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State/Territory Name: Washington

State Plan Amendment (SPA) #: 17-0007

This file contains the following documents in the order listed:

- 1) Supplemental Letter
- 2) Approval Letter
- 3) CMS 179 Form
- 4) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Seattle Regional Office
701 Fifth Avenue, Suite 1600, MS/RX-200
Seattle, WA 98104



Division of Medicaid & Children's Health Operations

March 19, 2018

Susan Birch, Director
Health Care Authority
PO Box 45502
Olympia, WA 98504-5010

RE: Revised Washington State Plan Amendment (SPA) Approval Package (Transmittal Number 17-0007)

Dear Ms. Birch:

This letter and the enclosed SPA approval package replaces the documents issued on March 2, 2018, by the Centers for Medicare & Medicaid Services' Division of Pharmacy and the Seattle Regional Office. The approved amendment implements Washington's participation in the multi-state program under the Optimal PDL Solution (TOP\$) supplement drug rebate agreement and includes Managed Care Organizations (MCO) utilization for accrual of supplemental rebates. The March 2, 2018, approval package reflected the state's originally requested October 1, 2017, effective date.

The revised SPA approval package contains technical corrections to update the 179, Attachment 3.1A (page 31), Attachment 3.1B (page 31), and the approved TOP\$ rebate template, to correct the effective date from October 1, 2017, to January 1, 2018, per the state's March 14, 2018, request. This SPA is approved with the new effective January 1, 2018. Enclosed is a copy of the CMS-179 summary form, as well as the approved pages with technical corrections for incorporation into the Washington State Plan.

If there are any questions concerning this approval, please contact me or your staff may contact Maria Garza at maria.garza@cms.hhs.gov or at (206) 615-2542.

Sincerely,

A black rectangular redaction box covering the signature of David L. Meacham.

David L. Meacham
Associate Regional Administrator

Enclosure

Page 2 –

cc:

Ann Myers, HCA

MaryAnne Lindeblad, Medicaid Director



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

March 15, 2018

Susan Birch, Director
MaryAnne Lindeblad, Medicaid Director
Health Care Authority
PO Box 45502
Olympia, WA 98504-5010

Dear Ms. Birch and Ms. Lindeblad:

This approval letter replaces the letter issued on March 2, 2018. We have reviewed Washington State Plan Amendment (SPA) 17-0007, Supplemental Rebate Program and New TOP\$ Supplemental Rebate Agreement Template, received in the Seattle Regional Office on December 13, 2017. Under this SPA, Washington is proposing to participate in The Optimal PDL Solution (TOP\$), a multi-state pooling supplemental rebate agreement. The state is proposing to include Medicaid Managed Care Organization (MCO) utilization for accrual of supplemental rebates.

This revised approval letter is a technical correction to correct the effective date per the state's request. This amendment is approved, with the new January 1, 2018 effective date. A copy of the CMS-179 form, as well as the pages approved for incorporation into the Washington state plan, will be forwarded by the Seattle Regional Office.

If you have any questions regarding this amendment, please contact Terry Simananda at (410) 786-8144.

Sincerely,

/s/

John M. Coster, Ph.D., R.Ph.
Director
Division of Pharmacy

cc: David Meacham, ARA, Seattle Regional Office
Maria Garza, Seattle Regional Office
Ann Myers, State of Washington, Health Care Authority

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

FOR: HEALTH CARE FINANCING ADMINISTRATION

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

**1. TRANSMITTAL NUMBER:
17-0007**

**2. STATE
Washington**

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

**4. PROPOSED EFFECTIVE DATE
~~October 1, 2017~~ January 1, 2018 (P&I)**

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 Social Security Act; 42 USC 1396r-8

7. FEDERAL BUDGET IMPACT:
a. FFY 2018 \$(18,823,970)
b. FFY 2019 \$(26,014,054)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment 3.1-A page 31
Attachment 3.1-B page 31
TOP\$ Supplemental Rebate Agreement Template Associated with
Supplement A to Att. 4.19-B (new)

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

Attachment 3.1-A page 31
Attachment 3.1-B page 31

10. SUBJECT OF AMENDMENT

Supplemental Rebate Program and New TOP\$ Supplemental Rebate Agreement Template

11. GOVERNOR'S REVIEW (Check One):

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT ☒ OTHER, AS SPECIFIED: Exempt
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME:
MARYANNE LINDEBLAD

14. TITLE:
MEDICAID DIRECTOR

15. DATE SUBMITTED:

12-12-17

16. RETURN TO:

Ann Myers
Office of Rules and Publications
Division of Legal Services
Health Care Authority
626 8th Ave SE MS: 42716
Olympia, WA 98504-2716

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:
12/13/17

18. DATE APPROVED:
3/2/18

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:
1/1/18

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:
David L. Meacham

22. TITLE:
Associate Regional Administrator

23. REMARKS:

3/14/18: State authorized P&I change to box 4

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State WASHINGTONAMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL
CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

12. a. Prescribed drugs (continued)

Supplemental Rebate Program

- (7) The state is in compliance with Section 1927 of the Act. Based on the requirements for Section 1927 of the Act, the state has the following policies for the supplemental rebate program for Medicaid recipients:
- a) All covered drugs of federal participating manufacturers remain available to the Medicaid program but may require prior authorization.
 - b) The current state supplemental rebate agreement between the state and a drug manufacturer for drugs provided to Medicaid recipients, submitted to CMS on July 15, 2008, and entitled "State of Washington Supplemental Rebate Contract" has been authorized by CMS remains in effect.
 - c) The state will continue the ability to have state-specific supplemental rebates and will also participate in a multi-state pooling program that will negotiate supplemental rebates in addition to federal rebates provided for in Title XIX. This multi-state pooling program is known as TOP\$sm The Optimal PDL \$olution (TOP\$). TOP\$ rebates will be separate from federal rebates.
 - d) A TOP\$ rebate agreement, submitted to CMS on December 13, 2017, for drugs provided to the Medicaid program has been authorized by CMS.
 - e) TOP\$ supplemental rebate agreements would apply to the drug benefit, both fee-for-service and those paid by contracted managed care organizations (MCOs), under prescribed conditions in Attachment A-2 to the TOP\$ Supplemental Rebate Agreement.
 - f) Supplemental rebates received by the state in excess of those required under the federal drug rebate agreement will be shared with the federal government on the same percentage basis as applied under the federal rebate agreement. The non-federal share of supplemental rebates received by the state will not be subject to the increased offset described in the Affordable Care Act.
 - g) The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification, in accordance with Section 1927(b)(3)(D).
 - h) Rebates paid under the CMS-authorized TOP\$sm agreement for Washington State Medicaid population do not affect AMP or best price under the Medicaid program.
 - i) The CMS-authorized TOP\$sm agreement for the Washington State Medicaid population only provides supplemental rebates for Medicaid programs eligible for federal rebates. It does not cover non-Medicaid programs.
 - j) Pharmaceutical manufacturers are allowed to audit utilization rates.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State WASHINGTONAMOUNT, DURATION, AND SCOPE OF SERVICES PROVIDED TO THE
MEDICALLY NEEDY GROUP(S): ALL

12. a. Prescribed drugs (cont.)

Supplemental Rebate Program

- (7) The state is in compliance with Section 1927 of the Act. Based on the requirements for Section 1927 of the Act, the state has the following policies for the supplemental rebate program for Medicaid recipients:
- a) All covered drugs of federal participating manufacturers remain available to the Medicaid program but may require prior authorization.
 - b) The current state supplemental rebate agreement between the state and a drug manufacturer for drugs provided to Medicaid recipients, submitted to CMS on July 15, 2008, and entitled "State of Washington Supplemental Rebate Contract" has been authorized by CMS remains in effect.
 - c) The state will continue the ability to have state-specific supplemental rebates and will also participate in a multi-state pooling program that will negotiate supplemental rebates in addition to federal rebates provided for in Title XIX. This multi-state pooling program is known as TOP\$sm The Optimal PDL \$olution (TOP\$). TOP\$ rebates will be separate from federal rebates.
 - d) A TOP\$ rebate agreement, submitted to CMS on December 13, 2017, for drugs provided to the Medicaid program has been authorized by CMS.
 - e) TOP\$ supplemental rebate agreements would apply to the drug benefit, both fee-for-service and those paid by contracted managed care organizations (MCOs), under prescribed conditions in Attachment A-2 to the TOP\$ Supplemental Rebate Agreement.
 - f) Supplemental rebates received by the state in excess of those required under the federal drug rebate agreement will be shared with the federal government on the same percentage basis as applied under the federal rebate agreement. The non-federal share of supplemental rebates received by the state will not be subject to the increased offset described in the Affordable Care Act.
 - g) The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification, in accordance with Section 1927(b)(3)(D).
 - h) Rebates paid under the CMS-authorized TOP\$sm agreement for Washington State Medicaid population do not affect AMP or best price under the Medicaid program.
 - i) The CMS-authorized TOP\$sm agreement for the Washington State Medicaid population only provides supplemental rebates for Medicaid programs eligible for federal rebates. It does not cover non-Medicaid programs.
 - j) Pharmaceutical manufacturers are allowed to audit utilization rates.

ATTACHMENT A-WA
TOP\$SM MEDICAID PROGRAM PARTICIPATION AGREEMENT
FOR
WASHINGTON STATE HEALTH CARE AUTHORITY

The State of Washington acting by and through the Washington State Health Care Authority, 626 8th Ave. SE, Olympia, WA 98501, hereinafter collectively referred to as "**Participating Medicaid Program**", hereby enters into this TOP\$SM Medicaid Program Participation Agreement ("**Agreement**") effective this 1st day of October, 2017, with Provider Synergies, L.L.C. ("**Administrator**").

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

WHEREAS, 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 Washington Administrative Code (WAC) 182-530-7500 and Revised Code of Washington (RCW) 41.05.021 and 41.05.160 and Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700, WSR 07-20-049, and WAC 388-530-7500; 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 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 Administrator agree as follows:

Definitions

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. 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. 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:

Washington State Health Care Authority
Prescription Drug Program
626 8th Ave SE
PO Box 45502
Olympia, WA 98504-5502
Telephone 360-725-1564
Telefacsimile 360-586-9551

To Administrator:

Provider Synergies, L.L.C.
Attention: Chief Financial Officer
With a copy to: Legal Department
11013 W. Broad St.
Suite 500
Glen Allen, Virginia 23060-5937

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 authorization and shall continue in effect until September 30, 2018. Thereafter, this Agreement shall automatically renew for successive one (1)-year terms, unless this Agreement is otherwise terminated as provided for in this Agreement or until such time as the Controlling Agreement between the Participating Medicaid Program and 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

Administrator. 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 authorizations to operate a PDL and State Supplemental Drug Rebate program and which is contracted to utilize 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 authorization. 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, 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, as 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-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 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-8. Transfer of Manufacturer Supplemental Covered Product(s) to TOP\$SM. Participating Medicaid Program and 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.

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

Administrator

By: _____

Gregory Kaupp

Title: SVP, Market General Manager

Date: _____

Washington State Health Care Authority

By: _____

Melanie Anderson

Title: Contracts Administrator

Date: _____

ATTACHMENT A-1

RESERVED

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

The State of Washington acting by and through the Washington State Health Care Authority (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 for:

☐ all preferred Supplemental Covered Products, OR

☐ limited to the following Supplemental Covered Product(s) or Product Category(ies):

1. _____
2. _____

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 MCOs 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: **Washington State Health Care Authority**

By: _____

Jim Gayton

Title: Contracts Administrator

Date: _____

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