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State/Territory Name: New York

State Plan Amendment (SPA)#: 22-0036

This file contains the following documents in the order listed below:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850



Center for Medicaid and CHIP Services
Disabled and Elderly Health Programs Group

September 14, 2022

Amir Bassiri, Acting State Medicaid Director
New York State Department of Health
Division of Finance and Rate Setting
99 Washington Ave-One Commerce Plaza
Suite 1432
Albany, NY 12210

Dear Amir Bassiri:

The CMS Division of Pharmacy team has reviewed New York's State Plan Amendment (SPA) 22-0036 received in the CMS Division of Program Operations on June 30th, 2022. This SPA proposes to amend the State Plan to allow the State to enter into outcomes-based contract arrangements with drug manufacturers through supplemental rebate agreements.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that NY-22-0036 is approved with an effective date of April 1, 2022.

If you have any questions regarding this request, please contact Whitney Swears at 410-786-6543 or Whitney.Swears@cms.hhs.gov.

Sincerely,



John M. Coster, Ph.D., R.Ph.
Director, Division of Pharmacy
DEHPG/CMCS/CMS

cc: Kimberly Leonard, New York State Department of Health, Michelle Levesque, New York State Department of Health, Bonny DeCastro, New York State Department of Health, Frankeena McGuire, CMS

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER <u>2 2</u> — <u>0 0 3 6</u>	2. STATE <u>NY</u>
3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT <input checked="" type="radio"/> XIX <input type="radio"/> XXI	

TO: CENTER DIRECTOR
CENTERS FOR MEDICAID & CHIP SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
April 1, 2022

5. FEDERAL STATUTE/REGULATION CITATION
42 CFR 447 Subpart I; 42 CFR § 447.502

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 04/01/22-09/30/22 \$ (500,000)
b. FFY 10/01/22-09/30/23 \$ (1,000,000)

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Attachment 3.1-A Supp-Page 2(b)
Attachment 3.1-B Supp-Page 2(b)

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

Attachment 3.1-A Supp-Page 2(b)
Attachment 3.1-B Supp-Page 2(b)


9. SUBJECT OF AMENDMENT

Value Based Outcomes Arrangements

10. 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:

11. SIGNATURE OF STATE AGENCY OFFICIAL


12. TYPED NAME
Amir Bassiri

13. TITLE
Acting Medicaid Director

14. DATE SUBMITTED **June 30, 2022**

15. RETURN TO
New York State Department of Health
Division of Finance and Rate Setting
99 Washington Ave – One Commerce Plaza
Suite 1432
Albany, NY 12210

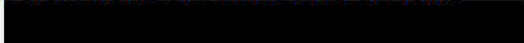
FOR CMS USE ONLY

16. DATE RECEIVED
June 30, 2022

17. DATE APPROVED
September 14, 2022

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
April 1, 2022

19. SIGNATURE OF APPROVING OFFICIAL


20. TYPED NAME OF APPROVING OFFICIAL
John Coster

21. TITLE OF APPROVING OFFICIAL
Director, Division of Pharmacy

22. REMARKS

**New York
2(b)**

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

1905(a)(12) Prescribed Drugs, Dentures, and Prosthetic Devices; and eyeglasses.

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.
 - i. Effective on or after July 1, 2020, the Department will implement a single statewide formulary for opioid dependence agents and opioid antagonists for all Medicaid participating managed care organizations (MCO's) and for Medicaid fee for service, under the prescribed conditions in Attachment A-2 of the NMPI Supplemental Rebate Agreement.
- 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 December 31, 2014 and has been authorized by CMS.
- c) CMS has authorized the State of New York to enter into outcomes-based contract arrangements with drug manufacturers for drugs provided to Medicaid beneficiaries. These contracts will be executed on the contract template titled "Outcome-Based Supplemental Rebate Agreement" submitted to CMS and authorized for use beginning April 1, 2022.

TN #22-0036

Supersedes TN #20-0039

Approval Date September 14, 2022

Effective Date April 1, 2022

**New York
2(b)**

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