating State(s), by its execution of the Participation Agreement. It is acknowledged that the intent of the previous sentence is that the addition of a new Participating State(s) by amendment shall only require the consent of Magellan Medicaid Administration and the approval of CMS, not Manufacturer. Manufacturer agrees that any Participating State may be a participant to this Agreement by signing a Participation Agreement and that said Participating State's covered Medicaid (and other non-Medicaid programs approved by CMS in the Medicaid state plan(s)) lives shall apply to the provisions of Schedules 2 and 3 and will affect the rebates to all Participating States in accordance with Schedules 2 and 3. The Participation Agreement shall be executed by Magellan Medicaid Administration and the new Participating State with a copy provided to Manufacturer for its records, along with an updated Catalogue of NMPI Participating Medicaid Programs (Attachment B) to this Agreement. Other than as stated herein, no individual is authorized to alter or vary the terms or make any representation or inducement relative to it, unless the alteration appears by way of a written amendment, signed by duly appointed representatives of Magellan Medicaid Administration, the Participating State and Manufacturer; and authorized by CMS.
- 9.10 The parties do not contemplate any circumstances under which indemnification of the other parties would arise. Nevertheless, should such circumstances arise, Manufacturer agrees to indemnify, defend and hold harmless the Participating States and Magellan Medicaid Administration, their officers, agents and employees from any and all claims and losses accruing or resulting to any person, firm or corporation who may be injured or damaged by the Manufacturer in the performance of this Agreement.
- 9.11 Participating States respectively represent and warrant that CMS has authorized this Agreement with respect to their respective State, and that it is the intent and expectation of such Participating States that State Supplemental Rebates hereunder shall be excluded from Manufacturer's calculation of Best Price or AMP.
- 9.12 If Magellan Medicaid Administration or a Participating State makes changes to a Product Category that are considered to be a material change in the structure of the supplemental

rebates	program,	Manufacturer	may	be	allowed	to	re-submit	bids	for	the	Product
Category/Categories affected.											
9.13 A	As evidence	of their Agreer	nent to	o the	e foregoin	g tei	rms and cor	nditior	is, th	e par	ties have
signed below.											
STATE OF	MICHIGAN	N, DEPARTMENT	r of co	MC	UNITY HE	ALT	H:				
Ву:					Date:			_			
Name: _											
Title: F											
Title: <u>Director, Bureau of Medicaid Program Operations and Quality Assurance</u>											
MANUFA	CTURER										
101711017	.oronzin										
Bv:						Date	e:				
Title:					_						
MAGELLA	AN MEDICA	AID ADMINISTRA	TION,	INC.							
Dv.						Dat					

Name: _____

Title: