NEW YORK
state department of
HEALTH

Nirav R. Shah, M.D., M.P.H.
Commissioner

Sue Kelly
Executive Deputy Commissioner

June 24, 2013

Mr. Michael Melendez
Associate Regional Administrator
Department of Health & Human Services
Centers for Medicare & Medicaid Services
New York Regional Office
Division of Medicaid and Children's Health Operations
26 Federal Plaza - Room 37-100 North
New York, New York 10278

RE: SPA #13-29
Non-Institutional Services

Dear Mr. Melendez:

The State requests approval of the enclosed amendment #13-29 to the Title XIX (Medicaid) State Plan for non-institutional services to be effective April 1, 2013 (Appendix I). This amendment is being submitted based on enacted legislation. A summary of the plan amendment is provided in Appendix II.

The State of New York reimburses these services through the use of rates that are consistent with and promote efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area as required by §1902(a)(30) of the Social Security Act and 42 CFR §447.204.

Copies of pertinent sections of enacted State statute are enclosed for your information (Appendix III).

If you have any questions regarding this State Plan submission, please do not hesitate to contact John E. Ulberg, Jr., Medicaid Chief Financial Officer, Division of Finance and Rate Setting at (518) 474-6350.

Sincerely,

Jason A. Helgerson
Medicaid Director
Office of Health Insurance Programs

Enclosures

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: HEALTH CARE FINANCING ADMINISTRATION	1. TRANSMITTAL NUMBER: **13-29**	2. STATE **New York**
	3. PROGRAM IDENTIFICATION: **TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)**	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE **April 1, 2013**	

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

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

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

6. FEDERAL STATUTE/REGULATION CITATION: **§1902 of the Social Security Act, and 42 CFR 447**	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: **Attachment 3.1-A Supplement: Page 2(b), 2(b.1)** **Attachment 3.1-B Supplement: Page 2(b), 2(b.1)**	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: **Attachment 3.1-A Supplement: Page 2(b)** **Attachment 3.1-B Supplement: Page 2(b)**

10. SUBJECT OF AMENDMENT:
Supplemental Rebate Program
(FMAP = 50%)

11. GOVERNOR'S REVIEW *(Check One)*:
☒ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:	16. RETURN TO: **New York State Department of Health** **Bureau of Federal Relations & Provider Assessments** **99 Washington Ave – One Commerce Plaza** **Suite 810** **Albany, NY 12210**
13. TYPED NAME: **Jason A. Helgerson**	
14. TITLE: **Medicaid Director** **Department of Health**	
15. DATE SUBMITTED: June 24, 2013	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:	18. DATE APPROVED:
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL:	20. SIGNATURE OF REGIONAL OFFICIAL:
21. TYPED NAME:	22. TITLE:

23. REMARKS:

Appendix I
2013 Title XIX State Plan
Second Quarter Amendment
Non-Institutional Services
Amended SPA Pages

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.

New York
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 [March 20, 2008] 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.

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.

Appendix II
2013 Title XIX State Plan
Second Quarter Amendment
Non-Institutional Services
Summary

SUMMARY
SPA #13-29

This State Plan Amendment proposes to extend the existing National Medicaid Pooling initiative (NMPI) Supplemental Rebate Agreements through June 30, 2013.

Appendix III
2013 Title XIX State Plan
Second Quarter Amendment
Non-Institutional Services
Authorizing Provisions

SPA 13-29

Public Health Law

§ 272. Preferred drug program. 1. There is hereby established a preferred drug program to promote access to the most effective prescription drugs while reducing the cost of prescription drugs for persons in state public health plans.

2. When a prescriber prescribes a non-preferred drug, state public health plan reimbursement shall be denied unless prior authorization is obtained, unless no prior authorization is required under this article.

3. The commissioner shall establish performance standards for the program that, at a minimum, ensure that the preferred drug program and the clinical drug review program provide sufficient technical support and timely responses to consumers, prescribers and pharmacists.

4. Notwithstanding any other provision of law to the contrary, no preferred drug program or prior authorization requirement for prescription drugs, except as created by this article, paragraph (a-1) or (a-2) of subdivision four of section three hundred sixty-five-a of the social services law, paragraph (g) of subdivision two of section three hundred sixty-five-a of the social services law, subdivision one of section two hundred forty-one of the elder law and shall apply to the state public health plans.

5. The drug utilization review board shall consider and make recommendations to the commissioner for the adoption of a preferred drug program. (a) In developing the preferred drug program, the board shall, without limitation: (i) identify therapeutic classes or drugs to be included in the preferred drug program; (ii) identify preferred drugs in each of the chosen therapeutic classes; (iii) evaluate the clinical effectiveness and safety of drugs considering the latest peer-reviewed research and may consider studies submitted to the federal food and drug administration in connection with its drug approval system; (iv) consider the potential impact on patient care and the potential fiscal impact that may result from making such a therapeutic class subject to prior authorization; and (v) consider the potential impact of the preferred drug program on the health of special populations such as children, the elderly, the chronically ill, persons with HIV/AIDS and persons with mental health conditions.

(b) In developing the preferred drug program, the board may consider preferred drug programs or evidence based research operated or conducted by or for other state governments, the federal government, or multi-state coalitions. Notwithstanding any inconsistent provision of section one hundred twelve or article eleven of the state finance law or section one hundred forty-two of the economic development law or any other law, the department may enter into contractual agreements with the Oregon Health and Science University Drug Effectiveness Review Project to provide technical and clinical support to the board and the department in researching and recommending drugs to be placed on the preferred drug list.

(c) The board shall from time to time review all therapeutic classes included in the preferred drug program, and may recommend that the commissioner add or delete drugs or classes of drugs to or from the preferred drug program, subject to this subdivision.

(d) The board shall establish procedures to promptly review prescription drugs newly approved by the federal food and drug administration.

6. The board shall recommend a procedure and criteria for the approval of non-preferred drugs as part of the prior authorization process. In developing these criteria, the board shall include consideration of the following:

(a) the preferred drug has been tried by the patient and has failed to produce the desired health outcomes;

(b) the patient has tried the preferred drug and has experienced unacceptable side effects;

(c) the patient has been stabilized on a non-preferred drug and transition to the preferred drug would be medically contraindicated; and

(d) other clinical indications for the use of the non-preferred drug, which shall include consideration of the medical needs of special populations, including children, the elderly, the chronically ill, persons with mental health conditions, and persons affected by HIV/AIDS.

7. The commissioner shall provide thirty days public notice on the department's website prior to any meeting of the board to develop recommendations concerning the preferred drug program. Such notice regarding meetings of the board shall include a description of the proposed therapeutic class to be reviewed, a listing of drug products in the therapeutic class, and the proposals to be considered by the board. The board shall allow interested parties a reasonable opportunity to make an oral presentation to the board related to the prior authorization of the therapeutic class to be reviewed. The board shall consider any information provided by any interested party, including, but not limited to, prescribers, dispensers, patients, consumers and manufacturers of the drug in developing their recommendations.

8. The commissioner shall provide notice of any recommendations developed by the board regarding the preferred drug program, at least five days before any final determination by the commissioner, by making such information available on the department's website. Such public notice may include: a summary of the deliberations of the board; a summary of the positions of those making public comments at meetings of the board; the response of the board to those comments, if any; and the findings and recommendations of the board.

9. Within ten days of a final determination regarding the preferred drug program, the commissioner shall provide public notice on the department's website of such determinations, including: the nature of the determination; and analysis of the impact of the commissioner's determination on state public health plan populations and providers; and the projected fiscal impact to the state public health plan programs of the commissioner's determination.

10. The commissioner shall adopt a preferred drug program and amendments after considering the recommendations from the board and any comments received from prescribers, dispensers, patients, consumers and manufacturers of the drug.

(a) The preferred drug list in any therapeutic class included in the preferred drug program shall be developed based initially on an evaluation of the clinical effectiveness, safety and patient outcomes, followed by consideration of the cost-effectiveness of the drugs.

(b) In each therapeutic class included in the preferred drug program, the board shall determine whether there is one drug which is significantly more clinically effective and safe, and that drug shall be included on the preferred drug list without consideration of cost. If, among two or more drugs in a therapeutic class, the difference in clinical effectiveness and safety is not clinically significant, then cost effectiveness (including price and supplemental rebates) may also be considered in determining which drug or drugs shall be included on

the preferred drug list.

(c) In addition to drugs selected under paragraph (b) of this subdivision, any prescription drug in the therapeutic class, whose cost to the state public health plans (including net price and supplemental rebates) is equal to or less than the cost of another drug in the therapeutic class that is on the preferred drug list under paragraph (b) of this subdivision, may be selected to be on the preferred drug list, based on clinical effectiveness, safety and cost-effectiveness.

(d) Notwithstanding any provision of this section to the contrary, the commissioner may designate therapeutic classes of drugs, including classes with only one drug, as all preferred prior to any review that may be conducted by the board pursuant to this section.

11. (a) The commissioner shall provide an opportunity for pharmaceutical manufacturers to provide supplemental rebates to the state public health plans for drugs within a therapeutic class; such supplemental rebates shall be taken into consideration by the board and the commissioner in determining the cost-effectiveness of drugs within a therapeutic class under the state public health plans.

(b) The commissioner may designate a pharmaceutical manufacturer as one with whom the commissioner is negotiating or has negotiated a manufacturer agreement, and all of the drugs it manufactures or markets shall be included in the preferred drug program. The commissioner may negotiate directly with a pharmaceutical manufacturer for rebates relating to any or all of the drugs it manufactures or markets. A manufacturer agreement shall designate any or all of the drugs manufactured or marketed by the pharmaceutical manufacturer as being preferred or non preferred drugs. When a pharmaceutical manufacturer has been designated by the commissioner under this paragraph but the commissioner has not reached a manufacturer agreement with the pharmaceutical manufacturer, then the commissioner may designate some or all of the drugs manufactured or marketed by the pharmaceutical manufacturer as non preferred drugs. However, notwithstanding this paragraph, any drug that is selected to be on the preferred drug list under paragraph (b) of subdivision ten of this section on grounds that it is significantly more clinically effective and safer than other drugs in its therapeutic class shall be a preferred drug.

(c) Supplemental rebates under this subdivision shall be in addition to those required by applicable federal law and subdivision seven of section three hundred sixty-seven-a of the social services law. In order to be considered in connection with the preferred drug program, such supplemental rebates shall apply to the drug products dispensed under the Medicaid program and the EPIC program. The commissioner is prohibited from approving alternative rebate demonstrations, value added programs or guaranteed savings from other program benefits as a substitution for supplemental rebates.

13. The commissioner may implement all or a portion of the preferred drug program through contracts with administrators with expertise in management of pharmacy services, subject to applicable laws.

14. For a period of eighteen months, commencing with the date of enactment of this article, and without regard to the preferred drug program or the clinical drug review program requirements of this article, the commissioner is authorized to implement, or continue, a prior authorization requirement for a drug which may not be dispensed without a prescription as required by section sixty-eight hundred ten of the education law, for which there is a non-prescription version within the same drug class, or for which there is a comparable non-prescription version of the same drug. Any such prior authorization requirement shall

be implemented in a manner that is consistent with the process employed by the commissioner for such authorizations as of one day prior to the date of enactment of this article. At the conclusion of the eighteen month period, any such drug or drug class shall be subject to the preferred drug program requirements of this article; provided, however, that the commissioner is authorized to immediately subject any such drug to prior authorization without regard to the provisions of subdivisions five through eleven of this section.

New York
2(b)

10. Prior approval is required for all dental care except preventive prophylactic and other routine dental care services and supplies.

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