



**CABINET FOR HEALTH AND FAMILY SERVICES  
DEPARTMENT FOR MEDICAID SERVICES**

**Steven L. Beshear**  
Governor

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**Audrey Tayse Haynes**  
Secretary

**Lawrence Kissner**  
Commissioner

December 10, 2013

Jackie Glaze  
Associate Regional Director  
Centers for Medicare and Medicaid Services  
61 Forsyth Street, SW, Suite 4T20  
Atlanta, Georgia 30303-8909

Re: Kentucky Title XIX State Plan Amendment No. 13-026

Dear Ms. Glaze:

The State of Kentucky is forwarding, for your review and approval, Kentucky Title XIX State Plan Amendment Transmittal Number 13-026. This State Plan Amendment provides for substantive changes to the existing ***National Medicaid Pooling Initiative ("NMPI") Supplemental Drug Rebate Agreement ("SRA")***, which includes revised definitions and structural changes to the SRA. In addition, definitions have been added to provide for the inclusion of Medicaid MCO utilization for accrual of supplemental rebates. The intent of the SRA has been expanded to cover both FFS and MCO populations, as long as the State retains control of the Preferred Drug List for both populations. Inclusion of the MCO population under the contract is optional and at the sole discretion of the State. The State understands, through communications with CMS Central Office, that a separate State Plan Amendment is required if the State intends to exercise this provision. Central Office has performed an initial review of the SRA and their suggested changes have been incorporated in the attached revised SRA.

Effective Date: October 1, 2013.

A brief description of additional changes to the NMPI SRA include:

- Clarified the terms under which supplemental rebates accrue for partial quarter invoicing.
- Revised the Confidentiality provision.
- Revised the Notice provision to reduce the administrative burden on the State.



Ms. Jackie Glaze  
December 9 2013  
Page 2

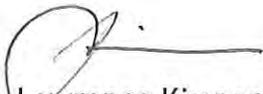
- Revised the Participating State Amendments (PSAs) to reduce the administrative burden on the State by linking the PSA to the Contract and not the individual manufacturer.
- Provided for the Participation Agreement to renew automatically for one-year terms, as long as the controlling agreement between Magellan/Provider Synergies and Participating State is active.
- Removed tiers from the bid grid.
- Added option to use alternative supplemental rebate calculation types to allow for different rebate accrual calculations than Guaranteed Net Unit Price (GNUP).

Enclosed for your review are the following documents:

- NMPI SRA Template Redline 5-31-13.docx
- NMPI SRA Template Clean 5-31-13.docx
- NMPI Schedule 1 Sample 5-14-13.docx
- NMPI Schedule 2 Redline 5-31-13.docx
- NMPI Schedule 2 Clean 5-31-13.docx
- NMPI Schedule 3 Supplemental Rebate Calculation Redline 5-31-13.docx
- NMPI Schedule 3 Supplemental Rebate Calculation Clean 5-31-13.docx
- NMPI Attachment A Participating State Amendment Redline 2-26-13.docx
- NMPI Attachment A - Participation Agmt Clean 2-26-13.docx
- NMPI Attachment A-1-List of Non-Medicaid Programs 2-26-13.docx
- NMPI Attachment A-2 Attestation for Medicaid MCOs 2-26-13.docx
- NMPI Attachment B - Catalogue of NMPI Participating States 2-26-13.docx
- Responses to Multi-State Supplemental Rebate Agreement Standard Questions

We look forward to gaining approval from CMS for this State Plan Amendment. If additional information is needed or if you have any questions, please contact Sharley Hughes.

Sincerely,

  
Lawrence Kissner  
Commissioner

LK/sjh

Enclosure

**TRANSMITTAL AND NOTICE OF APPROVAL OF  
STATE PLAN MATERIAL**

1. TRANSMITTAL NUMBER:  
13-026

2. STATE  
Kentucky

**FOR: HEALTH CARE FINANCING ADMINISTRATION**

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE  
SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR  
HEALTH CARE FINANCING ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE  
October 1, 2013

5. TYPE OF PLAN MATERIAL (*Check One*):

NEW STATE PLAN                       AMENDMENT TO BE CONSIDERED AS NEW PLAN                       AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (*Separate Transmittal for each amendment*)

6. FEDERAL STATUTE/REGULATION CITATION:  
Section 1927 of the SSA

7. FEDERAL BUDGET IMPACT:  
a. FFY 2014                      Budget Neutral  
b. FFY 2015                      Budget Neutral

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Att. 3.1-A, Page 7.5.1, 7.5.2, 7.5.2(a)  
Att. 3.1-B, Page 31, 31.1, 31.1(a)  
Att. 4.19-B, Page 20.1, 20.1(a), 20.1(b), 20.2

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION  
OR ATTACHMENT (*If Applicable*):

Same

10. SUBJECT OF AMENDMENT:

This SPA provides for substantive changes to the existing National Medicaid Pooling Initiative (NMPI)  
Supplemental Drug Rebate Agreement

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: Review delegated  
to Commissioner, Department for Medicaid  
Services

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME: Lawrence Kissner

14. TITLE: Commissioner, Department for Medicaid Services

15. DATE SUBMITTED: 11/25/13

16. RETURN TO:

Department for Medicaid Services  
275 East Main Street 6W-A  
Frankfort, Kentucky 40621

**FOR REGIONAL OFFICE USE ONLY**

17. DATE RECEIVED:

18. DATE APPROVED:

**PLAN APPROVED – ONE COPY ATTACHED**

19. EFFECTIVE DATE OF APPROVED MATERIAL:

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:

22. TITLE:

23. REMARKS:

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**12. Prescribed Drugs, Dentures, Prosthetic Devices, and Eyeglasses**

If medical necessity is established, limitations in this section do not apply to EPSDT eligible children in accordance with 1905 (r)(5) of the Social Security Act.

**a. Prescribed Drugs**

- (1) Coverage is provided for drugs included in the Medicaid drug lists that are prescribed for outpatient use by a physician, osteopath, dentist, podiatrist, optometrist, physician assistant, or advanced registered nurse practitioner. Drugs added to the Preferred Drug List (PDL) are based on recommendations submitted by the Pharmacy and Therapeutics Advisory Committee to the Commissioner of the Kentucky Department for Medicaid Services for approval. Drugs requiring prior authorization must follow the process listed below. Approval of prior authorization is based on FDA-approved indications or a medically accepted indication documented in official compendia or peer-reviewed medical literature.
- (2) Kentucky will provide reimbursement for covered outpatient drugs when prescribed by an enrolled licensed provider within the scope of their license and practice as allowed by State law and in accordance with Section 1927 of the Social Security Act. This will apply to drugs of any manufacturer that has entered into a rebate agreement with the Centers for Medicare and Medicaid Services (CMS). All drugs covered by the National Drug Rebate Agreements remain available to Medicaid beneficiaries, although some may require prior authorization. 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 1 927(d)(4) of the Social Security Act.
- (3) 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 lists or prior authorized 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 (IRS)” to an LTE drug;
  - (b) A drug that has reached the termination date 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 1396r-8(a) unless there has been a review and determination by the department that it shall be in the best interest of Medicaid recipients for the department to make payment for the non-rebated drug. Note: Because federal financial participation is not generally available for a non-rebated drug, state funds will be used to cover such drugs if necessary to protect the health of a Medicaid recipient and no other appropriate options exist;

- (d) A drug provided to a recipient in an institution in which drugs are considered a part of the reasonable allowable costs under the Kentucky Medicaid Program;
- (e) A drug or its medical use in one (1) of the following categories unless the drug or its medical use is designated as covered in the drug list:
  - 1. A drug if used for anorexia, weight loss, or weight gain;
  - 2. A drug if used to promote fertility;
  - 3. A drug if used for cosmetic purposes or hair growth;
  - 4. A drug if used for the symptomatic relief of cough and colds;
  - 5. Vitamin or mineral products other than prenatal vitamins and fluoride preparations;
  - 6. An over-the-counter drug provided to a Medicaid nursing facility service recipient if included in the nursing facility's standard price;
  - 7. A barbiturate;
  - 8. A benzodiazepine;
  - 9. A drug 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; or
  - 10. A drug utilized for erectile dysfunction therapy unless the drug is used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the United States Food and Drug Administration;
- (f) A drug dispensed as part of, or incident to and in the same setting as, an inpatient hospital service, an outpatient hospital service, or an ambulatory surgical center service. However, a legend drug may be provided through prior authorization to a recipient admitted to an inpatient facility that does not bill patients, Medicaid, or other third-party payers for health care services.
- (g) A drug for which the department requires prior authorization if prior authorization has not been approved; and
- (4) Except for emergencies, a recipient "locked-in" to one pharmacy due to over-utilization may receive prescriptions:
  - (a) Only from his/her designated lock-in pharmacy and prescribed by his/her lock-in provider; or
  - (b) For specified controlled substances prescribed by his/her designated controlled substance lock-in prescriber.
- (5) If authorized by the prescriber, a prescription for a controlled substance in Schedule III-V may be refilled up to five times within a six month period from the date the prescription was written or ordered; a non-controlled substance may be refilled up to 11 times within a 12 month period from the date the prescription was written or ordered. In addition, a prescription fill for a maintenance drug may be dispensed in a 92-day supply if a recipient has demonstrated stability on the maintenance drug. However, a 92-day supply of a maintenance drug shall not be dispensed if a prescribing provider specifies that the quantity should be less. Also, individuals receiving supports for community living services, long term care, and personal care shall not be subject to the 92-day supply requirement.

- (6) A refill of a prescription shall not be covered unless at least 90 percent of the prescription time period has elapsed. However, a refill may be covered before 90 percent of the prescription time period has elapsed if the prescribing provider or dispensing pharmacy submits a prior authorization request by phone, fax, or web submission. Medicaid recipients residing in a long-term care facility or personal care home will be exempt from the 90 percent requirement and remain at the current 80 percent.
- (7) Supplemental Rebate Program:

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

- (a) CMS has authorized the Commonwealth of Kentucky to enter into the Michigan multi-state pooling agreement (MMSPA) also referred to as the National Medicaid Pooling Initiative (NMPI) for drugs provided to Medicaid beneficiaries. The NMPI Supplemental Rebate Agreement (SRA) and the Amendment to the SRA submitted to CMS on January 6, 2005 have been authorized for pharmaceutical manufacturers' existing agreements through their current expiration dates. The updated NMPI SRA has been authorized for renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid beneficiaries.
- (b) CMS has authorized Kentucky's collection of supplemental rebates through the MMSPA.
- (c) Supplemental rebates received by the State 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) All drugs covered by the program, irrespective of a supplemental rebate agreement, will comply with the provision of the national drug rebate agreement.
- (e) Any contracts not authorized by CMS will be submitted for CMS approval in the future.
- (f) As specified in Section 1927(b)(3)(D) of the Act, notwithstanding any other provisions of law, rebate information disclosed by a manufacturer shall not be disclosed by the state for purposes other than rebate invoicing and verification.
- (8) Tobacco Cessation

The state will provide coverage for tobacco cessation drugs (legend or OTC) if prescribed by a Medicaid enrolled provider authorized to prescribe drugs. Coverage will be limited to two (2) three (3) month supplies of tobacco cessation prescription drugs in a calendar year. Prior authorization is required.

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Methods and Standards for Establishing Payment Rates — Other Types of Care

I. Drugs

A. Reimbursement

1. Participating pharmacies are reimbursed for the cost of the drug plus a dispensing fee. Payments shall not exceed the federal upper limits specified in 42 CFR 447.331 through 447.334.
2. Participating dispensing physicians are reimbursed for the cost of the drug only.
3. Providers will be reimbursed only for drugs supplied from pharmaceutical manufacturers who have signed a rebate agreement with CMS.

B. Payment Limits — Payment for the cost of drugs shall be the lesser of:

1. The Federal Upper Limit (FUL) means the maximum federal financial participation available toward reimbursement for a given drug dispensed to a Medicaid recipient.
2. The State Maximum Allowable Cost (SMAC). A SMAC may be established for any drug for which two or more A-rated therapeutically equivalent, multi- source, non-innovator drugs with a significant cost difference exist. The SMAC will be determined taking into account drug price status (non-rebatable, rebatable), marketplace status (obsolete, regional availability), equivalency rating (A-rated), and relative comparable pricing. Other factors considered are clinical indications of generic substitution, utilization and availability in the marketplace. The source of comparable drug prices will be nationally recognized comprehensive data files maintained by a vendor under contract with the Department for Medicaid Services. Resources accessed to determine SMAC include Wholesale Acquisition Cost (WAC), and Direct Price (to retail pharmacies) with weights applied based on the distribution of the volume purchased.
  - a. Multiple drug pricing resources are utilized to determine the estimated acquisition cost for the generic drugs. These resources include pharmacy providers, wholesalers, drug file vendors such as First Data Bank (FDB), and pharmaceutical manufacturers;

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- b. The Estimated Acquisition Cost (EAC) for each product is maintained in a WAC pricing file database;
  - c. Products are then sorted into drug groups by Generic Code Number (GCN), which denotes the same generic name, strength, and dosage form;
  - d. A filter is applied to remove all drug products that are obsolete, are not therapeutically equivalent, or are not available in the marketplace;
  - e. The acquisition cost for the remaining drug products are analyzed to produce the estimated acquisition cost for the drug group giving due consideration (which consists of utilization and availability in the marketplace) to the lower cost products;
  - f. The resulting estimated acquisition cost is used to produce a SMAC rate. The resulting SMAC is always greater than the pharmacy provider actual acquisition cost and is designed to provide the pharmacy with an appropriate profit margin;
  - g. The SMAC rate will then be applied to all brand and generic drug products in that specific GCN;
  - h. The SMAC file is updated monthly. Kentucky's MAC list may be downloaded from the following website: <http://www.chfs.ky.gov/dms>.
  - i. A pharmacy provider may appeal a SMAC price;
3. Effective October 1, 2011, the Estimated Acquisition Cost (EAC) for a generic drug shall equal the Wholesale Acquisition Cost (WAC) plus 3.2% and for a brand drug shall equal the WAC plus 2%; or
  4. If WAC pricing is not available, the provider will be required to contact the manufacturer for WAC or produce an invoice price or
  5. The provider's Usual and Customary charge (U&C).

4. The department shall reimburse the following drugs at the lesser of:

- Branded Drugs: WAC + 2% (plus dispensing fee) OR
- Generic Drugs: WAC + 3.2 % (plus dispensing fee) OR
- FUL + dispense fee OR
- MAC + dispense fee OR
- Usual & Customary (U & C)
  - Dispensing fees:
  - Branded drugs: \$4.50
  - Generic drugs: \$5.00

if the drug is administered in a physician's office:

- a. Rho(D) immune globulin injection;
- b. An injectable antineoplastic drug;
- c. Medroxyprogesterone acetate for contraceptive use, 150 mg;
- d. Penicillin G benzathine injection;
- e. Ceftriaxone sodium injection;
- f. Intravenous immune globulin injection;
- g. Sodium hyaluronate or hylan G-F for intra-articular injection;
- h. An intrauterine contraceptive device;
- i. An implantable contraceptive device;
- j. Long acting injectable risperidone; or
- k. An injectable, infused, or inhaled drug or biological that is:
  - (1) Not typically self-administered;
  - (2) Not listed as a non-covered immunization or vaccine; and
  - (3) Requires special handling, storage shipping, dosing or administration.

If long acting injectable risperidone is provided to an individual covered under both Medicaid and Medicare and administered by a physician employed by a Community Mental Health Center (CMHC) or other licensed medical professional employed by a CMHC, the department shall provide reimbursement at the same rate it reimburses for these drugs provided to a Medicaid recipient, except that the department shall reduce reimbursement by the amount of the third party obligation.

Methods and Standards for Establishing Payment Rates - Other Types of Care

C. Dispensing Fee

1. Effective February 23, 2005, the dispensing fee for a generic drug prescription is \$5.00 and for a brand name drug prescription is \$4.50. The dispensing fee is applied to outpatient pharmacies and to long term care facilities.
2. For nursing facility residents meeting Medicaid patient status, an incentive of two (2) cents per unit dose shall be paid to long term care, personal care, and supports for community living pharmacists for repackaging a non-unit dose drug in unit dose form.

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**a. Prescribed Drugs**

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- (2) Kentucky will provide reimbursement for covered outpatient drugs when prescribed by an enrolled licensed provider within the scope of their license and practice as allowed by State law and in accordance with Section 1927 of the Social Security Act. This will apply to drugs of any manufacturer that has entered into a rebate agreement with the Centers for Medicare and Medicaid Services (CMS). All drugs covered by the National Drug Rebate Agreements remain available to Medicaid beneficiaries, although some may require prior authorization. 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 1 927(d)(4) of the Social Security Act.
- (3) 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 lists or prior authorized 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:
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- (d) A drug provided to a recipient in an institution in which drugs are considered a part of the reasonable allowable costs under the Kentucky Medicaid Program;
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  - 2. A drug if used to promote fertility;
  - 3. A drug if used for cosmetic purposes or hair growth;
  - 4. A drug if used for the symptomatic relief of cough and colds;
  - 5. Vitamin or mineral products other than prenatal vitamins and fluoride preparations;
  - 6. An over-the-counter drug provided to a Medicaid nursing facility service recipient if included in the nursing facility's standard price;
  - 7. A barbiturate;
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  - 9. A drug 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; or
  - 10. A drug utilized for erectile dysfunction therapy unless the drug is used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the United States Food and Drug Administration;
- (f) A drug dispensed as part of, or incident to and in the same setting as, an inpatient hospital service, an outpatient hospital service, or an ambulatory surgical center service. However, a legend drug may be provided through prior authorization to a recipient admitted to an inpatient facility that does not bill patients, Medicaid, or other third-party payers for health care services.
- (g) A drug for which the department requires prior authorization if prior authorization has not been approved; and
- (4) Except for emergencies, a recipient "locked-in" to one pharmacy due to over-utilization may receive prescriptions:
  - (a) Only from his/her designated lock-in pharmacy and prescribed by his/her lock-in provider; or
  - (b) For specified controlled substances prescribed by his/her designated controlled substance lock-in prescriber.
- (5) If authorized by the prescriber, a prescription for a controlled substance in Schedule III-V may be refilled up to five times within a six month period from the date the prescription was written or ordered; a non-controlled substance may be refilled up to 11 times within a 12 month period from the date the prescription was written or ordered. In addition, a prescription fill for a maintenance drug may be dispensed in a 92-day supply if a recipient has demonstrated stability on the maintenance drug. However, a 92-day supply of a maintenance drug shall not be dispensed if a prescribing provider specifies that the quantity should be less. Also, individuals receiving supports for community living services, long term care, and personal care shall not be subject to the 92-day supply requirement.

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- (7) Supplemental Rebate Program:

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

- (a) CMS has authorized the Commonwealth of Kentucky to enter into the Michigan multi-state pooling agreement (MMSPA) also referred to as the National Medicaid Pooling Initiative (NMPI) for drugs provided to Medicaid beneficiaries. The NMPI Supplemental Rebate Agreement (SRA) and the Amendment to the SRA submitted to CMS on January 6, 2005 have been authorized for pharmaceutical manufacturers' existing agreements through their current expiration dates. The updated NMPI SRA has been authorized for renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid beneficiaries.
- (b) CMS has authorized Kentucky's collection of supplemental rebates through the MMSPA.
- (c) Supplemental rebates received by the State 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) All drugs covered by the program, irrespective of a supplemental rebate agreement, will comply with the provision of the national drug rebate agreement.
- (e) Any contracts not authorized by CMS will be submitted for CMS approval in the future.
- (f) As specified in Section 1927(b)(3)(D) of the Act, notwithstanding any other provisions of law, rebate information disclosed by a manufacturer shall not be disclosed by the state for purposes other than rebate invoicing and verification.
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**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 Medicaid Administration**”), \_\_\_\_\_ (“**Manufacturer**”), and such other states that subsequently join into this Agreement upon the terms hereafter set forth (“**Participating 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.

3.4 '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)].

3.6 '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.

3.9 '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 HHS-approved 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.

4.4 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.

4.6 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**

5.1 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**

6.1 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.

6.4 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.

9.2 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; 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 be 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 Street Suite 500  
Glen Allen, VA 23060-5937

*Notice to Manufacturer shall be sent to:*

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

STATE OF MICHIGAN, DEPARTMENT OF COMMUNITY HEALTH:

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

Name: \_\_\_\_\_

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

MANUFACTURER

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

Name: \_\_\_\_\_

Title: \_\_\_\_\_

MAGELLAN MEDICAID ADMINISTRATION, INC.

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

Name: \_\_\_\_\_

Title: \_\_\_\_\_

**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 Medicaid Administration**”), \_\_\_\_\_ (“**Manufacturer**”), and such other states that subsequently join into this Agreement upon the terms hereafter set forth (“**Participating 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.

3.4 '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)].

3.6 '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.

3.9 '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 HHS-approved 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.

4.4 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.

4.6 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**

5.1 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**

6.1 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.

6.4 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.

9.2 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; 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 be 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 Street Suite 500  
Glen Allen, VA 23060-5937

*Notice to Manufacturer shall be sent to:*

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

STATE OF MICHIGAN, DEPARTMENT OF COMMUNITY HEALTH:

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

Name: \_\_\_\_\_

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

MANUFACTURER

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

Name: \_\_\_\_\_

Title: \_\_\_\_\_

MAGELLAN MEDICAID ADMINISTRATION, INC.

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

Name: \_\_\_\_\_

Title: \_\_\_\_\_

### Schedule 3 State Supplemental Rebate Calculation

**This Schedule 3 to the SUPPLEMENTAL DRUG REBATE AGREEMENT provides as follows:**

The State Supplemental Rebate amount per Unit (SRPU) is calculated for each NDC of a Supplemental Covered Product according to the following formula, as applicable:

- **WAC Based GNUP (Guaranteed Net Unit Price):** (SRPU) = WAC per Unit minus CMS Unit Rebate Amount minus Discount Per Unit; or
- **Alternative Calculation Type:** SPRU = as defined in Schedule 2

(SRPU) will be greater than or equal to zero.

State Supplemental Rebate amount due = State Supplemental Rebate amount per Unit times State Utilization\*.

\*New NDCs for Supplemental Covered Products will be automatically included in this agreement unless specifically excluded.

The “Discount Per Unit” is determined based on the following variables:

The product position (1 of 1, 1 of 2 etc.) of a Supplemental Covered Product will be determined as compared to the PDL status of the other products listed in Schedule 1. Manufacturer will pay State Supplemental Rebates on Supplemental Covered Products associated with their Product’s(s’) position held from the first day in which the PDL was in effect for the Participating State or Supplemental Covered Product was listed on the PDL as a preferred drug. In addition, should the number of Supplemental Covered Products change during the applicable quarter, for the purpose of invoicing, the preferred count shall be determined by the number of Supplemental Covered Products during the majority of the preferred period. By way of example; In 1<sup>st</sup> quarter, Supplemental Covered Products A and B are preferred and invoiced at the Discount Per Unit corresponding with the 1 of 2 position. In the 2<sup>nd</sup> quarter, Supplemental Covered Product C is added to the PDL during the first 30 days of the quarter. Upon invoicing, Supplemental Covered Products A, B and C will all be invoiced at the 1 of 3 position (Supplemental Covered Product A and B invoiced for 90 days and Supplemental Covered Product C invoiced for 60 days). Conversely, in 3<sup>rd</sup> quarter, Supplemental Covered Product C is removed from the PDL during the first 30 days of the quarter. Upon invoicing, Supplemental Covered Products A and B will be invoiced at the 1 of 2 position while Supplemental Covered Product C is invoiced at the 1 of 3 position (Supplemental Covered Product A and B invoiced for 90 days and Supplemental Covered Product C invoiced for 30 days).

### Schedule 3 State Supplemental Rebate Calculation

**This Schedule 3 to the SUPPLEMENTAL DRUG REBATE AGREEMENT provides as follows:**

The State Supplemental Rebate amount per Unit (SRPU) is calculated for each NDC of a Supplemental Covered Product according to the following formula, as applicable:

- **WAC Based GNUP (Guaranteed Net Unit Price):** (SRPU) = WAC per Unit minus CMS Unit Rebate Amount minus Discount Per Unit; or
- **Alternative Calculation Type:** SPRU = as defined in Schedule 2

(SRPU) will be greater than or equal to zero.

State Supplemental Rebate amount due = State Supplemental Rebate amount per Unit times State Utilization\*.

\*New NDCs for Supplemental Covered Products will be automatically included in this agreement unless specifically excluded.

The “Discount Per Unit” is determined based on the following variables:

The product position (1 of 1, 1 of 2 etc.) of a Supplemental Covered Product will be determined as compared to the PDL status of the other products listed in Schedule 1. Manufacturer will pay State Supplemental Rebates on Supplemental Covered Products associated with their Product’s(s’) position held from the first day in which the PDL was in effect for the Participating State or Supplemental Covered Product was listed on the PDL as a preferred drug. In addition, should the number of Supplemental Covered Products change during the applicable quarter, for the purpose of invoicing, the preferred count shall be determined by the number of Supplemental Covered Products during the majority of the preferred period. By way of example; In 1<sup>st</sup> quarter, Supplemental Covered Products A and B are preferred and invoiced at the Discount Per Unit corresponding with the 1 of 2 position. In the 2<sup>nd</sup> quarter, Supplemental Covered Product C is added to the PDL during the first 30 days of the quarter. Upon invoicing, Supplemental Covered Products A, B and C will all be invoiced at the 1 of 3 position (Supplemental Covered Product A and B invoiced for 90 days and Supplemental Covered Product C invoiced for 60 days). Conversely, in 3<sup>rd</sup> quarter, Supplemental Covered Product C is removed from the PDL during the first 30 days of the quarter. Upon invoicing, Supplemental Covered Products A and B will be invoiced at the 1 of 2 position while Supplemental Covered Product C is invoiced at the 1 of 3 position (Supplemental Covered Product A and B invoiced for 90 days and Supplemental Covered Product C invoiced for 30 days).

**Schedule 2**  
**State Supplemental Rebate Matrix – PDL Matrix Form – \_\_\_\_\_ [Year]**

<b>LABEL NAME</b>	<b>NDC</b>	<b>POSITION</b>	<b>CALC. TYPE</b>	<b>DISCOUNT PER UNIT</b>	<b>PRODUCT CATEGORY</b>
PRODUCT A		1 Preferred			CATEGORY A
PRODUCT A		2 Preferred			CATEGORY A
PRODUCT A		3 Preferred			CATEGORY A
PRODUCT A		>3 Preferred			CATEGORY A

**Alternative Calculation Type** ['CALCULATION TYPE'] (if different than **WAC Based GNUP** defined in Schedule 3): State Supplemental Rebate amount per Unit = **[FORMULA]**

Positioning: For Product A and associated NDCs, the following terms shall apply:

- 1 Preferred: 1 of 1 Products on the Preferred Drug List as defined by Schedule 1.
- 2 Preferred: 1 of 2 Products on the Preferred Drug List as defined by Schedule 1.
- 3 Preferred: 1 of 3 Products on the Preferred Drug List as defined by Schedule 1.
- >3 Preferred: 1 of Many Products on the Preferred Drug List as defined by Schedule 1.

**State Supplemental Rebate Matrix**

BID CERTIFICATION

By submitting the attached bid(s) and having a duly authorized representative of Manufacturer sign below, Manufacturer certifies:

- a. That the bid(s) submitted are firm offers that Manufacturer will not retract unless rejected as insufficient by Magellan Medicaid Administration and
- b. That Manufacturer will enter into binding contract(s) incorporating the Manufacturer's bid(s) that are accepted; and
- c. That Manufacturer understands and agrees that the acceptance of its bid(s) does not require any individual Participating State to include Manufacturer's bidded product(s) on its preferred drug list; and
- d. That the signature below is that of a duly authorized representative of Manufacturer with the authority to execute agreements binding Manufacturer.

\_\_\_\_\_  
Manufacturer Name ("Manufacturer")

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Title

**Schedule 2**  
**State Supplemental Rebate Matrix – PDL Matrix Form – \_\_\_\_\_ [Year]**

<b>LABEL NAME</b>	<b>NDC</b>	<b>POSITION</b>	<b>CALC. TYPE</b>	<b>DISCOUNT PER UNIT</b>	<b>PRODUCT CATEGORY</b>
PRODUCT A		1 Preferred			CATEGORY A
PRODUCT A		2 Preferred			CATEGORY A
PRODUCT A		3 Preferred			CATEGORY A
PRODUCT A		>3 Preferred			CATEGORY A

**Alternative Calculation Type ['CALCULATION TYPE']** (if different than **WAC Based GNUP** defined in Schedule 3): State Supplemental Rebate amount per Unit = **[FORMULA]**

Positioning: For Product A and associated NDCs, the following terms shall apply:

- 1 Preferred: 1 of 1 Products on the Preferred Drug List as defined by Schedule 1.
- 2 Preferred: 1 of 2 Products on the Preferred Drug List as defined by Schedule 1.
- 3 Preferred: 1 of 3 Products on the Preferred Drug List as defined by Schedule 1.
- >3 Preferred: 1 of Many Products on the Preferred Drug List as defined by Schedule 1.

**State Supplemental Rebate Matrix**

BID CERTIFICATION

By submitting the attached bid(s) and having a duly authorized representative of Manufacturer sign below, Manufacturer certifies:

- a. That the bid(s) submitted are firm offers that Manufacturer will not retract unless rejected as insufficient by Magellan Medicaid Administration and
- b. That Manufacturer will enter into binding contract(s) incorporating the Manufacturer's bid(s) that are accepted; and
- c. That Manufacturer understands and agrees that the acceptance of its bid(s) does not require any individual Participating State to include Manufacturer's bidded product(s) on its preferred drug list; and
- d. That the signature below is that of a duly authorized representative of Manufacturer with the authority to execute agreements binding Manufacturer.

\_\_\_\_\_  
Manufacturer Name ("Manufacturer")

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Title

**Schedule 1**  
**Product Category Listing**  
**Revision Date: [DATE]**

PRODUCT CATEGORY ID	PRODUCT CATEGORY	PRODUCT	MANUFACTURER NAME
4	ANGIOTENSIN RECEPTOR BLOCKERS	TEVETEN	ABBOTT LABS.
4	ANGIOTENSIN RECEPTOR BLOCKERS	ATACAND	ASTRAZENECA
4	ANGIOTENSIN RECEPTOR BLOCKERS	AVAPRO	BMS PRIMARYCARE
4	ANGIOTENSIN RECEPTOR BLOCKERS	MICARDIS	BOEHRINGER-INGELHEIM
4	ANGIOTENSIN RECEPTOR BLOCKERS	BENICAR	DAIICHI-SANKYO
4	ANGIOTENSIN RECEPTOR BLOCKERS	DIOVAN	NOVARTIS
4	ANGIOTENSIN RECEPTOR BLOCKERS	EDARBI	TAKEDA
6	NARCOTICS: LONG ACTING	KADIAN	ACTIVAS
6	NARCOTICS: LONG ACTING	OPANA ER	ENDO PHARM INC.
6	NARCOTICS: LONG ACTING	DURAGESIC	OMJ
6	NARCOTICS: LONG ACTING	AVINZA	KING PHARM
6	NARCOTICS: LONG ACTING	EMBEDA	KING PHARM
6	NARCOTICS: LONG ACTING	OXYCONTIN	PURDUE PHARMA
6	NARCOTICS: LONG ACTING	EXALGO ER	MALLINCKRODT
6	NARCOTICS: LONG ACTING	ULTRAM ER	OMJ
6	NARCOTICS: LONG ACTING	BUTRANS	PURDUE
6	NARCOTICS: LONG ACTING	CONZIP ER	VERTICAL PHARM
6	NARCOTICS: LONG ACTING	NUCYNTA ER	JANSSEN PHARM.
7	NSAIDS	VIMOVO	ASTRAZENECA
7	NSAIDS	CELEBREX	PFIZER
7	NSAIDS	ARTHROTEC	PFIZER US PHARM
7	NSAIDS	INDOCIN RECTAL	IROKO PHARMACEU
7	NSAIDS	INDOCIN SUSPENSION	IROKO PHARMACEU
7	NSAIDS	ZIPSOR	XANODYNE PHARM
7	NSAIDS	DUEXIS	HORIZON PHARMA
7	NSAIDS	NALFON	PEDINOL PHARM.
7	NSAIDS	NAPRELAN	SCIELE PHARMA
7	NSAIDS	PONSTEL	SCIELE PHARMA
7	NSAIDS	DIFLUNISAL	TEVA
7	NSAIDS	MOBIC SUSP	BOEHRINGER ING.
7	NSAIDS	NAPROSYN ORAL SUSP	GENENTECH, INC.
7	NSAIDS	SPRIX	AMER. REGENT
9	CEPHALOSPORINS AND RELATED ANTIBIOTICS	SPECTRACEF	CORNERSTONE
9	CEPHALOSPORINS AND RELATED ANTIBIOTICS	SUPRAX & SUPRAX SUSP & SUPRAX TAB CHEW	LUPIN
9	CEPHALOSPORINS AND RELATED ANTIBIOTICS	CEDAX & CEDAX SUSP RECON	ZYBER PHARMACEUTICALS

**ATTACHMENT A**

**National Medicaid Pooling Initiative (“NMPI”) Medicaid Program Participation Agreement**

**For**

\_\_\_\_\_ **[STATE AGENCY]**

**WHEREAS**, the State of \_\_\_\_\_ [STATE] acting by and through the \_\_\_\_\_ [STATE AGENCY], \_\_\_\_\_ [ADDRESS] (hereinafter collectively referred to as “**Participating State**”), hereby enters into this NMPI Medicaid Program Participation Agreement (“**Participation Agreement**”) effective as of \_\_\_\_\_ [DATE], with Magellan Medicaid Administration, Inc. (“**Magellan Medicaid**”).

**WHEREAS**, the Participating State administers Participating State’s Medicaid Program pursuant to the Social Security Act (42 U.S.C. 1396 *et seq.*); and

**WHEREAS**, Magellan Medicaid has negotiated and, along with the State of Michigan, entered into Supplemental Rebate Agreements (“**NMPI Agreement(s)**”) with prescription drug manufacturers (“**Manufacturers**”) to provide discounts and rebates (“**State Supplemental Rebate(s)**”) on certain of such Manufacturers’ drug products that are covered by the Participating State’s Medicaid Program; and

**WHEREAS**, the Participating State represents and warrants that it has determined any Medicaid MCO for which State Supplemental Rebates will be invoiced hereunder (a “**Participating Medicaid MCO**”) is eligible for such Supplemental Rebates and has documented such determination via applicable regulation, law, contract, or other formal state agency issuance.

**WHEREAS**, the Participating State desires to access State Supplemental Rebates; and

**WHEREAS**, the Participating State has contracted with Magellan Medicaid for the provision of State Supplemental Rebate contracting and preferred drug list (“**PDL**”) administration and invoicing services; and

**WHEREAS**, “**Controlling Agreement**” shall mean the contract between Magellan Medicaid, as either a prime contractor or a subcontractor, and a Participating State pursuant to which Magellan Medicaid is obligated to provide one or more of the following services to the Participating State: State Supplemental Rebate negotiation, contracting services, PDL design and maintenance, and pharmacy and therapeutics committee administration services.

**WHEREAS**, the states named in the NMPI Catalogue of Participating State Medicaid Programs

(Attachment B to the NMPI Agreement) have signed a Participation Agreement; and

**NOW, THEREFORE**, in consideration of the mutual covenants, promises, and conditions contained herein and in the NMPI Agreement, the parties agree as follows:

- 1. Obligations of Parties:** Participating State hereby agrees to participate in the multi-state State Supplemental Rebate pooling program known as the National Medicaid Pooling Initiative (“**NMPI**”) and understands and agrees to be bound by the terms of the NMPI Agreement. Magellan Medicaid agrees to negotiate and enter into State Supplemental Rebate Agreements on behalf of Participating State and other state Medicaid agencies who agree to participate in NMPI.
  
- 2. 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) transmitted by telefacsimile, producing a document indicating the date and time of successful transmission, to the address or telefacsimile number set forth below. A party may at any time give notice in writing to the other parties of a change of name, address, telephone, or telefacsimile number.

**To Participating State:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Telephone  
Telefacsimile

**To Magellan Medicaid:**

Magellan Medicaid Administration, Inc.  
Attn: Chief Financial Officer  
With a copy to: Legal Department  
11013 W. Broad St.  
Suite 500  
Glen Allen, Virginia 23060-5937

- 3. Term.** This Participation Agreement shall be effective as to Participating State as of the date herein stated above in this Participation Agreement, subject to CMS authorization, and shall continue in effect until \_\_\_\_\_ [DATE]. Thereafter, this Participation Agreement shall automatically renew for successive one (1)-year terms, unless this Participation Agreement is otherwise terminated as provided for in this Participation Agreement or until such time as the Controlling Agreement between the Participating State and Magellan Medicaid is terminated. Notwithstanding the forgoing, no rebates shall accrue hereunder with respect to any drug product until the latter of the date: (i) such drug product is effective upon public dissemination of Participating State's Preferred Drug List via website for providers and prescribers, (ii) the applicable 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.
- 4. Termination by Participating State.** Participating State may terminate its participation in the NMPI Agreements by giving Manufacturer and Magellan Medicaid Administration written notice at least (90) days prior to the anniversary date of the NMPI Agreement, in which case termination shall become effective as to the terminating Participating State on the anniversary date of the NMPI Agreement and as further defined in Sections 8.3 of the NMPI Agreement.
- 5. Addition of Participating Medicaid MCOs.** To the extent permitted by: (i) CMS, (ii) applicable law, and (iii) the Participating State Medicaid Plan, any Participating State added hereunder may elect, but shall not be required, to include Medicaid Utilization from all Participating Medicaid MCOs in their Supplemental Rebate invoices, provided that the Participating State provide to Magellan Medicaid an executed and complete copy of Attachment A-2 indicating such election, along with any required attachments thereto. Supplemental Rebates shall begin to accrue to Participating Medicaid MCO(s) pursuant to this Participation Agreement for a Covered Product upon the later of: (i) Magellan Medicaid receiving the applicable State's complete and executed Attachment A-2 (along with any required attachments) electing to include Participating Medicaid MCO utilization hereunder, or (ii) effective date for such Participating Medicaid MCO utilization, as set forth on Attachment A-2. The Participating State shall be solely responsible for ensuring that all Participating Medicaid MCOs for which utilization is invoiced for Supplemental Rebates comply with all applicable terms and conditions of this Participation Agreement, applicable law, the State Medicaid Plan, and the Participating State's contracts with its Medicaid MCOs.
- 6.** The undersigned Participating State acknowledges that manufacturer rebate pricing information is confidential information under applicable Federal law and shall be exempt from public disclosure pursuant to \_\_\_\_\_.

7. The undersigned Participating State represents that it has not requested authorization from CMS to include any state pharmaceutical assistance program within the rebate provisions of the NMPI Agreement [or CMS has authorized the inclusion of Not Applicable within the NMPI Agreement]. The above representation shall not prohibit the undersigned Participating State from requesting CMS authorization to include (other) pharmaceutical assistance programs within the NMPI Agreement at a later date. Upon receipt of CMS authorization, Participating State shall give written notice to Manufacturer of the date Manufacturer's Supplemental Covered Product is effectively placed on the preferred drug list of the undersigned Participating State's non-Medicaid programs approved by CMS in the Medicaid state plan(s) by completing the attached Exhibit A-1.
  
8. Any state which has the necessary state and CMS authorizations to operate a PDL and State Supplemental Rebate program and which is contracted to utilize Magellan Medicaid Administration to administer its PDL and Supplemental Rebate program is eligible to join NMPI as a Participating State subject to CMS authorization. Upon the expansion or contraction of NMPI, to either include a state Medicaid agency as a Participating State Medicaid Program or exclude a Participating State Medicaid Program, Magellan Medicaid Administration shall expressly notify in writing all Participating States as to the identity of the newly included state agency or the identity of newly excluded Participating State along with the effective date for such inclusion or exclusion.

**IN WITNESS WHEREOF**, the Participating State and Magellan Medicaid have caused this Participation Agreement to be executed on the dates shown below by representatives authorized to bind the respective parties.

**[Participating State]  
Administration, Inc.**

**Magellan**

**Medicaid**

\_\_\_\_\_  
By: \_\_\_\_\_

By: \_\_\_\_\_

\_\_\_\_\_

Name:

Title:

Date:

Name:

Title:

Date:

**ATTACHMENT A**  
**National Medicaid Pooling Initiative (“NMPI”) Medicaid Program Participation Agreement**  
**For**

\_\_\_\_\_ **[STATE AGENCY]**

**WHEREAS**, the State of \_\_\_\_\_ [STATE] acting by and through the \_\_\_\_\_ [STATE AGENCY], \_\_\_\_\_ [ADDRESS] (hereinafter collectively referred to as “**Participating State**”), hereby enters into this NMPI Medicaid Program Participation Agreement (“**Participation Agreement**”) effective as of \_\_\_\_\_ [DATE], with Magellan Medicaid Administration, Inc. (“**Magellan Medicaid**”).

**WHEREAS**, the Participating State administers Participating State’s Medicaid Program pursuant to the Social Security Act (42 U.S.C. 1396 *et seq.*); and

**WHEREAS**, Magellan Medicaid has negotiated and, along with the State of Michigan, entered into Supplemental Rebate Agreements (“**NMPI Agreement(s)**”) with prescription drug manufacturers (“**Manufacturers**”) to provide discounts and rebates (“**State Supplemental Rebate(s)**”) on certain of such Manufacturers’ drug products that are covered by the Participating State’s Medicaid Program; and

**WHEREAS**, the Participating State represents and warrants that it has determined any Medicaid MCO for which State Supplemental Rebates will be invoiced hereunder (a “**Participating Medicaid MCO**”) is eligible for such Supplemental Rebates and has documented such determination via applicable regulation, law, contract, or other formal state agency issuance.

**WHEREAS**, the Participating State desires to access State Supplemental Rebates; and

**WHEREAS**, the Participating State has contracted with Magellan Medicaid for the provision of State Supplemental Rebate contracting and preferred drug list (“**PDL**”) administration and invoicing services; and

**WHEREAS**, “**Controlling Agreement**” shall mean the contract between Magellan Medicaid, as either a prime contractor or a subcontractor, and a Participating State pursuant to which Magellan Medicaid is obligated to provide one or more of the following services to the Participating State: State Supplemental Rebate negotiation, contracting services, PDL design and maintenance, and pharmacy and therapeutics committee administration services.

**WHEREAS**, the states named in the NMPI Catalogue of Participating State Medicaid Programs (Attachment B to the NMPI Agreement) have signed a Participation Agreement; and

**NOW, THEREFORE**, in consideration of the mutual covenants, promises, and conditions contained herein and in the NMPI Agreement, the parties agree as follows:

- 1. Obligations of Parties:** Participating State hereby agrees to participate in the multi-state State Supplemental Rebate pooling program known as the National Medicaid Pooling Initiative (“**NMPI**”) and understands and agrees to be bound by the terms of the NMPI Agreement.

Magellan Medicaid agrees to negotiate and enter into State Supplemental Rebate Agreements on behalf of Participating State and other state Medicaid agencies who agree to participate in NMPI.

- 2. 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) transmitted by telefacsimile, producing a document indicating the date and time of successful transmission, to the address or telefacsimile number set forth below. A party may at any time give notice in writing to the other parties of a change of name, address, telephone, or telefacsimile number.

**To Participating State:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Telephone \_\_\_\_\_  
Telefacsimile \_\_\_\_\_

**To Magellan Medicaid:**

Magellan Medicaid Administration, Inc.  
Attn: Chief Financial Officer  
With a copy to: Legal Department  
11013 W. Broad St.  
Suite 500  
Glen Allen, Virginia 23060-5937

- 3. Term.** This Participation Agreement shall be effective as to Participating State as of the date herein stated above in this Participation Agreement, subject to CMS authorization, and shall continue in effect until \_\_\_\_\_ [DATE]. Thereafter, this Participation Agreement shall automatically renew for successive one (1)-year terms, unless this Participation Agreement is otherwise terminated as provided for in this Participation Agreement or until such time as the Controlling Agreement between the Participating State and Magellan Medicaid is terminated. Notwithstanding the forgoing, no rebates shall accrue hereunder with respect to any drug product until the latter of the date: (i) such drug product is effective upon public dissemination of Participating State's Preferred Drug List via website for providers and prescribers, (ii) the applicable 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.
- 4. Termination by Participating State.** Participating State may terminate its participation in the NMPI Agreements by giving Manufacturer and Magellan Medicaid Administration written notice

at least (90) days prior to the anniversary date of the NMPI Agreement, in which case termination shall become effective as to the terminating Participating State on the anniversary date of the NMPI Agreement and as further defined in Sections 8.3 of the NMPI Agreement.

5. **Addition of Participating Medicaid MCOs.** To the extent permitted by: (i) CMS, (ii) applicable law, and (iii) the Participating State Medicaid Plan, any Participating State added hereunder may elect, but shall not be required, to include Medicaid Utilization from all Participating Medicaid MCOs in their Supplemental Rebate invoices, provided that the Participating State provide to Magellan Medicaid an executed and complete copy of Attachment A-2 indicating such election, along with any required attachments thereto. Supplemental Rebates shall begin to accrue to Participating Medicaid MCO(s) pursuant to this Participation Agreement for a Covered Product upon the later of: (i) Magellan Medicaid receiving the applicable State's complete and executed Attachment A-2 (along with any required attachments) electing to include Participating Medicaid MCO utilization hereunder, or (ii) effective date for such Participating Medicaid MCO utilization, as set forth on Attachment A-2. The Participating State shall be solely responsible for ensuring that all Participating Medicaid MCOs for which utilization is invoiced for Supplemental Rebates comply with all applicable terms and conditions of this Participation Agreement, applicable law, the State Medicaid Plan, and the Participating State's contracts with its Medicaid MCOs.
6. The undersigned Participating State acknowledges that manufacturer rebate pricing information is confidential information under applicable Federal law and shall be exempt from public disclosure pursuant to \_\_\_\_\_.
7. The undersigned Participating State represents that it has not requested authorization from CMS to include any state pharmaceutical assistance program within the rebate provisions of the NMPI Agreement [or CMS has authorized the inclusion of Not Applicable within the NMPI Agreement]. The above representation shall not prohibit the undersigned Participating State from requesting CMS authorization to include (other) pharmaceutical assistance programs within the NMPI Agreement at a later date. Upon receipt of CMS authorization, Participating State shall give written notice to Manufacturer of the date Manufacturer's Supplemental Covered Product is effectively placed on the preferred drug list of the undersigned Participating State's non-Medicaid programs approved by CMS in the Medicaid state plan(s) by completing the attached Exhibit A-1.
8. Any state which has the necessary state and CMS authorizations to operate a PDL and State Supplemental Rebate program and which is contracted to utilize Magellan Medicaid Administration to administer its PDL and Supplemental Rebate program is eligible to join NMPI as a Participating State subject to CMS authorization. Upon the expansion or contraction of NMPI, to either include a state Medicaid agency as a Participating State Medicaid Program or exclude a Participating State Medicaid Program, Magellan Medicaid Administration shall expressly notify in writing all Participating States as to the identity of the newly included state agency or the identity of newly excluded Participating State along with the effective date for such inclusion or exclusion.

**IN WITNESS WHEREOF**, the Participating State and Magellan Medicaid have caused this Participation Agreement to be executed on the dates shown below by representatives authorized to bind the respective parties.

**[Participating State]**

**Magellan Medicaid Administration, Inc.**

\_\_\_\_\_  
By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

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

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

**ATTACHMENT B**

**CATALOGUE OF NMPI PARTICIPATING STATE MEDICAID PROGRAMS**

The Participating State Medicaid Programs participating in NMPI are summarized in Table B-1 Catalogue of NMPI Participating Medicaid Programs.

<b><u>Table B-1 Catalogue of NMPI Participating State Medicaid Programs</u></b>
<b>Alaska</b>
<b>District of Columbia</b>
<b>Kentucky</b>
<b>Michigan</b>
<b>Minnesota</b>
<b>Montana</b>
<b>New Hampshire</b>
<b>New York</b>
<b>North Carolina</b>
<b>Rhode Island</b>
<b>South Carolina</b>

This Attachment will be updated in accordance with Section 3.13 and 8.4 of the Agreement.

**ATTACHMENT A-2**

Attestation of Inclusion/Exclusion of Medicaid MCOs

The State of \_\_\_\_\_ acting by and through the \_\_\_\_\_ (hereinafter collectively referred to as “**Participating State**”), hereby represents and warrants the following with respect to Medicaid MCOs (**must check one**):

Effective for utilization dispensed to Participating Medicaid MCO members on or after \_\_\_\_\_ [DATE\*], the Participating State will include utilization of Participating Medicaid MCO(s) for Supplemental Rebates under this Agreement. I certify on behalf of the Participating State listed below that the State Medicaid Plan permits the inclusion of Medicaid MCO utilization in Supplemental Rebates, and that the State’s contracts with Participating MCOs do not prohibit such inclusion. I further certify on behalf of the Participating State listed below that the State has reasonably determined that: (i) the utilization of any Participating Medicaid MCO submitted hereunder is eligible for CMS Rebates under 42 U.S.C. § 1396r-8 and (ii) each such Participating Medicaid MCO shall align their respective formulary(ies) and/or preferred drug list(s), as applicable, assuring access to preferred Supplemental Covered Product is no more restrictive than the applicable Participating State PDL requirements for any period with respect to which the Participating State will invoice for Supplemental Rebates for utilization under this Agreement. It is the intent and expectation of the Participating Medicaid Programs that Supplemental Rebates hereunder shall be excluded from Manufacturer’s calculation of Best Price or AMP. ***If this option is checked, the State must have documented the above determination via applicable regulation, law, contract, or other formal state agency issuance and the State must attach hereto: (1) a copy of such documentation, as well as (2) a copy of the applicable Participating State Medicaid Plan (and/or amendment thereto) permitting the election of this option.***

The Participating State will exclude utilization from all of its Medicaid MCO(s) under this Agreement.

The Participating State has no Medicaid MCOs.

MANUFACTURER CONSENT SHALL NOT BE REQUIRED FOR A STATE TO AMEND THIS ATTACHMENT A-2.

***So Certified:***

Participating State: \_\_\_\_\_

By: \_\_\_\_\_

Title: \_\_\_\_\_

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

***\*Effective date for including Participating MCO utilization shall not predate the date this Attachment A-2 is executed by the Participating State.***

**ATTACHMENT A-1**

**Participating State's Non-Medicaid Programs Approved by CMS in the Medicaid State Plan(s)**

Participating State: \_\_\_\_\_

Non-Medicaid programs approved by CMS in the Medicaid State Plan(s) – Date of Approval

1. \_\_\_\_\_

2. \_\_\_\_\_

3. \_\_\_\_\_

4. \_\_\_\_\_

5. \_\_\_\_\_

6. \_\_\_\_\_

Multi-State Supplemental Rebate Agreement  
Standard Questions

----Preferred Drug List (PDL)/Prior Authorization (PA) Questions---

**Section: PDL and PA**

**Q1) Does the prior authorization requirement within the State plan make medically necessary prescription drugs available to financially needy individuals?**

The Kentucky Medicaid Preferred Drug List (PDL) Program contains a prior authorization process to ensure that all drugs remain available to the beneficiaries of Medicaid. While all drugs are available, beneficiaries are expected to use the medications identified as preferred. If a Medicaid beneficiary has a need for a drug that is not on the preferred list, the beneficiary will be subject to the prior authorization process. If the prior authorization process determines there is justification for the prescribing of a non-PDL drug, the beneficiary will be given the non-PDL drug. This prior authorization will remain in place for thirty (30) days, six (6) months, or twelve (12) months dependent on the drug/drug class. Under certain conditions, the prior authorization may be extended through the duration of the program.

**Q2) How will the State ensure that patients continue to have access to needed medications?**

Through the use of the prior authorization process, beneficiaries have the ability to continue the use of non-preferred medications if the prescribing provider can provide medical justification. The prior authorization process requires prescribers to examine the medication therapy of their patients and make a medical justification for the continuation of therapy of a non-preferred drug. When a prior authorization is approved, the prior authorization will last for thirty (30) days, six (6) months, or twelve (12) months. A beneficiary may have to repeat the prior authorization process for the same drug once the authorization has expired for continuation of therapy. In all circumstances, the State's goal will be to manage the prior authorization process so as to assure that beneficiaries have access to medications that are genuinely needed for their care with regards to their individual health situations.

**Q3) Does the State have a Pharmaceutical and Therapeutics (P&T) Committee that recommends which drugs should be on the PDL?**

Yes. The State does have a P&T Committee that recommends which medications should be on the PDL. The Committee meets to discuss the evidence-based merits and financial data of medications in a specified therapeutic class. In all cases the evidence-based merits of a product outweigh the financial data.

**Q4) How will the P&T determine which drugs will go on the PDL?**

The Kentucky P&T Committee conducts their review of the medications in the therapeutic categories based on the clinical and evidence-based merits of drugs, the therapeutic value of the

products in each class, and the financial data. The Committee uses research articles and compendia that relate to the medications under review.

**Q5) What criteria will the P&T Committee use to make recommendations for the PDL?**

The P&T Committee meets in an open session to discuss the evidence-based merits and financial data of medications in a specified therapeutic class. In all cases, the evidence-based merits of a product outweigh the financial data.

**Q6) Will all covered outpatient drugs that are not included on the PDL remain available pursuant to prior authorization, consistent with section 1927(d)(5) of the Act?**

Yes. Under the State's current plan (with the exception of drugs permitted to be restricted by section 1927(d)(2) of the Act) all drugs will be available with non-preferred drugs subject to the prior authorization process, which is consistent with Section 1927(d)(5) of the Act.

**Q7) Is the PDL consistent with Medicaid goals and objectives of section 1902(a) (19) of the Act?**

Yes. The goal of the PDL is to provide the appropriate clinically approved medications to Kentucky Medicaid beneficiaries.

**Q8) How will the State ensure continuity of care for patients who are stabilized on previously prescribed, non-preferred medications?**

Through the use of the prior authorization process, beneficiaries have the ability to continue the use of non-preferred medications if the prescribing providers can provide medical justification. The prior authorization process requires providers to examine the medication therapy of their patients and make a medical justification for the continuation of therapy of a non-preferred drug. In all circumstances, the State's goal will be to administer the prior authorization process so as to assure that beneficiaries have access to medications that are genuinely needed for their care with regards to their individual health situations.

**Q9) How will the State address the impact on beneficiaries of a sudden change in therapy as a result of implementing the State PDL?**

The State's Preferred Drug List Program is pre-existing and sudden changes in therapy are not expected as a result of modifications to the Multi-State Supplemental Rebate Agreement.

**Q10) How does the State PDL balance the interest of beneficiaries in receiving medically necessary drugs while taking into account the state's interest in ensuring that Medicaid pays for prescription drugs in an efficient and economical manner?**

The prior authorization process is structured to be minimally intrusive to providers and beneficiaries alike. In anticipation of major PDL changes, notifications to prescribers are disseminated to prevent delays and/or confusion relating to the process providers must utilize to continue the current course of medication therapy.

**Q11) How will the State address the needs of beneficiaries with special and complex medical conditions, such as individuals with HIV/AIDS, cancer and mental health conditions?**

The Kentucky P&T Committee conducts their review of the drugs in the therapeutic categories based on the clinical and therapeutic value of the medications in each class. The Committee uses research articles and compendia that relate to the products under review. The AIDS/HIV drug class is not included in the PDL due to the special needs of these beneficiaries. The P&T Committee is cognizant of the needs of special interest groups during their review process. The P&T Committee includes doctors and pharmacists with specialties from various fields of medicine and meetings of the P&T Committee are open to the public. The wants of the special needs population can be brought to the attention of the P&T Committee via public speakers. The State's PDL is comprised of clinically and therapeutically selected medications that provide an economical benefit to the State and the Federal Government.

**Q12) How will the State annually evaluate participation in the multi-State supplemental rebate program?**

It is the intent of the agency to prepare quarterly reports on the PDL Program that also consists of the prior authorization process results. This includes aggregate SFY totals of savings; see example below.

	Supplemental Rebates Total Invoiced	Supplemental Rebates Total Collections	Supplemental Rebates % Collected
3Q2012	\$530,439	\$485,635	91.55%
2Q2012	\$646,921	\$635,840	98.29%
1Q2012	\$482,906	\$480,231	99.45%
4Q2011	\$4,385,165	\$4,332,313	98.79%

**Q13) Will the State issue a public report on the aggregate cost savings associated with the State's participation in the multi-State pool?**

It is the intent of the agency to prepare quarterly reports on the PDL Program that also consists of the prior authorization process results. This includes aggregate savings data as a result of the implementation of the PDL Program; however, aggregate data is available and could be included in a State issued public report.

**Section: Contracting**

**Q14) Is the multi-state pooling arrangement for the contract with the pharmacy benefit administration (PBA) services vendor included in the original contractual arrangement with the PBA services vendor?**

The contract with the PBA services vendor speaks to responsibility for negotiating and managing the supplemental rebate agreements with the pharmaceutical manufacturers.

**Q15) Is the arrangement included in the request for proposals (RFP) issued in the procurement process for that contract (and if not, when will the arrangement be included in the contract)?**

The pooling arrangement was part of the PBA's initial response in the fee-for-service (FFS) PBA RFP.

**Q16) Does it constitute a modification of the original contract, and the effect on that contract of the addition of multiple states?**

No. The supplemental rebate agreements between the State and the manufacturers will change, but we see no need to modify the contract with the PBA services vendor.

**Q17) If a vendor has been selected, please answer the following question: Please describe the State's procurement process for selecting the pharmacy benefit administrator (PBA) that will be managing the states participation in the multi-state supplemental rebate program**

It was a competitive bidding process, which met all of the State's procurement guidelines.

**Q18) If a vendor has been selected, please answer the following question: How did the State consider other vendors and competitive factors?**

Kentucky released a competitive RFP for a vendor to conduct a variety of pharmacy functions, including negotiating and managing the supplemental rebate agreements. Kentucky had a choice of negotiating our own standalone state supplemental rebate contracts or joining the pooling arrangement with other states for supplemental rebates. The resulting contract with our PBA services vendor did not lock us in to a particular mechanism for negotiating and managing such agreements.

**Q19) If a vendor has been selected, please answer the following question: Please provide assurance that the State procured the services of its vendor in a manner consistent with federal and State procurement standards?**

The evaluation of the response to the FFS RFP was conducted under the guidance of the Kentucky Department for Medicaid Services, the Finance and Administration Cabinet, and the Division of Procurement Services who assured all state and federal procurement rules, standards, and best practices were strictly adhered to.

**Q20) If a vendor has been selected, please answer the following question: Please describe any and all types of remuneration, and the methodology for calculating any such remuneration, all rebate offers being made by manufacturers, and any pertinent information, including vendor administrative costs and incentives related to vendor supplemental rebate negotiation and PDL development? Please include any and all payment from manufacturers to other entities involved in the manufacture, distribution, sale or payment of pharmaceuticals.**

There is no additional cost to the state of Kentucky for joining the multi-state pool. One hundred percent (100%) of the rebate dollars from the pooling program are passed on to Kentucky with the Federal Government receiving their share based on the Federal Medical

Assistance Percentages (FMAP). During the procurement process, Kentucky conducted a thorough evaluation of costs and benefits prior to the selection of the PBA.

### **Section: SR Agreement Funding**

*Section 1927(b) (1) (B) of the Act requires that amounts received by a state under an agreement authorized by the Secretary shall be considered to be a reduction in the amount expended under the state plan for medical assistance for purposes of section 1903(a) (1). Therefore, any pharmacy expenditures subject to a supplemental rebate resulting from an agreement authorized by CMS (or agreements that CMS has not yet authorized because the state has failed to submit them), must be reduced by the rebate prior to the state submitting a claim for federal financial participation (FFP). This being the case, please respond to the following questions:*

**Q21) Under the current state plan or proposed amendment, does the state receive a supplemental rebate or any revenue back from manufacturers in addition to the national Medicaid drug rebate?**

Yes. The state will receive supplemental rebates above the national Medicaid drug rebate.

**Q22) Does the state reduce the Medicaid expenditures under the State plan by the amount of the rebates or revenue?**

Kentucky will reduce the Medicaid expenditures under the State Plan by the amount of the rebates or revenue.

**Q23) Under the current state plan or proposed amendment, does the state receive any goods, services or other benefits for their Medicaid covered population from the pharmaceutical manufacturer?**

Other than the acknowledged supplemental rebates, the State does not receive any goods, services, or other benefits from the pharmaceutical manufacturers.

**Q24) Does the manufacturer provide these goods, services or other benefits for including the manufacturer's drugs on a Medicaid preferred drug list?**

The State will not receive any goods, services, or other benefits outside of the supplemental rebates.

**Q25) Does the state receive goods or services from a manufacturer if the manufacturer's drugs are not subject to prior authorization?**

No. Kentucky does not receive goods or services from a manufacturer when the manufacturer's drugs are not subject to prior authorization.

**Q26) If the state receives goods or services from the manufacturer, what kinds of goods or services are provided? What is the value of these goods and services?**

Kentucky does not receive goods or services from manufacturers.

**Q27) Does the state share the savings realized by these manufacturer goods, services, revenues and rebates with the federal government by offsetting total computable Medicaid expenditures by the costs of these services?**

The Federal Government will benefit from the supplemental rebates by an offset to the computable Medicaid expenditures. The supplemental rebates are shared with the Federal Government in accordance with the current FMAP rate.

**Section: State Plan Reimbursement Funding**

*Section 1903(a) (1) of the Social Security Act provides that Federal financial participation is only available for expenditures made by states for services under the approved State Plan. To ensure that program dollars are used only to pay for Medicaid services, we are asking states to confirm to CMS that pharmacies retain 100 percent of the payments provided to them as indicated in attachment 4.19B. Specifically, please answer the following questions regarding the proposed amendment and current reimbursement made under the Medicaid plan for pharmacy providers:*

**Q28) Do pharmacy providers retain all of the state and Federal Medicaid payment (including dispensing fees, ingredient cost, benefit management costs, etc.) or are providers obligated to return any portion of the Medicaid payment to the state or local government entity, or any other intermediary organization or entity?**

Yes. Pharmacy providers retain all of the state and federal Medicaid payments provided to them.

**Q29) If pharmacy providers are obligated to return any portion of the payment, the state must provide a full description of the repayment methodology including: a complete list of pharmacy providers that return their payments; the amount or percentage of the payment; and the disposition and use of the funds once they are returned to the state (i.e. general revenue fund, medical services account, etc.)**

This is not applicable to Kentucky pharmacy providers as they retain all payments provided to them.

*Section 1902(a) (2) provides that the lack of adequate funds from local sources will not result in the lowering the amount, duration, scope, or quality of care and services available under the plan. Please describe how the state share of your Medicaid pharmacy payment in attachment 4.19B is funded, including the payments made under the proposed amendment. Specifically:*

**Q30) Describe whether the state share is from appropriation from the legislature, through intergovernmental transfer agreements (IGT), certified public expenditures (CPE), provider taxes, or any other mechanism used by the state to provide the state share.**

Payments for the pharmacy benefit contained in the budget for Kentucky are from an appropriation from the legislature.

**Q31) Please provide your estimate of total expenditures and state share amount for your Medicaid pharmacy payments.**

The pharmacy cost for Medicaid FFS is estimated for FFY 13 at \$63.2 million.

**Q32) If any of the state share is being funded by the IGTs or CPEs, please fully describe the matching arrangement. If CPEs are used, please describe how the state verifies that the expenditures being certified are eligible for Federal matching funds in accordance with 42 CFR 433.51(b).**

This is not applicable to Kentucky as the pharmacy benefit provided to Medicaid beneficiaries is from appropriations from the legislature.

*Section 1902(a) (30) of the Act requires that payments for services be consistent with efficiency, economy, and quality of care. Section 1903(a) (1) provides for FFP to states for expenditures for services under an approved state plan. If you are providing, or propose to provide under this amendment, an enhanced or supplemental payment to pharmacy providers under section 4.19B of the plan, please provide the following information:*

**Q33) The total amount for each enhanced or supplemental payment provided to pharmacy providers and the precise service cost this payment is covering.**

There is no supplemental payment to pharmacy providers in this SPA.

**Q34) Indicate whether there are public pharmacy providers and if they are receiving payments in accordance with attachment 4.19B that in the aggregate exceed its reasonable costs of providing services. If the payment exceeds the reasonable costs of services (for pharmacy that would be a reasonable dispensing fee and ingredient cost) please indicate whether the state recoups the excess and returns the Federal share of the excess to CMS on the quarterly expenditure report.**

Kentucky reimburses pharmacies through a standard reimbursement process. There are no exceptions to these standards. The reimbursement methodology is based on reasonable costs of providing medications to Kentucky beneficiaries.