DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID AND MEDICAL ASSISTANCE

Statutory Authority: 31 Delaware Code, Section 512 (31 **Del.C.** §512)

PROPOSED

Medicaid Reimbursement for Prescription Drugs – Multi-State Purchasing Pool Supplemental Drug Rebate Agreement

PUBLIC NOTICE

In compliance with the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the Delaware Code) and under the authority of Title 31 of the Delaware Code, Chapter 5, Section 512 and with 42 CFR §447.205, Delaware Health and Social Services (DHSS) / Division of Medicaid and Medical Assistance (DMMA) is proposing to amend the Title XIX Medicaid State Plan to modify the *Multi-State Purchasing Pool Supplemental Rebate Agreement* for pharmaceutical products.

Any person who wishes to make written suggestions, compilations of data, testimony, briefs or other written materials concerning the proposed new regulations must submit same to Sharon L. Summers, Planning & Policy Development Unit, Division of Medicaid and Medical Assistance, 1901 North DuPont Highway, P.O. Box 906, New Castle, Delaware 19720-0906 or by fax to 302-255-4425 by September 30, 2013.

The action concerning the determination of whether to adopt the proposed regulation will be based upon the results of Department and Division staff analysis and the consideration of the comments and written materials filed by other interested persons.

SUMMARY OF PROPOSAL

The Division of Medicaid and Medical Assistance (DMMA) hereby affords the public notice of its intention to amend the Title XIX Medicaid State Plan to modify the *Multi-State Purchasing Pool Supplemental Rebate Agreement* for pharmaceutical products.

Statutory Authority

- Patient Protection and Affordable Care Act (Pub. L. No. 111-148 as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152)), together known as the Affordable Care Act. Specifically, Section 2501, *Prescription Drug Rebates*
- 1927(a)(1) and 1927 (a)(4) of the Social Security Act, *Authorizes state to enter directly into separate or supplemental rebate agreements with manufacturers*
- 1902(a)(19) of the Social Security Act, *Care and services under a Medicaid state plan be provided in a manner consistent with simplicity of administration and the best interests of beneficiaries*
- 42 CFR §440.120, Prescribed drugs
- 42 CFR §447.201, *State plan requirements*
- 42 CFR §447.205, *Public notice of changes in Statewide methods and standards for setting payment rates*

Background

Medicaid Supplemental Drug Rebate Agreements

The federal Omnibus Budget Reconciliation Act of 1990, section 4401 added §1927 to the Social Security Act. Section 1927 provides that States may enter separate or supplemental drug rebate agreements as long as such agreements achieve drug rebates equal to or greater than the drug rebates set forth in the Secretary's national rebate agreement with drug manufacturers, which is published at 56 F.R. 7049 (1991). Specifically, the drug rebate statute, at section 1927(a)(1) of the Social Security Act (Act), provides that "the Secretary may authorize a State to enter directly into agreements with a manufacturer." Also, section 1927(a)(4) of the Act provides that any drug rebate agreement between a State and drug manufacturers and in effect on November 5, 1990, may constitute a rebate agreement in compliance with the statute if the Centers for Medicare and Medicaid Services (CMS) determines that any such agreement "provides for rebates that are at least as large as the rebates otherwise required under this section." CMS accordingly believes that Congress intended that States that seek CMS approval under section 1927(a)(1) to enter directly into agreements with manufacturers must ensure that any such agreement will achieve drug rebates that are at least equal to the rebates set forth in the Secretary's rebate agreements with manufacturers.

Currently, prescription drug manufacturers are required to enter into a rebate agreement. The agreement requires manufacturers to provide state Medicaid programs with rebates for the drugs purchased for recipients on an outpatient basis. *Section 2501* of the Patient Protection and Affordable Care Act (ACA) makes two modifications to the prescription

drug rebate program. The first modification, which took effect on January 1, 2010, increases the minimum rebate amount but requires the State to remit 100 percent of the additional rebates collected to the federal government. The second modification, which took effect on March 23, 2010, extends the application of the prescription drug rebates program to prescription drugs that are provided to Medicaid recipients who are enrolled in Medicaid Managed Care Organizations (MCOs).

Summary of Proposal

Among the services provided to recipients of services under the Delaware Medical Assistance Program (DMAP) are prescription drugs and related pharmacy services. Expenditures for pharmacy services are offset in part by rebate agreements with suppliers of prescription drugs. Part of the system by which Delaware receives these rebates is a multi−state purchasing pool supplemental rebate agreement.

The existing multi-state supplemental rebate agreement between the State of Delaware and pharmaceutical manufacturers for legend drugs provided fee-for-service to Medicaid individuals was originally effective October 1, 2005. Delaware participates in the TOP$ program, the multistate Medicaid pharmaceutical purchasing pool administered by Provider Synergies, LLC, an affiliate of Magellan Medicaid Administration.

The Division of Medicaid and Medical Assistance (DMMA) intends to make substantive changes to the existing ***TOP$[SM] The Optimal PDL $solution ("TOP$") State Supplemental Rebate Agreement ("SRA")***, which includes revised definitions, and structural changes to the SRA. Specifically, *Definitions* have been added to provide for the inclusion of Medicaid Managed Care Organization (MCO) utilization for accrual of supplemental rebates.

The intent of the SRA has been expanded to cover both fee-for-service (FFS) and MCO populations, as long as the State retains control of the Preferred Drug List (PDL) for both populations. Inclusion of the MCO population under the contract is *optional* and at the sole discretion of the State. The proposed changes will be effective October 1, 2013 and will apply to claims with dates of service on or after that date.

A brief description of additional changes to the TOP$ SRA include:

- Clarified the terms under which supplemental rebates accrue for partial quarter invoicing.
- Changed the rebate calculation to use Wholesale Acquisition Cost (**WAC**) on the last day of the quarter.
- Limited termination by the manufacturer to the entire agreement not by National Drug Code (NDC) or product.
- Removed "termination without cause" language.
- Added an interest penalty of ten percent (10%) to the SRA.
- 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 other than Guaranteed Net Unit Price (GNUP).

Draft of Proposed State Supplemental Rebate Agreement

See attachment to the regulation for a draft of "TOP$[SM] The Optimal PDL $solution ("TOP$") State Supplemental Rebate Agreement".

DMMA is required by federal regulation to submit its supplemental rebate agreement for approval prior to its use. As such, the provisions of this state plan amendment relating to the multi-state supplemental rebate agreement are subject to approval by CMS.

Fiscal Impact Statement

There is minimal fiscal impact expected. The change in TOP$ contract language will allow the State to apply supplemental rebates to the medication costs paid for by the participating MCO. It is anticipated that the net-net cost will remain the same. There is also a stipulation of interest charges for late payment which will assist with maintaining the timely payment of the quarterly invoices.

DMMA PROPOSED REGULATION #13-26
REVISION:

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE: **DELAWARE**
LIMITATIONS

12.a. Prescribed Drugs Continued:

Drug Rebate Agreements

The Centers for Medicare and Medicaid Services (CMS) has authorized a rebate agreement between the State and a drug manufacturer that provides supplemental rebates for drugs provided to the Delaware Medicaid program as follows:

- CMS has authorized the state of Delaware to enter into The State of Delaware Department of Health and Social Services supplemental drug rebate agreement. This supplemental drug rebate agreement was submitted to CMS on April 7, 2005 and has been authorized by CMS.
- CMS has authorized the State of Delaware to enter into "The Optimal PDL Solution (TOP$) State Supplemental Drug Rebate Agreement, a Medicaid multi-state pooling program. The amendment to the Supplemental Drug Rebate Agreement was submitted to CMS on December 20, 2005 and CMS has authorized the State of Delaware to enter into the "TOP$ Medicaid Program Participation Agreement".
- A supplemental rebate agreement (to be) submitted to CMS on November 10, 2013 amended the December 20, 2005 version of the "State of Delaware TOP$SM The Optimal PDL $solution ("TOP$") State Supplemental Rebate Agreement" authorized under Transmittal Number SP-412, has been authorized by CMS.
  - Pharmaceutical manufacturers are allowed to audit utilization rates;
  - Compliance with the reporting requirements for state utilization information and restrictions to coverage;
  - The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification; and,
  - Rebate agreements between the state and a pharmaceutical manufacturer that are separate from the drug rebate agreements of Section 1927 are authorized by the Centers for Medicare and Medicaid Services. The state reports rebates from separate agreements to the Secretary for Health and Human Services. The state will remit the federal portion of any state supplemental rebates collected.
  - Participation in the TOP$ multi-state rebate program will not limit the state's ability to submit a SPA to authorize the implementation of a state-specific supplemental rebate agreement.

DMMA PROPOSED REGULATION #13-26 ATTACHMENT

Proposed Multi-State Purchasing Pool Supplemental Rebate Agreement and Attachments
TOP$sm *The Optimal PDL $olution*
State Supplemental Rebate Agreement
Among
Participating Medicaid Programs
Provider Synergies, L.L.C.
And
(Manufacturer)

This **TOP$sm, *The Optimal PDL $olution*** ("**TOP$sm**") State Supplemental Rebate Agreement ("**Agreement**") among definite and certain Participating Medicaid Programs herein identified and made a party to this Agreement via the attached and incorporated Medicaid Program Participation Agreement, Provider Synergies, L.L.C. ("**Provider Synergies**"), and _____ (**Manufacturer**"), sets forth the terms and conditions regarding the provision of state supplemental rebates on certain of Manufacturer's drug products and/or supplies reimbursed by Participating ~~(Title XIX)~~ Medicaid Programs that have elected to participate in TOP$sm, a multi-state Medicaid state supplemental drug rebate pooling initiative approved by CMS and administered by Provider Synergies; and

WHEREAS, Provider Synergies administers TOP$sm on behalf of and for the benefit of Participating Medicaid Programs in a manner intended to be consistent with simplicity of administration and the best interests of Medicaid programs that desire to efficiently acquire prescription drugs and the best interests of Medicaid Recipients; and

WHEREAS, Provider Synergies administers TOP$sm on behalf of and for the benefit of Participating Medicaid Programs individually identified in each attached and incorporated TOP$sm Medicaid Program Participation Agreement (Attachment A) and collectively identified in the attached and incorporated Catalogue of TOP$sm Participating Medicaid Programs (Attachment C) so as to further the goals and objectives of the Medicaid program in compliance with and pursuant to ~~Title XIX of~~ the Social Security Act (the "**Act**") (42 U.S.C. §§1396, *et seq.*); and

WHEREAS, each Participating Medicaid Program operates an autonomous pharmacy and therapeutics committee with an independent preferred drug list ("**PDL**") consistent with section 1902(a)(19) of the Act; and

WHEREAS, each Participating Medicaid Program may as the result of historical accident and pre-existing marketplace realities already share common or identical drug utilization patterns for significant portions of their Medicaid Recipient populations; and

~~WHEREAS, the pooling of the purchasing (market) power of the Participating Medicaid Programs as market participants seeking to cost-effectively deliver optimal levels of access to quality healthcare through the optimally efficient acquisition of prescription drugs would create an optimally efficient marketplace in which to negotiate state supplemental rebates that would directly and significantly benefit all current and future Medicaid Recipients serviced by the Participating Medicaid Programs by enabling state governments and the federal government to fund the delivery of more quality healthcare services and supplies for more Medicaid Recipients with the limited resources available (existing budgetary allocations); and~~

WHEREAS, the state agencies and departments executing the attached and incorporated TOP^{sm} Medicaid Program Participation Agreement (Attachment A) may enter into ~~transparent~~ contracts with entities that each agency or department may deem necessary to carry out the general intent and purposes of each Medicaid program; and

NOW THEREFORE, in consideration of the mutual promises and covenants contained herein, the parties agree to enter into this Agreement in accordance with the terms and conditions as follows:

Article 1. Definitions. As used in this Agreement, the following terms have the following meanings:

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

1.2. **"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~~, excluding State Supplemental Rebate amounts~~.

1.3. **"CMS"** shall mean the Centers for Medicare and Medicaid Services ~~(formerly known as the Health Care Financing Administration)~~ of the United States Department of Health and Human Services, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.

1.4 ~~"Participating Medicaid Program" shall mean the joint federal and state medical assistance program as established and defined pursuant to Title 42 U.S.C. §§1396, et seq., and state enabling legislation that provides reimbursement for or coverage of prescription drug Products to Medicaid Recipients as administered by a duly enabled state governmental agency or department that has contracted with Provider Synergies to provide Preferred Drug List and Supplemental Rebate Program related management services and/or supplies and has executed a TOP$sm Medicaid Program Participation Agreement (Attachment A) to this Agreement and is listed in The Catalogue of TOP$sm Participating Medicaid Programs (Attachment C) which are attached hereto and incorporated herein by reference.~~ "**Covered Outpatient Drug**" will have the meaning as set forth in 42 U.S.C. § 1396r-8(k)(2),(k)(3) and (k)(4).

1.5. ~~"Fiscal Quarter" shall mean one of the four three-month periods by which the fiscal year is divided, that fiscal year beginning January 1 and ending on the following December 31.1.6.~~ "**Guaranteed Net Unit Price", "GNUP"** or "**Discount Per Unit**" means the amount(s) agreed upon by the parties to this Agreement in the attached ~~is the net price per unit specified in~~ TOP^{sm} Multistate Supplemental Drug Rebate Formulae (Attachment B). ~~The GNUP is equal to the per unit Wholesale Acquisition Cost ("WAC") WAC of the product less National Rebate and State Supplemental Rebate unit amounts, if any.~~

1.6. **"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.

1.7. **"Medicaid Recipient"** shall mean any person enrolled in a Participating Medicaid Program and eligible to receive prescription drug benefits.

1.8. "**Medicaid Utilization**" means the total number of Units of each dosage form and strength of the Manufacturer's Supplemental Covered Product(s) reimbursed during a quarter under a Participating Medicaid Program. This utilization is based on claims paid by the Participating Medicaid Program during a calendar quarter and not drugs that were dispensed during a calendar quarter, except it shall not include drugs dispensed prior to January 1, 1991. Where a Participating Medicaid Program has elected to seek Supplemental Rebates for Medicaid MCO utilization as permitted under this Agreement, the term "**Medicaid Utilization**" shall also include the total number of Units of each dosage form and strength of the Manufacturer's 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 Medicaid Program elects to include such Medicaid MCO utilization under Attachment A-2, and provides all required documentation supporting such election to Provider Synergies.

1.9. **"National Drug Code"** or **"NDC"** shall mean the unique nine (9) or eleven (11) character code assigned to drug products composed of three distinct sub-codes to include the labeler code, product code, and package size as requested by Provider Synergies at the time of bid solicitation.

~~1.9.~~1.10.**"National Rebate"** shall mean any discount provided by a manufacturer pursuant to 42 U.S.C. §1396r-8 and includes both the "Basic Rebate" and any applicable "Additional Rebate" as defined in 42 U.S.C. §1396r-8.

~~1.10."Pharmacy" shall mean a facility or pharmacy licensed in accordance with the laws of the state in which the facility or pharmacy is located, as applicable, to dispense legend drugs and over-the-counter (OTC) drugs, and enrolled as a Medicaid provider. The definition of Pharmacy shall not include any Pharmacy located outside of the United States.~~

1.11.**"Participating Medicaid MCO"** means a Medicaid MCO that a Participating Medicaid Program has determined is eligible for Supplemental Rebates consistent with the applicable Participating Medicaid Program's Medicaid Plan and the applicable Participating Medicaid Program'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 Medicaid Program PDL requirements applicable to the Supplemental Covered Product.

1.12.**"Participating Medicaid Program"** shall mean the joint federal and state medical assistance program as established and defined pursuant to Title 42 U.S.C. §§1396, *et seq.*, and state enabling legislation that provides reimbursement for or coverage of prescription drug products to Medicaid Recipients as administered by a duly enabled state governmental agency or department that has contracted with Provider Synergies to provide Preferred Drug List and Supplemental Rebate Program related management services and/or supplies and has executed a TOP$[sm] Medicaid Program Participation Agreement (Attachment A) to this Agreement and is listed in The Catalogue of TOP$[sm] Participating Medicaid Programs (Attachment C) which are attached hereto and incorporated herein by reference.

1.13**"Pharmaceutical and Therapeutics Committee"** or **"P&T Committee"** shall mean the committee established pursuant to 42 USC 1396r-8 ~~and a~~ or Participating Medicaid Program enabling legislation, as ~~amended~~ applicable, for the purpose of consulting with the state agency or department responsible for administering the Participating Medicaid Program toward adoption of a Preferred Drug List for the Participating Medicaid Program.

~~1.12~~1.14.**"Preferred Drug List"** or **"PDL"** shall mean the list of drugs adopted by a Participating Medicaid Program in consultation with the respective state's P&T Committee pursuant to that state's relevant enabling legislation, as ~~amended~~ applicable.

1.15.**"Quarter"** shall mean one of the four three-month periods by which the calendar year is divided, that fiscal year beginning January 1 and ending on the following December 31.

~~1.13.~~1.16.**"Supplemental Covered Product"** shall mean any ~~drug product and/or supply~~ Covered Outpatient Drug listed in TOP$[sm] Multistate Supplemental Drug Rebate Formulae (Attachment B) which is attached hereto and incorporated herein by reference.

~~1.14.~~1.17.**"~~State~~ Supplemental Rebate"** shall mean ~~any cash rebate that offsets: (a) a Participating Medicaid Program expenditure and supplements a CMS National Rebate. State Supplemental Rebate amounts shall be~~ the quarterly amount invoiced by a State Medicaid Agency under this Agreement, as calculated in accordance with the TOP$[sm] Multistate Supplemental Drug Rebate Formulae (Attachment B). Where a Participating Medicaid Program has elected to include Medicaid MCO utilization as permitted under this Agreement and the Participating Medicaid Program's Medicaid Plan, the term "State Supplemental Rebate" shall include the rebates invoiced hereunder with respect to such Medicaid MCO utilization, in addition to the applicable state fee-for-service Medicaid utilization. In no case may the State Supplemental Rebate amount be a negative amount.

~~1.15.~~1.18.**"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.

~~1.16.~~1.19.**"Wholesale Acquisition Cost"** or **"WAC"** shall mean the ~~Direct Manufacturer Price Wholesale Unit Price (BB_P)~~ wholesale acquisition cost as of the ~~first~~ last day of a ~~Fiscal~~ Quarter published in ~~the National Drug Data File by~~ a national drug data file, such as First Data Bank, ~~Incorporated~~ Inc. or MediSpan, or its successor publication, if any.

Article 2. Term and Scope of Agreement.

2.1. **Term**. The term of this Agreement shall be from _____~~,~~ through _____, unless the Agreement is otherwise terminated as set forth herein.

2.2. **Entirety of Agreement**. The terms and conditions of this Agreement together with any and all attached and/or expressly incorporated addenda, attachments, documents or exhibits along with any and all applicable Participating Medicaid Program administrative regulations and any documents expressly incorporated therein, shall constitute the entire present agreement between the parties. This Agreement constitutes a total integration of all previously existing rights, benefits and obligations of the parties, and there exist no other agreements or understandings, oral or otherwise, which

bind any of the parties regarding State Supplemental Rebates pertaining to the identical Supplemental Covered Product subject matter of this Agreement. Further, it is understood by all the parties that the transition from supplemental rebate agreements between a Manufacturer and a Participating Medicaid Program to TOP$[sm] may not occur all at the same time for all Participating Medicaid Programs and that therefore, for certain Supplemental Covered Products on a Participating Medicaid Program's PDL, other pre-existing state supplemental rebate agreements between a Participating Medicaid Program and a Manufacturer may remain in effect until such time as all Manufacturer Supplemental Covered Products migrate or are transferred to this Agreement. The Parties agree that the intent of the Parties is to replace existing state supplemental rebate agreements relating to the same or similar Supplemental Covered Product subject matter between a Participating Medicaid Program and Manufacturer with this Agreement within one (1) year from the execution of a TOP$[sm] Medicaid Program Participation Agreement (Attachment A). Nothing in this Agreement shall preclude a Participating Medicaid Program from maintaining state supplemental drug rebate agreements, however, except as provided for in Section ~~5.2.C~~ 5.2 herein, this Agreement shall at all times supersede any and all other previously existing agreements including any state supplemental drug rebate agreements between a Participating Medicaid Program and a Manufacturer to the extent such agreements pertain to the same NDC. Notwithstanding anything in this Agreement to the contrary, this Agreement shall have no effect whatsoever on Manufacturer's rights and obligations under its National Rebate agreement with CMS to pay National Rebates.

Article 3. Termination.

3.1 **Termination ~~Without Cause~~ By Manufacturer**. This Agreement may not be terminated by Manufacturer, except that, Subject to Section 3.7: (i) this Agreement shall be co-terminous with the National Rebate agreement with CMS, in the event that such agreement is terminated for any reason, and (ii) this Agreement may be terminated by Manufacturer in its entirety~~, or as to any Product(s) or NDC(s) but not as to one or more Participating Medicaid Programs at the option of Manufacturer without cause~~ as of the end of the calendar quarter upon ninety (90) days written notice to Manufacturer for reasons of material breach by Provider Synergies~~. Provider Synergies will there upon be obligated to notify the Participating Medicaid Program in writing of such termination~~, provided that Provider Synergies is unable to reasonably cure the breach within such ninety (90) day period.

3.2 **Termination Without Cause By Provider Synergies.** This Agreement may be terminated by Provider Synergies in its entirety or as to any Supplemental Covered Product(s) or NDC(s) with the advice of, notice to and express written consent of each affected Participating Medicaid Program without cause as of the end of the calendar quarter upon ninety (90) days written notice to Manufacturer. Provider Synergies shall request and must receive the written permission of all Participating Medicaid Programs prior to the exercise of elective termination under this ~~section~~ Section. Provider Synergies shall provide copies of Participating Medicaid Program written termination consents along with notice of termination of this Agreement to Manufacturer.

3.3 ~~A.~~ **Termination Without Cause by a Participating Medicaid Program**. In the event that a Participating Medicaid Program terminates its TOP$[sm] Program Participation Agreement in whole or in part upon thirty (30) days prior written notice to Provider Synergies, Provider Synergies will then be obligated to communicate in writing such Participating Medicaid Program termination notice to Manufacturer. ~~The~~ Subject to Section 3.7, the obligations of Manufacturer, Participating Medicaid Program and Provider Synergies arising under this Agreement relating to the terminating Participating Medicaid Program shall cease as of the effective date of the Participating Medicaid Program's termination notice. In the event of nonrenewal or termination with respect to one or more Participating Medicaid Programs, this Agreement shall remain in effect with respect to the remaining parties.

~~3.3.~~3.4 **Non-waiver**. Failure of Provider Synergies, Manufacturer or any Participating Medicaid Program to insist on performance of any term or condition of this Agreement or to exercise any right or privilege hereunder shall not be construed as a continuing or future waiver of such term, condition, right or privilege.

~~3.4.~~3.5 **Violation of Law**. ~~Manufacturer~~ Any party may immediately terminate this Agreement if there is a determination by any court of competent jurisdiction or any authorized governmental authority that the arrangements and transactions under this Agreement or any similar agreement constitute a violation of any law or regulation including without limitation § 42 U.S.C. 1320a-7b(b) prohibiting illegal remuneration.

~~3.5.~~3.6 **Bankruptcy and Insolvency**. Provider Synergies shall have the right to cancel this Agreement immediately without prior notice in the event that Manufacturer is adjudicated bankrupt, or makes an assignment for the benefit of creditors without Provider Synergies' or the Participating Medicaid Program's prior written consent, which shall not be unreasonably withheld, or in the event that a receiver is appointed for Manufacturer.

~~3.6.~~3.7 **Effect on Accrued Obligations**. Termination of this Agreement shall have no effect upon the rights and obligations of the parties arising out of any transaction occurring prior to the effective date of such termination, including, without limitation, Supplemental Rebates accrued hereunder but not yet paid and/or invoiced. Notwithstanding the forgoing, in the event that a Participating Medicaid Program terminates its TOP$[sm] Program Participation Agreement, Provider Synergies shall have no additional obligation to administer the terms of this Agreement as to such Participating Medicaid Program as of the effective date of such termination, and the Participating Medicaid Program shall be solely and directly responsible for any recoveries of accrued but unpaid and/or uninvoiced Supplemental Rebates hereunder. In addition,

Supplemental Rebates shall cease to accrue with respect to a Participating Medicaid Program as of the effective date that a Participating Medicaid Program terminates its TOP$[sm] Program Participation Agreement.

Article 4. Agreement Management and Notices.

4.1. **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; or (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. All telephonic communications between the parties shall be made to the telephone number(s) set forth below. A party may at any time give notice in writing to other parties of a change of name, address, telephone or telefacsimile number~~, to the address set forth below. Notwithstanding the forgoing, notices other than those pertaining to contract termination, amendment, assignment, and breach, shall not be subject to the formal "notice" requirements, and may be transmitted by Provider Synergies and/or the applicable Participating Medicaid Program 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 National Rebate invoicing guidance (Medicaid Drug Rebate Program Release No. 80 (Jan. 5, 2010)).

To Manufacturer:	~~[Primary Contact]~~	Primary Contact
Address	~~[Street Number]~~	Street Number
	~~[City, State, Zip]~~	City, State, Zip
Telephone	~~[Phone Number]~~	Phone Number
Telefacsimile	~~[Fax Number]~~	Fax Number

~~**To Provider Synergies:**~~ ~~Steve Liles, RPh~~
~~Address~~ ~~Provider Synergies, L.L.C.~~
~~Attention: Sr. Director, Value Based Purchasing~~
~~10101 Alliance Rd.~~
~~Ste 201~~
~~Cincinnati, OH 45242~~
~~Telephone:~~ ~~(513) -774-8500~~
~~Telefacsimile:~~ ~~(513) -697-5762~~

To Provider Synergies: Provider Synergies, L.L.C. (c/o 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

Article 5. Provider Synergies Rights and Responsibilities.

5.1 **Role of Provider Synergies.** Provider Synergies provides Participating Medicaid Programs with State Supplemental Rebate Program and PDL management services and supplies, including but not limited to research into the relative safety, clinical efficacy and relative value of Supplemental Covered Products within defined therapeutic drug classes.

~~5.2~~5.2 **Addition of Participating Medicaid Programs and Participating Medicaid MCOs.** Any state Medicaid agency which has the necessary delegated authority and CMS authorization to operate a PDL and state supplemental rebate program and which is contracted to utilize Provider Synergies to administer its PDL and state supplemental rebate program is eligible to join TOP$[sm] as a Participating Medicaid Program subject to CMS authorization.

A. ***Notice to Manufacturers*.** Provider Synergies shall notify Manufacturer in writing when a new state Medicaid agency joins TOP$[sm] as a Participating Medicaid Program by providing Manufacturer with a copy of the relevant executed TOP$[sm] Medicaid Program Participation Agreement (Attachment A) and an updated Catalogue of TOP$[sm] Participating Medicaid Programs (Attachment C) to this Agreement.

B. ***Effective Dates for New TOP$sm States*.** Whenever TOP$[sm] is expanded, subject to CMS authorization, to incorporate a new state Medicaid agency as a Participating Medicaid Program, the relevant TOP$[sm] Medicaid Program Participation Agreement (Attachment A) for the new state shall be effective as of the first (1[st]) day of the calendar quarter immediately following the date of such notice to Manufacturer. Upon such an occurrence, Provider Synergies shall notify all Participating Medicaid Programs by providing them with an updated copy of the Catalogue of TOP$[sm] Participating

Medicaid Programs (Attachment C). Each Participating Medicaid Program may then forward such notice to CMS.

C. ***Accrual of State Supplemental Rebates***. ~~State~~ Supplemental Rebates shall begin to accrue to the new Participating Medicaid Program pursuant to this Agreement for a Supplemental Covered Product ~~once~~ at the later of the date: (a) the state Medicaid agency is effectively added to this Agreement as a Participating Medicaid Program pursuant to Section 5.2. ~~A herein; and (b) the Product is subsequently reviewed by the Participating Medicaid Program's P&T Committee; and (c) the~~ B herein; or (b) the effective date the Supplemental Covered Product is listed on the Participating Medicaid Program's PDL ~~by publication~~ in accordance with Section 7.2.A herein.

D. ***Addition of Participating Medicaid MCOs***. To the extent permitted by: (i) CMS, (ii) applicable law, and (iii) the Participating Medicaid Program's Medicaid Plan, any Participating Medicaid Program added hereunder may elect, but shall not be required, to include Medicaid Utilization from Participating Medicaid MCOs in their Supplemental Rebate invoices, provided that such Participating Medicaid Program provide to Provider Synergies an executed and complete copy of Attachment A-2 electing to include Participating Medicaid MCO utilization hereunder, along with any required attachments thereto.

Article 6. Manufacturer's Rights and Responsibilities.

6.1. **State Supplemental Rebate Payment**. Manufacturer will provide each Participating Medicaid Program a National Rebate for the Supplemental Covered Product(s) in accordance with Manufacturer's CMS Agreement. Manufacturer's obligation for National Rebates will continue for the duration of the Manufacturer's CMS Agreement and shall not be impacted by Supplemental Rebates hereunder. In addition to the National Rebates, Manufacturer agrees to provide a Supplemental Rebate to Participating Medicaid Programs for ~~each Manufacturer Product that is administered by authorized provider facilities or dispensed or administered by Pharmacies to Medicaid Recipients for each Fiscal~~ Medicaid Utilization on each Supplemental Covered Product invoiced for each Quarter, or portion thereof, that such Supplemental Covered Product is included in the Preferred Drug List as adopted by a Participating Medicaid Program. Manufacturer shall pay to the Participating Medicaid Program the State Supplemental Rebate amount in accordance with the formula set forth in the TOP$sm Multistate Supplemental Drug Rebate Formulae (Attachment B). For the avoidance of doubt, as is the case with National Rebates, Supplemental Rebates applicable to Participating Medicaid MCO utilization shall be payable to the Participating Medicaid Programs, and shall not be paid directly to the Participating Medicaid MCOs, notwithstanding that the Participating Medicaid MCO utilization may be invoiced separately from fee-for-service Medicaid utilization. Nothing in this Agreement shall be construed to relieve Manufacturer from its obligation to pay National Rebates under contracts, if any, with CMS for utilization by Medicaid Recipients. All Participating Medicaid Programs shall remit ~~State~~ Supplemental Rebate payments made under this Agreement to CMS ~~as~~ and/or the Participating Medicaid MCOs as may be required pursuant to a Medicaid State Plan and applicable law.

A. ***Payment Timeframe.*** Manufacturer shall pay to Participating Medicaid Program the State Supplemental Rebate amount, including any applicable interest as outlined in 6.1.C. of this Agreement, to which that Participating Medicaid Program is entitled in accordance with the formula set forth in Attachment B, within thirty-eight (38) days of receipt of an invoice from a Participating Medicaid Program.

B. ***Timeliness. M***anufacturer's failure to remit the State Supplemental Rebate amount in a timely manner may result in the removal of the relevant Supplemental Covered Product or Supplemental Covered Products from one or more Participating Medicaid Program Preferred Drug Lists, pursuant to the application of the dispute resolution process set forth in Paragraph ~~D~~E, below.

C. ***Interest. M***anufacturer will pay the Supplemental Rebates, including any applicable interest in accordance with Section 1903(d)(5) of the Social Security Act. Interest on the Supplemental Rebates payable under Section 6.1 of this Agreement begins accruing 38 calendar days from the postmark date of each Participating Medicaid Program's invoice 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 Supplemental Rebate payable under Section 6.1 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 6.1 but will be increased by ten percentage points (10%) or the maximum allowed by that Participating Medicaid Program's state law. If a Participating Medicaid Program has not received the Supplemental Rebates payable under Section 6.1 of this Agreement, including interest, within 180 days of the postmark date of said Participating Medicaid Program's invoice sent to the Manufacturer, such Participating Medicaid Program may deem the Manufacturer to be in default and Participating Medicaid Program may terminate its participation in this Agreement by giving Manufacturer and Provider Synergies ninety (90) days advance written notice.

~~C~~D. ***Incomplete Submission***. Manufacturer shall have no obligation for claims that are not submitted as part of an invoice in accordance with Section 7.3 of this Agreement. Manufacturer shall notify the affected Participating Medicaid Program and Provider Synergies of any incomplete submission within thirty-eight (38) days after Manufacturer's receipt of such submission pursuant to Section 7.3.

~~D~~E. ***Over/Underpayment***. If any party discovers an error in the payment of ~~State~~ Supplemental Rebates by Manufacturer, it shall notify the other affected parties of such error. 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 Medicaid Program or CMS in disputes concerning

National Rebates. Manufacturer shall deduct any overpayment from subsequent ~~State~~ Supplemental Rebates payable under this Agreement. In the event that no subsequent ~~State~~ Supplemental Rebates are payable, the affected Participating Medicaid Program will refund any such overpayment to Manufacturer within thirty (30) days after its acknowledgment of the overpayment. Manufacturer will remit any underpayment, including interest accrued under Section 6.1(C) of this Agreement, to the affected Participating Medicaid Program within thirty (30) days after Manufacturer's acknowledgment of such underpayment. All other disputes will be resolved in accordance with generally applicable procedures followed by the affected Participating Medicaid Program and CMS in disputes concerning an affected Participating Medicaid Program. Notwithstanding anything to the contrary herein, any dispute relating to eligibility of Participating MCO utilization for Supplemental Rebates hereunder shall be resolved exclusively between the Manufacturer and the Participating Medicaid Program.

~~E~~F. ***Supplemental Covered Product Utilization Eligible for Rebate***. Supplemental Covered Product utilization ~~under Preferred Drug List(s)~~ shall not be ~~eligible~~ invoiced for ~~State~~ Supplemental Rebates pursuant to TOP$[sm] Multistate Supplemental Drug Rebate Formulae (Attachment B), ~~only if and when it meets all of the following conditions: 1. Own Use. The Product shall have~~ if: (i) the Participating Medicaid Program is aware that the Supplemental Covered Product has not been dispensed and used in connection with this Agreement only for Medicaid Recipients and only for their own use, (ii) the Supplemental Covered Product is not listed on the applicable Participating Medicaid Program Preferred Drug List, or (iii) with respect to Medicaid MCO utilization, for those States opting to include such utilization under Section 7.3, such utilization was also subject to discounts under Section 340B of the Public Health Service Act.

~~F~~G. **Partial Quarter Submissions**. In the event that a Supplemental Covered Product is placed on or removed from the Preferred Drug List after the beginning of a ~~Fiscal~~ Quarter, the ~~State~~ Supplemental Rebate for the Supplemental Covered Product for that ~~Fiscal~~ Quarter shall be ~~estimated~~ calculated by multiplying the Supplemental Rebate Per Unit ("**SRPU**") ~~for that Fiscal Quarter by prorated~~ by utilization for the ~~proportionate~~ number of days within the ~~Fiscal~~ Quarter that the Supplemental Covered Product was included in the Preferred Drug List.

6.2. **Discretion to Market**. Nothing in this Agreement shall be construed to prohibit Manufacturer from discontinuing production, marketing or distribution of any Supplemental Covered Product or from transferring or licensing any Supplemental Covered Product to a third party. It is understood that Manufacturer is liable for the payment of ~~State~~ Supplemental Rebates only on Supplemental Covered Products, ~~(~~as identified by their ~~eleven (11) digit~~ NDCs that were distributed directly or through the wholesale channel~~) that Pharmacies dispense~~, and dispensed to Medicaid Recipients. If Manufacturer elects to discontinue production, marketing or distribution of any Supplemental Covered Product or to transfer or license any Supplemental Covered Product to a third party, Manufacturer shall notify Provider Synergies and Participating Medicaid Programs as soon as commercially reasonable of such action. Provider Synergies and Participating Medicaid Programs have the right to terminate this Agreement without cause upon such notification. If Manufacturer fails to notify Provider Synergies and Participating Medicaid Programs, Manufacturer shall continue to be responsible for all ~~State~~ Supplemental Rebates until such notification is given.

6.3. **Best Price Contingency**. Performance under this Agreement shall be contingent on applicable law and regulations permitting Manufacturer's Best Price and AMP ~~not being affected by State~~ to exclude Supplemental Rebates and the non-occurrence of the events described in Section ~~3.4~~ 3.5 of this Agreement.

Article 7. Medicaid Program's Rights and Responsibilities.

7.1. **Covered Benefit**. Each Participating Medicaid Program shall provide or arrange for the provision of pharmacy services to Medicaid Recipients.

7.2. **Preferred Drug List.** As a part of its process of drug prior authorization, each Participating Medicaid Program shall adopt and maintain a Preferred Drug List. No Supplemental Covered Product on the Preferred Drug List shall be discouraged or disadvantaged in any way relative to any other single source brand name prescription drug in its therapeutic class unless specifically stated otherwise in TOP$[sm] Multistate Supplemental Drug Rebate Formulae (Attachment B). Notwithstanding the forgoing, a Participating Medicaid Program may apply prior authorization, step therapy or similar controls to all products in a particular therapeutic class, or where the Manufacturer has explicitly agreed to the terms of such controls in writing as part of its Supplemental Rebate terms, without violation of this Section 7.2.

A. ***Medicaid Program's Preferred Drug List Documentation and Publication.*** Each Participating Medicaid Program shall publish its Preferred Drug List for each therapeutic class on Participating Medicaid Program's ~~(~~or its designee's~~)~~ website within thirty (30) days after the effective date of such Preferred Drug List ~~is adopted~~ for that therapeutic class, and shall update such website quarterly or after each therapeutic class review by the P&T Committee. For the avoidance of doubt, the effective date of a drug on a PDL may pre-date by up to thirty (30) days, the publication of the applicable PDL on the applicable website.

B. ***P&T Committee***. Each Participating Medicaid Program shall maintain a P&T Committee that shall review and recommend drug products and/or supplies for inclusion on the Preferred Drug List, at the sole discretion of the Participating Medicaid Program.

~~C. Notice of Preferred Drug List Review. Except for situations deemed emergencies, Participating Medicaid Program or Provider Synergies will notify Manufacturer at least forty-five (45) days prior to any scheduled review of a~~

~~Product and shall provide Manufacturer the opportunity to provide information in support of the Product's inclusion on the Preferred Drug List.~~

7.3. **Invoicing**. Each Participating Medicaid Program, or its designee, which designee may include but not be limited to Provider Synergies, shall invoice ~~State~~ Supplemental Rebates separately from National Rebates~~, using the invoice formats set forth in Attachment A to this Agreement~~ in accordance with the formulae set forth in Attachment B to this Agreement and any applicable CMS requirements regarding invoice format. In addition, where Supplemental Rebates are invoiced for Medicaid MCO utilization, such Medicaid MCO utilization may be invoiced separately from Medicaid fee-for-service utilization, in accordance with applicable State invoicing practices. Participating Medicaid Programs or ~~Provider Synergies~~ its designee shall submit the ~~State~~ Supplemental Rebate invoices to Manufacturer within ninety (90) days after the ~~Fiscal~~ Quarter in which the Supplemental Covered Product was paid for by Participating Medicaid Program. Participating Medicaid Program or Provider Synergies shall not provide to Manufacturer any ~~patient identifiable information or protected health information or any other~~ information the disclosure of which is prohibited or regulated by laws or regulations governing confidentiality of medical or other information.

7.4. **CMS Authorization**. Participating Medicaid Programs respectively represent and warrant that CMS has authorized this Agreement with respect to their respective State, and ~~found~~ that it is the ~~payment of State~~ intent and expectation of such Participating Medicaid Programs that Supplemental Rebates hereunder shall ~~not affect~~ be excluded from Manufacturer's calculation of Best Price or AMP.

Article 8. General Terms.

8.1. **Agreement to Obey All Laws**. Manufacturer and Provider Synergies shall at all times observe, comply with, and perform all obligations hereunder in accordance with, all laws, ordinances, codes and regulations of Federal, State, county and local governmental agencies which in any manner affect the terms of this Agreement.

8.2. **Amendments and Change Orders**. This Agreement ~~may be amended or modified by the parties as authorized by CMS at any time during its term. Amendments must be in writing and~~ will not be altered except by an amendment in writing signed by the parties. No ~~change in, addition to, or waiver of any term or condition of this Agreement shall be binding on Participating Medicaid Programs unless approved in writing by an authorized representative of Participating Medicaid Programs and as~~ 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 Provider Synergies, the Participating Medicaid Program and Manufacturer, and authorized by CMS.

8.3 **Manufacturer Acknowledgement.** ~~A.~~ Manufacturer acknowledges that the addition of a Participating Medicaid Program via the execution of TOP$[sm] Medicaid Program Participation Agreement (Attachment A) and any related changes to Catalogue of TOP$[sm] Participating Medicaid Programs (Attachment C) shall not require the consent of ~~Provider Synergies only~~ Manufacturer.

8.3~~4~~**Amendments Necessary for Statutory or Regulatory Compliance.** ~~A.~~Manufacturer shall, upon request by a Participating Medicaid Program through Provider Synergies and upon receipt of a proposed amendment to this Agreement, negotiate in good faith with Provider Synergies to amend this Agreement if and when required, in the opinion of one or more affected Participating Medicaid Programs and Provider Synergies, to comply with Federal or State laws or regulations, subject to CMS approval of such amendment as set forth in Section 8.2, as may be required. If the parties are unable to agree upon an amendment within sixty (60) days, or such shorter time required by Federal or State law or regulation, Participating Medicaid Program may terminate its TOP$[sm] Medicaid Program Participation Agreement and/or Provider Synergies may terminate this Agreement with the advice and consent of all affected Participating Medicaid Programs.

~~B. Manufacturer acknowledges that Section 8.3 specifically includes, without limitation, reference to the Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191, and regulations promulgated there under; and Manufacturer agrees that this Agreement will be amended prior to the Compliance Date specified in those regulations if Participating Medicaid Programs and Provider Synergies determine that amendment is necessary to ensure compliance with the regulations.~~

8.4~~5~~**Assignment**. This Agreement may not be assigned in whole or in part by a party without the express written consent of the other party and of the Participating Medicaid Programs. Notwithstanding the foregoing, where Provider Synergies has delegated authority from a Participating Medicaid Program, Provider Synergies may accept or reject such assignment on behalf of such Participating Medicaid Program. Such consent shall not be unreasonably withheld. However, in the event of a transfer of ownership of a Supplemental Covered Product or of a ~~manufacturer~~ Manufacturer, this Agreement ~~may~~ shall be automatically assigned to the new owner subject to the terms of this Agreement. If this Agreement or any Supplemental Covered Product is assigned by Manufacturer, Manufacturer shall notify Provider Synergies and Participating Medicaid Programs of the new contact information for purposes of Section 4.1 Notices, and any assignee shall be fully responsible for compliance with all terms and conditions of this Agreement applicable to Manufacturer. Additionally, and notwithstanding anything herein to the contrary, Provider Synergies may assign and/or delegate any of its rights or obligations hereunder, in whole or in part, to its affiliate Magellan Medicaid Administration, Inc., without notice or consent.

8.~~5~~6**Audits and Records**.

A. ***Right of Audit***. This Agreement, and all books, records, and supporting documents related thereto, shall be available for review or audit by each Participating Medicaid Program, the Office of Inspector General for Participating Medicaid Program, the Medicaid Fraud Control Unit of the state's Participating Medicaid Program, the United States Department of Health and Human Services, the state legislative branch or state executive branch auditor or other auditor and other state and federal agencies with monitoring authority related to the subject matter of this Agreement ("**Authorized Persons**"), but subject to 42 U.S.C. § 1396r-8(b)(3)(D), and Manufacturer and Provider Synergies agree to cooperate fully with any such review or audit. Upon reasonable notice by any Authorized Person, Manufacturer shall provide, in the appropriate venue for the affected Participating Medicaid Program or at any other location designated by the Authorized Person, during normal business hours, full and complete access to the relevant portions of Manufacturer's books and billing records as they relate to payments under this Agreement. ~~If the audit findings indicate overpayment(s) to a Participating Medicaid Program, Manufacturer shall adjust future or final payments otherwise due to a Participating Medicaid Program. If no payments are due and owing to a Participating Medicaid Program, or if the overpayment(s) exceed the amount otherwise due to Participating Medicaid Program, Participating Medicaid Program shall refund all amounts, which may be due to the Manufacturer~~ Any identified over-or under-payments shall be resolved in accordance with Section 6.1(E) of this Agreement.

B. ***Retention of Records***. Manufacturer shall maintain, during the term of this Agreement in accordance with 42 C.F.R. ~~§ 447.534(h)~~ pt. 447 and other applicable law, all business, professional and other records, written or electronic, in accordance with applicable law, the specific terms and conditions of this Agreement, and pursuant to generally accepted accounting practice. Failure to maintain books, records, and supporting documents required by this Agreement shall establish a presumption in favor of a Participating Medicaid Program for the recovery of any funds owed to a Participating Medicaid Program under the Agreement for which adequate books, records, and other documents are not available to support the purported disbursement.

8.~~6~~7**Choice of Law.** The Manufacturer agrees to be bound by the laws of the United States of America and with respect to a Participating Medicaid Program, the state law governing the affected Participating Medicaid Program with the exception of any choice of law provisions. Proper venue in any legal or equitable action shall be the venue of the affected Participating Medicaid Program. Any action brought by Manufacturer must be filed separately against the affected Participating Medicaid Program and/or Provider Synergies. A Participating Medicaid Program does not waive sovereign immunity by entering into this Agreement.

8.~~7~~8**Confidentiality.**

A. ***Confidential Information.*** Subject to 42 U.S.C. § 1396r-8(b)(3)(D) and subject to any other applicable state and federal law, as may be amended from time to time, performance of the Agreement may require Manufacturer to have access to and use of documents and data, including without limitation Medicaid utilization data, which may be considered and/or identified as confidential and/or proprietary by one or more Participating Medicaid Program(s) and/or by Provider Synergies and/or by a Participating Medicaid Program contractor~~(~~", including without limitation a Medicaid MCO ("**Medicaid Confidential Information**"). Any ~~documents or data~~ Medicaid Confidential Information obtained by Manufacturer ~~from any Participating Medicaid Program~~ in connection with carrying out the services under this Agreement shall be kept confidential and not provided to any third party unless disclosure is approved in writing by an actual agent of the affected Participating Medicaid Program(s), Provider Synergies and/or by a Participating Medicaid Program contractor, as applicable. In addition, pursuant to 42 U.S.C. § 1396r-8(b)(3)(D) and this agreement, information pertaining to a Manufacturer's National Rebate, Supplemental Rebate, and/or the components and calculations thereof disclosed by the Manufacturer in connection with this Agreement (the "**Manufacturer Confidential Information**") is confidential and, not withstanding other laws, will not be disclosed by the Participating Medicaid Program(s) and/or by Provider Synergies and/or by a Participating Medicaid Program contractor in a form which reveals the Manufacturer, or prices charged by the Manufacturer, except as necessary to carry out the provisions of 42 U.S.C. § 1396r-8, and to permit review under 42 U.S.C. § 1396r-8 by the U.S. Comptroller General. Each party shall protect the confidentiality of the other party's Confidential Information ~~provided by the other party or from a Participating Medicaid Program or from a Participating Medicaid Program contractor, or~~ to which the receiving party obtains access by virtue of its performance under this Agreement, that either has been identified as confidential by the disclosing party or by its nature warrants confidential treatment. The receiving party shall use such Confidential Information of the other party only for the purpose of this Agreement and shall not disclose it to anyone except those of its employees, consultants, contractors, agents, and assigns who need to know the information provided that such persons and/or entities are notified of all confidentiality and non-disclosure provisions stated herein and expressly warrant and represent that they shall abide by such. These nondisclosure obligations shall not apply to Confidential Information that is or becomes public through no breach of this Agreement, which is received from a third party free to disclose it, that is independently developed by the receiving party, or that is required by law to be disclosed~~. Confidential Information shall be returned to the disclosing party upon request. In addition, Provider Synergies agrees that this Agreement and any Confidential Information provided to Participating Medicaid Program or its contractors or designees pursuant to this Agreement is exempt from disclosure under 42 U.S.C. § 1396r-8(b)(3)(D)~~. In the event that either party is required by law to disclose any provision of this Agreement or any Confidential Information provided pursuant to this Agreement to any person, such party shall, to the extent permitted by applicable law, 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. ~~To the extent that Participating Medicaid Program utilizes the services of a third-party or Provider Synergies to develop and maintain the PDL and/or administer any portion of this Agreement, all provisions of this section shall apply to the third-party, and the Participating Medicaid Program shall have the third-party sign a written agreement ensuring the third-party's compliance with all aspects of this section before disclosing any information to the third-party. This section~~ This Section shall survive termination or expiration of this Agreement as to all parties.

B. ***Confidentiality of Program Recipient Identification***. Manufacturer shall ensure that all information, records, data, and data elements pertaining to applicants for and recipients of public assistance, or to providers, facilities, and associations, shall be protected from unauthorized disclosure by Manufacturer and Manufacturer's employees, by Manufacturer's corporate affiliates and their employees, and by Manufacturer's subcontractors and their employees, pursuant to 42 CFR Part 431, Subpart F and any other applicable federal or state law.

8.~~8~~9**Fraud & Abuse**. It is Provider Synergies' and the Participating Medicaid Programs' ~~belief~~ intent that the business arrangement contemplated by this Agreement is not ~~subject to~~ prohibited by the provisions of 42 U.S.C. §1320a-7b(b), prohibiting certain illegal remuneration~~. Should the above~~, as such provisions may be amended from time to time. In any event, should the provisions of 42 U.S.C. § 1320a-7b(b) apply to this arrangement, it is Provider Synergies' and Participating Medicaid Programs' ~~belief~~ intent that the business arrangement contemplated by this Agreement meets the discount exception found in 42 U.S.C. 1320a-7b(b)(3)(A), ~~which excludes from prohibited activities the practice of discounting or other reductions in price obtained by a provider of services or other entity under a Federal health care program, if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program~~ and regulatory safe harbor for discounts at 42 C.F.R. §1001.952(d), each of which as may be amended from time to time. Participating Medicaid Programs currently provide CMS full and unfettered access to all information held by Participating Medicaid Programs regarding the implementation of health care delivery and reimbursement policies, and shall continue to do so throughout the implementation of State Supplemental Rebate and Preferred Drug List programs.

8.~~9~~10 **Nondiscrimination.** ~~In compliance with the applicable provisions of State and Federal Constitutions, state civil rights acts, the U. S. Civil Rights Act, and Section 504 of the Federal Rehabilitation Act, Participating Medicaid Program and Provider Synergies do not unlawfully discriminate in employment, contracts, or any other activity.~~ In the performance of its obligations under this Agreement, Manufacturer shall abide by, ~~(~~and shall cause any Manufacturer subcontractor to abide by~~)~~ all applicable Federal and State laws, regulations and orders which prohibit discrimination because of race, creed, color, religion, sex, sexual orientation, national origin, ancestry, age, or physical or mental disability, including but not limited to, the Federal Civil Rights Act of 1964, the Americans with Disabilities Act of 1990 and the Federal Rehabilitation Act of 1973.

8.~~10~~11**Rules of Construction**. Unless the context otherwise requires or unless otherwise specified, the following rules of construction apply to this Agreement:

A. Provisions apply to successive events and transactions;

B. "Or" is not exclusive;

C. References to statutes and rules include subsequent amendments and successors thereto;

D. The various headings of this Agreement are provided for convenience only and shall not affect the meaning or interpretation of this Agreement or any provision hereof;

E. If any payment or delivery hereunder shall be due on any day that is not a business day, such payment or delivery shall be made on the next succeeding business day;

F. "Days" shall mean calendar days; "business day" shall mean a weekday (Monday through Friday), excepting State holidays, between the hours of 8:00 a.m. Eastern Standard Time and 5:00 p.m. Eastern Standard Time;

G. Use of the male gender (*e.g.*, "he", "him", "his") shall be construed to include the female gender (*e.g.*, "she", "her"), and vice versa; and

H. Words in the plural which should be singular by context shall be so read, and vice versa.

8.~~11~~12 **Federal Rebate Statute.** This Agreement shall be governed and construed in accordance 42. U.S.C. § 1396r-8 and all other applicable federal and state law and regulations, as may be amended from time to time.

8.~~12~~13 **Use of Trade Names and Trademarks.** No party shall use the registered or claimed mark of another in any type of promotional or advertising material without the express written consent of the other party except that Manufacturer agrees that any Participating Medicaid Program and/or Provider Synergies may use a Manufacturer claimed or registered trade name and/or trademark to communicate the inclusion of a Manufacturer Supplemental Covered Product in a Preferred Drug List to a Participating Medicaid Program's prescribing clinicians, Pharmacies and Medicaid Recipients.

8.~~13~~14 **Severability.** In the event that any provision, term or condition of this Agreement is declared void, unenforceable, or against public policy, then said provision, term or condition shall be construed as though it did not exist and shall not affect the remaining provisions, terms, or conditions of this Agreement, and this Agreement shall be interpreted as far as possible to give effect to the parties' intent.

8.~~14~~15 **Survival of Obligations**. Those obligations under this Agreement that, by their nature, are intended to continue beyond the termination or expiration of this Agreement, shall survive the termination or expiration of this Agreement.

IN WITNESS WHEREOF, Provider Synergies and Manufacturer have caused this Agreement to be executed on the dates shown below by representatives authorized to bind the respective parties. Participating Medicaid Programs have caused this Agreement to be executed on the dates shown in the attached and incorporated TOP$sm Medicaid Program Participation Agreement (Attachment A) ~~and Sample Invoice Form~~ by a representative with actual agency authorization to bind his/her respective Participating Medicaid Program.

	Provider Synergies, L.L.C.
By:	By:
Title:	Title:
Date:	Date:

ATTACHMENT A-DE
TOP$sm MEDICAID PROGRAM PARTICIPATION AGREEMENT
~~AND~~
~~SAMPLE INVOICE FORM~~
FOR
THE STATE OF DELAWARE
DEPARTMENT OF HEALTH AND SOCIAL SERVICES

The State of Delaware acting by and through the Delaware Department of Health and Social Services~~, Address, City, Delaware Zip~~ **(**hereinafter collectively referred to as **"Participating Medicaid Program**"**),** hereby enters into this TOP$sm Medicaid Program Participation Agreement **("Agreement")** effective this ~~1~~st____ day of ~~January 2006~~_____, with [Provider Synergies, L.L.C. or Magellan Medicaid Administration, Inc., as applicable] **("~~Provider Synergies~~ Administrator").**

WHEREAS, the Participating Medicaid Program administers Delaware Medicaid pursuant to ~~Title XIX of~~ the Social Security Act (42 U.S.C. 1396 *et seq*.); and

WHEREAS, ~~Provider Synergies~~ Administrator has negotiated and entered into agreements with prescription drug manufacturers ("**Manufacturers**") to provide discounts and rebates ("**State Supplemental Drug Rebate(s)**") on certain of such Manufacturers' drug products that are covered by the Participating Medicaid Program; and

WHEREAS, the Participating Medicaid Program is authorized to enter into State Supplemental Drug Rebate agreements pursuant to [*Delaware statutory citation for PDL and state supplemental rebate enabling legislation*] and the Code of [*any applicable Delaware regulations*]; and

WHEREAS, the Participating Medicaid Program represents and warrants that it is the intent and expectation of such Participating Medicaid Programs that Supplemental Rebates invoiced hereunder shall be excluded from Manufacturer's calculation of Best Price or AMP.

WHEREAS, the Participating Medicaid Program desires to access State Supplemental Drug Rebates; and

WHEREAS, the Participating Medicaid Program has contracted with ~~**Provider Synergies**~~ Administrator for the provision of State Supplemental Drug Rebate contracting and preferred drug list ("**PDL**") administration services; and

NOW THEREFORE, in consideration of the mutual promises and covenants contained herein, Participating Medicaid Program and ~~**Provider Synergies**~~ Administrator agree as follows:

Definitions

~~"Controlling Agreement" shall mean the contract, between Provider Synergies, as either a prime contractor or a subcontractor, and a Participating Medicaid Program pursuant to which Provider Synergies is obligated to provide State Supplemental Drug Rebate negotiation and contracting services and PDL and pharmacy and therapeutics committee administration services to the Participating Medicaid Program.~~

WHEREAS, "**Controlling Agreement**" shall mean the contract between Administrator, as either a prime contractor or a subcontractor, and a Participating State pursuant to which Administrator 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.

A-1.Obligations of Parties: Participating Medicaid Program hereby agrees to participate in the multi-state State Supplemental Drug Rebate pooling program known as the The Optimal PDL $olution or TOP$[sm]. ~~**Provider Synergies**~~ Administrator agrees to negotiate and enter into State Supplemental Drug Rebate agreements on behalf of Participating Medicaid Program and other state Medicaid agencies who agree to participate in TOP$[sm].

A-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. All telephonic communications between the parties shall be made to the telephone number(s)~~ 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 Medicaid Program:

Delaware Department of Health and Social Services
Pharmacy Program Director
1901 N. DuPont Highway
Main Building
New Castle, DE 19720

Telephone	(302) 255-9040/(302) 744-4700
Telefacsimile	(302) 255-4429

To ~~Provider Synergies~~ Administrator:

Provider Synergies, L.L.C. (c/o Magellan Medicaid Administration, Inc.
~~Attention: Director, Pharmacy Operations~~
~~10101 Alliance Rd.~~
~~Suite 201~~
~~Cincinnati, Ohio 45242~~
Attn: Chief Financial Officer
With a copy to: Legal Department
11013 W. Broad St.
Suite 500
Glen Allen, Virginia 23060-5937

~~Telephone:~~	~~(513) 774-8500~~
~~Telefacsimile:~~	~~(513) 697-5762~~

A-3.Term. This Agreement shall be effective as to Participating Medicaid Program as of the date herein stated above in this Agreement subject to CMS approval and shall continue in effect until ~~June 30, 2010~~ _____ ~~until such time as t~~Thereafter, this Agreement shall automatically renew for successive one (1)-year terms, unless this Agreement is otherwise terminated as provided for this Agreement or until such time as the Controlling Agreement between the Participating Medicaid Program and ~~Provider Synergies~~ Administrator 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 Medicaid Program's Preferred Drug List via website for providers and prescribers, (ii) the applicable Manufacturer Participation Agreement is fully executed and returned to the Manufacturer, or (iii) the effective date of CMS approval of the Participating Medicaid Program's applicable state plan amendment.

A-4.Termination Without Cause by Participating Medicaid Program. Notwithstanding any contrary provision in this Agreement, this Agreement may be terminated by Participating Medicaid Program as to the entirety of Participating

Medicaid Program's participation herein, or as to any Manufacturer Supplemental Covered Product(s) or as to any NDC(s) at the option of Participating Medicaid Program without cause as of the end of the calendar quarter upon thirty (30) days written notice to Provider Synergies (c/o Magellan Medicaid Administration, Inc.). ~~Provider Synergies~~ Administrator will thereupon be obligated to notify Manufacturer of such termination in writing. In the event that Administrator is no longer contracted to provide or administer Preferred Drug List and State Supplemental Rebate services, the Participating Medicaid Program may not disseminate information regarding the State Supplemental Drug Rebates to any nonparties to this Agreement, except as may be required by law or necessary for the reconciliation of State Supplemental Drug Rebate invoices.

A-5.Addition of Participating Medicaid Programs. Any Medicaid program which has the necessary state and CMS approvals to operate a PDL and State Supplemental Drug Rebate program and which is contracted to utilize ~~Provider Synergies~~ Administrator to administer its PDL and State Supplemental Drug Rebate program is eligible to join TOP$sm as a Participating Medicaid Program subject to CMS approval. Upon the expansion or contraction of TOP^{sm}, to either include a state Medicaid agency as a Participating Medicaid Program or exclude a Participating Medicaid Program, ~~Provider Synergies~~ Administrator shall expressly notify in writing all Participating Medicaid Programs as to the identity of the newly included state Medicaid agency or the identity of newly excluded Participating Medicaid Program along with the effective date for such inclusion or exclusion.

A-6.Addition of Participating Medicaid MCOs. To the extent permitted by: (i) CMS, (ii) applicable law, and (iii) the Participating State Medicaid Program's Medicaid Plan, any Participating Medicaid Program added hereunder may elect, but shall not be required, to include Medicaid Utilization from Participating Medicaid MCOs in their Supplemental Rebate invoices, provided that the Participating Medicaid Program provide to Administrator an executed and complete copy of Attachment A-2 indicating such election, well as a copy of the applicable Participating Medicaid Program's Medicaid Plan (and/or amendment thereto) permitting such election. Supplemental Rebates shall begin to accrue to any new Participating Medicaid MCO pursuant to this Agreement for a Supplemental Covered Product upon the later of: (i) Administrator receiving the applicable State's complete and executed Attachment A-2 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 Medicaid Program 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 Agreement and applicable law, the State Medicaid Plan, and the Medicaid Program's contracts with its Medicaid MCOs.

A-~~6~~7.Bankruptcy and Insolvency. Participating Medicaid Program shall have the right to cancel this TOP^{sm} Medicaid Program Participation Agreement immediately without prior notice in the event that Manufacturer is adjudicated bankrupt, or makes an assignment for the benefit of creditors without ~~Provider Synergies~~ Administrator's and the Participating Medicaid Program's prior written consent, which shall not be unreasonably withheld, or in the event that a receiver is appointed for Manufacturer.

A-~~7~~8.Transfer of Manufacturer Supplemental Covered Product(s) to TOP^{sm}. Participating Medicaid Program and P~~rovider Synergies~~ Administrator agree that Participating Medicaid Program will realize optimal savings if the Supplemental Covered Products listed on current State Supplemental Drug Rebate agreement(s) between Participating Medicaid Program and Manufacturer are transferred to this Agreement within one (1) year.

~~**A-8 Sample Invoice Form.** A sample invoice form labeled as TOP$sm Sample Invoice Form (Attachment A-DE) is attached and incorporated herein.~~

IN WITNESS WHEREOF, the Participating Medicaid Program and ~~Provider Synergies~~ Administrator have caused this Agreement to be executed on the dates shown below by representatives authorized to bind the respective parties.

~~PROVIDER SYNERGIES, L.L.C.~~ ADMINISTRATOR	DELAWARE DEPARTMENT OF HEALTH AND SOCIAL SERVICES
By:	By:
Title:	Title:
Date:	Date:

~~ATTACHMENT A-DE~~
~~TOP$sm SAMPLE INVOICE FORM~~
~~State of Delaware~~

~~Delaware Department of Health and Social Services~~

~~MANUFACTURER: XYZ PHARMACEUTICALS STATE CODE:DEInvoice #: 2003-1-00001~~
~~ADDRESS 1: 123 MAIN ST~~
~~PERIOD COVERED: 1st QUARTER 2003~~
~~ADDRESS 2: ROOM 100~~
~~ADDRESS 3:~~
~~CITY: ANYTOWNSTATE:STZIP:12345~~

~~NDC NUMBER~~	~~DRUG NAME~~	~~REBATE AMT PER UNIT~~	~~TOTAL UNITS REIMB~~	~~TOTAL REBATE CLAIMED~~	~~NO OF SCRIPTS~~	~~TOTAL REIMB AMOUNT~~	~~CORR COV~~	~~QTR FLAG~~
~~00000007231~~	~~PLACEBO ON~~	~~$0.121651~~	~~5,810.000~~	~~$706.79~~	~~194~~	~~$ 13,386.06~~	~~0~~	~~20031~~
~~00000007228~~	~~PLACEBO ON~~	~~$0.121651~~	~~2,508.000~~	~~$305.10~~	~~88~~	~~$ 5,958.38~~	~~0~~	~~20031~~
~~00000003144~~	~~PLACEBO ON~~	~~$0.000000~~	~~13,316.000~~	~~$0.00~~	~~3,327~~	~~$203,903.37~~	~~0~~	~~20031~~
~~00000003121~~	~~PLACEBO ON~~	~~$0.000000~~	~~844.000~~	~~$0.00~~	~~181~~	~~$ 12,041.83~~	~~0~~	~~20031~~
~~Totals:~~			~~22,478.000~~	~~$1,011.89~~	~~3,790~~	~~$235,289.64~~		

~~PLEASE REMIT THIS AMOUNT TO:~~
~~DELAWARE DEPARTMENT OF HEALTH AND SOCIAL SERVICES~~
~~SUPPLEMENTAL DRUG REBATE PROGRAM~~
~~P.O. BOX XXXXX~~
~~CITY, DE XXXX~~

ATTACHMENT A-1

☐ ***RESERVED***

ATTACHMENT A-2
ATTESTATION OF INCLUSION/EXCLUSION OF MEDICAID MCOS

The State of _____ acting by and through the _____ (hereinafter collectively referred to as **"Participating Medicaid Program"**), 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 Medicaid Program will include utilization of Participating Medicaid MCO(s) for State Supplemental Drug Rebates under this Agreement. I certify on behalf of the Participating Medicaid Program listed below that the State Medicaid Plan permits the inclusion of Medicaid MCO utilization in State Supplemental Drug Rebates, and that the State's contracts with Participating MCOs do not prohibit such inclusion. I further certify on behalf of the Participating Medicaid Program listed below that the State has reasonably determined that: (i) the utilization of any Participating Medicaid MCO submitted hereunder is eligible for National 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 Participating Medicaid Program Medicaid PDL, for any period with respect to which the Participating Medicaid Program 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 Medicaid Program's Medicaid Plan (and/or amendment thereto) permitting the election of this option.

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

The Participating Medicaid Program has no Medicaid MCOs.

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

So Certified:

State Participating Medicaid Program:

By: _____

Title: _____

Date: _____

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

ATTACHMENT B
TOP$sm MULTISTATE SUPPLEMENTAL DRUG REBATE FORMULAE
FOR
(Manufacturer)

B.1.Addition of Participating Medicaid Program. Manufacturer and Provider Synergies agree that a Participating Medicaid Program may access the TOP$sm State Supplemental Rebate pricing contained in Table 1.0 Manufacturer Supplemental Covered product State Supplemental Drug Rebate Formulae for TOP$sm of this Attachment via the execution of a TOP$sm Medicaid Program Participation Agreement (Attachment A) ~~and that such addition of such Participating Medicaid Program may serve to increase the State Supplemental Rebate amounts payable to the Participating Medicaid Programs~~.

B.2.Subtraction of Participating Medicaid Program. The termination of a TOP$sm Participating Medicaid Program Participation Agreement (Attachment A) ~~may operate so as to reduce the amount of a State Supplemental Rebate amount due to Participating Medicaid Programs pursuant to Table 1.0 Manufacturer Product Supplemental Drug Rebate Formulae for TOP$sm, but~~ shall not operate so as to terminate this Agreement or otherwise affect the obligations of Manufacturer and/or Provider Synergies to any remaining Participating Medicaid Program(s) pursuant to this Agreement.

B.3.Absence of National Rebate for Supplemental Covered Product. In the event that a Supplemental Covered Product is not subject to either a National Rebate or a separate agreement between Manufacturer and a Participating Medicaid Program that requires payment of a rebate amount equivalent to the National Rebate, for purposes of this Agreement, the National Rebate shall be deemed to be zero ($0) dollars per unit for each such Supplemental Covered Product and all discounts calculated in accordance with Attachment B hereto shall be calculated as State Supplemental Rebates.

Table 1.0 – Manufacturer Product Supplemental ~~Drug~~ Covered Product Rebate Formulae for TOP$sm

~~Label Name~~	~~NDC~~	~~Position~~	~~1 to 3 States GNUP~~	~~4 to 6 States GNUP~~	~~7 to 9 States GNUP~~	~~10+ States GNUP~~

~~Supplemental Rebates shall be calculated according to the following formulae:~~

~~State Supplemental Rebate = (SRPU) x number of Units paid for by Participating Medicaid Program during the Fiscal Quarter.~~

~~State Supplemental Rebate Per Unit (SRPU) = WAC- National Rebate per Unit - Guaranteed Net Unit Price.~~

~~Positioning: For [Insert Product Name] and associated NDCs, the following terms shall apply:~~

~~Position 1: [Insert detailed description of positioning offer from Manufacturer]~~
~~Position 2: [Insert detailed description of positioning offer from Manufacturer]~~
~~Position 3: [Insert detailed description of positioning offer from Manufacturer]~~State

LABEL NAME	NDC	POSITION	CALC TYPE	DISCOUNT PER UNIT

State Supplemental Rebate = Supplemental Rebate Per Unit (SRPU) x Medicaid Utilization during the Quarter.

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 within its therapeutic class.

SRPU shall be calculated according to the following formulae, as applicable:

1. **WAC Based GNUP**: SRPU = WAC per Unit minus CMS Unit Rebate Amount minus Discount Per Unit.

OR

2. **Alternative Calculation Type ['CALCULATION TYPE']** (if different than WAC Based GNUP defined above): SRPU = **[FORMULA]**

Manufacturer will pay Supplemental Rebates on Supplemental Covered Products associated with their Supplemental Covered Product's(s') position held from the first day in which the PDL was in effect for the Participating Medicaid Program 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 product position shall be determined by the number of Supplemental Covered Products during the majority of the preferred period. By way of example: in 1st 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 2nd 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 3rd 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 all 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).

Positioning: For [*Insert Supplemental Covered Product Name*] and associated NDCs, the following terms shall apply:

Position 1: [*Insert detailed description of positioning offer from Manufacturer*]
Position 2: [*Insert detailed description of positioning offer from Manufacturer*]
Position 3: [*Insert detailed description of positioning offer from Manufacturer*]

ATTACHMENT C
CATALOGUE OF TOP$sm PARTICIPATING MEDICAID PROGRAMS

The Participating Medicaid Programs participating in TOP^{sm} are summarized in Table C-1 Catalogue of TOP^{sm} Participating Medicaid Programs.

~~Table C-1 Catalogue of TOPS^{sm} Participating Medicaid Programs~~

	~~TOPS^{sm} Participation (Yes) r No)~~

~~State~~	~~Title XIX Medicaid Program~~
~~Delaware~~	~~Yes~~
~~Idaho~~	~~Yes~~
~~Louisiana~~	~~Yes~~
~~Maryland~~	~~Yes~~
~~Nebraska~~	~~Yes~~
~~Pennsylvania~~	~~Yes~~
~~Wisconsin~~	~~Yes~~

Table C-1 Catalogue of TOP$[sm] Programs

Connecticut
Delaware
Idaho
Louisiana
Maryland
Nebraska
Pennsylvania
Wisconsin

This Attachment will be updated in accordance with Section 5.2 of the Agreement.

17 DE Reg. 285 (09/01/13) (Prop.)