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State/Territory Name: New York

State Plan Amendment (SPA) #: 20-0039

This file contains the following documents in the order listed:

- 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

October 21, 2020

Ms. Donna Frescatore
State Medicaid Director, Deputy Commissioner
State of New York, Department of Health
Empire State Plaza, Corning Tower, Room 1466
Albany, New York 12237

Dear Ms. Frescatore:

The CMS Division of Pharmacy team has reviewed New York's State Plan Amendment (SPA) 20-0039 received in the CMS Division of Program Operations on August 25, 2020. This SPA proposes for the state to implement a single statewide formulary for opioid dependence agents and opioid antagonists in their NMPI Supplemental Rebate Agreement for both fee-for-service and Medicaid participating managed care organizations.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 20-0039 is approved with an effective date of July 1, 2020. CMS Division of Program Operations will forward a copy of the signed CMS-179 form, as well as the pages approved for incorporation into New York's state plan.

If you have any questions regarding this amendment, please contact Lisa Shochet at (410) 786-5445 or lisa.shochet@cms.hhs.gov.

Sincerely,



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

cc: Regina Deyette, State of New York, State Plan Coordinator
James G. Scott, Division Director, CMS Division of Program Operations
Maria C. Tabakov, CMS, Medicaid and CHIP Operations Group

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

1. TRANSMITTAL NUMBER

2. STATE

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

TO: REGIONAL ADMINISTRATOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE

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

7. FEDERAL BUDGET IMPACT

a. FFY _____ \$ _____

b. FFY _____ \$ _____

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (*If Applicable*)

10. SUBJECT OF AMENDMENT

11. GOVERNOR'S REVIEW (*Check One*)

GOVERNOR'S OFFICE REPORTED NO COMMENT

OTHER, AS SPECIFIED

COMMENTS OF GOVERNOR'S OFFICE ENCLOSED

NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. SIGNATURE OF STATE AGENCY OFFICIAL

16. RETURN TO

13. TYPED NAME

14. TITLE

15. DATE SUBMITTED August 25, 2020

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED August 25, 2020

18. DATE APPROVED October 21, 2020

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL
July 1, 2020

20. SIGNATURE

21. TYPED NAME
John M. Coster, Ph.D., R.Ph.

22. TITLE
Director, Division of Pharmacy

23. 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.
- 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.

TN #20-0039

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Supersedes TN #14-0038

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**New York
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