

CC: John Leberg/  
Karla Knuth-

Department of Health & Human Services  
Centers for Medicare & Medicaid Services  
26 Federal Plaza, Room 37-100 North  
New York, NY 10278



November 12, 2013

Jason A. Helgeson  
Medicaid Director & Deputy Commissioner  
New York State Department of Health  
Corning Tower  
Empire State Plaza  
Albany, NY 12237

RECEIVED

JAN 10 2014

NYS DOH-OFFICE OF  
HEALTH INSURANCE PROGRAMS

M-10

Dear Mr. Helgeson:

We have received a copy of Larry Reed's letter to you, in which he notified you of the approval of New York's State Plan Amendment (SPA) 13-29. This SPA revises the National Medicaid Pooling Initiative (NMPI) Supplemental Rebate Agreement (SRA) previously submitted to CMS on March 20, 2008 to include definitions and structural changes that would provide the option of including Medicaid managed care utilization for accrual of supplemental rebates.

Mr. Reed advised you that the New York Regional Office would forward you the signed CMS-179 form as well as copies of the approved pages. These documents are enclosed. The revised pages of Attachment 3.1-A Supplement, pages 2(b) & 2(b.1), and Attachment 3.1-B Supplement, pages 2 (b) & 2 (b.1) submitted to us on June 24, 2013 have replaced the corresponding pages that was included in the State's original SPA submission package.

Please note the approval date of the SPA is November 12, 2013 and the effective date is April 1, 2013.

If you have any questions, please contact Ivelisse Salce at (212) 616-2411

Sincerely,

A handwritten signature in blue ink, appearing to read 'Michael Melendez', is written over the word 'Sincerely,'.

Michael Melendez  
Associate Regional Administrator  
Division of Medicaid and Children's Health

Cc: Delaine Deardorff-Beck

<b>TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL</b>  <b>FOR: HEALTH CARE FINANCING ADMINISTRATION</b>		1. TRANSMITTAL NUMBER: <b>13-29</b>	2. STATE <b>New York</b>
		3. PROGRAM IDENTIFICATION: <b>TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)</b>	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES		4. PROPOSED EFFECTIVE DATE <b>April 1, 2013</b>	
5. TYPE OF PLAN MATERIAL ( <i>Check One</i> ):  <input type="checkbox"/> NEW STATE PLAN <input type="checkbox"/> AMENDMENT TO BE CONSIDERED AS NEW PLAN <input checked="" type="checkbox"/> AMENDMENT COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT ( <i>Separate Transmittal for each amendment</i> )			
6. FEDERAL STATUTE/REGULATION CITATION: <b>§1902 of the Social Security Act, and 42 CFR 447</b>		7. FEDERAL BUDGET IMPACT: a. FFY 08/01/13-09/30/13 \$ 0 b. FFY 10/01/13-09/30/14 \$ 0	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:  <b>Attachment 3.1-A Supplement: Page 2(b), 2(b.1)</b> <b>Attachment 3.1-B Supplement: Page 2(b), 2(b.1)</b>  <b>**Please see remarks</b>		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT ( <i>If Applicable</i> ):  <b>Attachment 3.1-A Supplement: Page 2(b)</b> <b>Attachment 3.1-B Supplement: Page 2(b)</b>	
10. SUBJECT OF AMENDMENT: <b>Supplemental Rebate Program (FMAP = 50%)</b>			
11. GOVERNOR'S REVIEW ( <i>Check One</i> ): <input checked="" type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="checkbox"/> OTHER, AS SPECIFIED: <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
12. SIGNATURE OF STATE AGENCY OFFICIAL:		16. RETURN TO: <b>New York State Department of Health Bureau of Federal Relations &amp; Provider Assessments 99 Washington Ave – One Commerce Plaza Suite 810 Albany, NY 12210</b>	
13. TYPED NAME: <b>Jason A. Helgerson</b>			
14. TITLE: <b>Medicaid Director Department of Health</b>			
15. DATE SUBMITTED: <b>June 24, 2013</b>			
<b>FOR REGIONAL OFFICE USE ONLY</b>			
17. DATE RECEIVED:		18. DATE APPROVED: <b>November 12, 2013</b>	
<b>PLAN APPROVED – ONE COPY ATTACHED</b>			
19. EFFECTIVE DATE OF APPROVED MATERIAL: <b>April 01, 2013</b>		20. SIGNATURE OF REGIONAL OFFICIAL:	
21. TYPED NAME: <b>Michael Melendez</b>		22. TITLE: <b>Associate Regional Administrator Division of Medicaid and State Operations</b>	
23. REMARKS:  <b>**This amendment proposes to revise the National Medicaid Pooling Initiative (NMPI) Supplemental Rebate Agreement (SRA) including definitions and structural changes that would provide the option of including Medicaid managed care utilization for accrual of supplemental rebates.</b>			



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2(b.1)**

- c) The prior authorization process complies with the requirements of Section 1927 of the Social Security Act and provides for a 24-hour turn-around response by either telephone or telecommunications device from the receipt of a prior authorization request. In emergency situations, providers may dispense a 72-hour supply of medications.
  - d) The terms of the supplemental rebate programs apply only to covered outpatient drugs for which the State is eligible for federal financial participation. Supplemental rebates received by the State in excess of those required under the National Drug Rebate Program will be shared with the Federal Government on the same percentage basis as applied under the National Drug Rebate Agreement.
  - e) Any Supplemental Rebate Agreement not authorized by CMS will be submitted to CMS for authorization.
  - f) All drugs covered by the programs will comply with the provisions of the national drug rebate agreement.
3. Any changes to the NMPI Supplemental Rebate Agreement must be submitted to CMS for authorization. Any changes to the State-specific Supplemental Rebate Agreement NY State holds directly with the manufacturer must be submitted to CMS for authorization.
  4. As provided by the Act, a new drug manufactured by a company which has entered into a rebate agreement may be covered subject to prior approval, unless the drug is subject to the allowable exclusion categories provided by the Act.
  5. As specified in Section 1927(b)(3)(D) of the Act, notwithstanding any other provisions of law, rebate information disclosed by a manufacturer shall not be disclosed by the state for purposes other than rebate invoicing and verification.

**TN#:** 13-29      **Approval Date:** NOV 12 2013  
**Supersedes TN#:** NEW      **Effective Date:** APR 01 2013

**NEW**

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2(b)**

12a. Prior authorization or dispensing validation is required for some prescription drugs. The State has established a preferred drug program with prior authorization for drugs not included on the preferred drug list. The prior authorization complies with the requirements of Section 1927(d)(5) of the Social Security Act and provides for a 24-hour turnaround by either telephone or other telecommunications device from receipt of request and provides for a 72-hour supply of drugs in emergency circumstances. In addition, brand-name drugs that have a FDA approved, A-rated generic equivalent must be prior authorized unless exempted by the Commissioner of Health. Prior authorization is required for a generic equivalent of a brand name drug, including a generic equivalent that is on the preferred drug list or the clinical drug review program, when the net cost of the brand name drug, after consideration of all rebates, is less than the cost of the generic equivalent.

Drugs for which Medical Assistance reimbursement is available are limited to the following:

1. Outpatient drugs of any manufacturer which has entered into and complies with a rebate agreement under Sections 1902(a)(54) and 1927(a) of the Act with the Centers for Medicare and Medicaid Services (CMS) which are prescribed for a medically accepted indication. All drugs covered by the National Drug Rebate Agreements remain available to Medicaid beneficiaries, although some may require prior authorization. Drugs for the treatment of erectile dysfunction, as set forth in 42 U.S.C. §1396r-8(d)(2)(K), are not a covered service, on and after April 1, 2006, unless such drugs are used to treat conditions other than sexual or erectile dysfunction and these uses have been approved by the Food and Drug Administration.
2. Supplemental Rebate Programs

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

- a) CMS has authorized the State of New York to enter into the National Medicaid Pooling Initiative (NMPI) for drugs provided to Medicaid beneficiaries. The NMPI Supplemental Rebate Agreement (SRA) and the Amendment to the SRA submitted to CMS on March 30, 2006 have been authorized for pharmaceutical manufacturers' existing agreements through their current expiration dates. The updated NMPI SRA submitted to CMS on June 30, 2013 has been authorized for renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid beneficiaries.
- b) CMS has authorized the State of New York to enter into Medicaid State-specific Supplemental Rebate Agreement directly with manufacturers to receive supplemental rebates of covered outpatient drugs for Medicaid beneficiaries. The State-specific Supplemental Rebate Agreement was submitted to CMS on March 31, 2010 and has been authorized by CMS.

**TN#:** 13-29

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**New York  
2(b.1)**

- c) The prior authorization process complies with the requirements of Section 1927 of the Social Security Act and provides for a 24-hour turn-around response by either telephone or telecommunications device from the receipt of a prior authorization request. In emergency situations, providers may dispense a 72-hour supply of medications.
  - d) The terms of the supplemental rebate programs apply only to covered outpatient drugs for which the State is eligible for federal financial participation. Supplemental rebates received by the State in excess of those required under the National Drug Rebate Program will be shared with the Federal Government on the same percentage basis as applied under the National Drug Rebate Agreement.
  - e) Any Supplemental Rebate Agreement not authorized by CMS will be submitted to CMS for authorization.
  - f) All drugs covered by the programs will comply with the provisions of the national drug rebate agreement.
3. Any changes to the NMPI Supplemental Rebate Agreement must be submitted to CMS for authorization. Any changes to the State-specific Supplemental Rebate Agreement NY State holds directly with the manufacturer must be submitted to CMS for authorization.
  4. As provided by the Act, a new drug manufactured by a company which has entered into a rebate agreement may be covered subject to prior approval, unless the drug is subject to the allowable exclusion categories provided by the Act.
  5. As specified in Section 1927(b)(3)(D) of the Act, notwithstanding any other provisions of law, rebate information disclosed by a manufacturer shall not be disclosed by the state for purposes other than rebate invoicing and verification.

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**Supersedes TN#:** NEW **Effective Date:** APR 01 2013

**New**