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State/Territory Name: **NEW YORK**

State Plan Amendment (SPA) #: **13-72**

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) Additional Companion letter
- 3) CMS 179 Form/Summary Form
- 4) 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

May 08, 2014

Jason A. Helgerson
Medicaid Director
New York State Department of Health
Bureau of Federal Relations & Provider Assessments
99 Washington Ave – One Commerce Plaza
Suite 1430
Albany, NY 12210

Dear Mr. Helgerson:

We have reviewed New York's State Plan Amendment (SPA) 13-72, Prescribed Drugs, received in the New York Regional Office on January 6, 2014. This amendment proposes to remove barbiturates, benzodiazepines, and agents used to promote smoking cessation from the list of drugs the state Medicaid program may exclude from coverage or otherwise restrict in order to comply with the requirements of Section 2502(a) of the Affordable Care Act.

Based on the information provided, we are pleased to inform you that consistent with the regulations at 42 CFR 430.20, SPA 13-72 is approved with an effective date of January 1, 2014. A copy of the signed CMS-179 form, as revised, as well as the pages approved for incorporation into the New York state plan will be forwarded by the New York Regional Office.

If you have any questions regarding this SPA, please contact Delaine Deardorff-Beck at (410) 786-2991.

Sincerely,

/s/

Joseph L. Fine
Acting Director
Division of Pharmacy

cc: Michael Melendez, ARA, New York Regional Office
Ivelisse Salce, New York Regional Office



DIVISION OF MEDICAID & CHILDREN'S HEALTH OPERATIONS

May 08, 2014

Jason A. Helgerson
Medicaid Director
New York State Department of Health
99 Washington Ave – One Commerce Plaza Suite 1430
Albany, NY 12210

Dear Mr. Helgerson:

This letter is being sent as a companion to our approval of your New York State Plan Amendment (SPA13-72), approved on May 08, 2014. During our processing of NY SPA 13-72, we also reviewed the services that appeared on the submitted pages and the associated coverage provisions corresponding to those same services. Based on that review, we determined that Attachment 3.1-A Supplement pages 2c and 2d and Attachment 3.1-B Supplement page 2d are not in compliance with current CMS regulations, statute, or guidance.

Section 1902 of the Social Security Act (the Act) requires that states have a state plan for medical assistance that meets certain federal requirements that set out a framework for the state program. Implementing regulations at 42 CFR 430.10 require that the state plan be a comprehensive written statement containing all information necessary for CMS to determine whether the plan can be approved as a basis for Federal financial participation (FFP) in the state program.

To that end, CMS welcomes the opportunity to work with you and your staff to discuss options for resolving concerns as outlined below:

Directly Observed Therapy (DOT): Attachment 3.1-A Supplement page 2c/2d and Attachment 3.1-B Supplement page 2d

1. Regulations at 42 CFR 440.130(d) specify that, "Rehabilitative services, except as otherwise provided under this subpart, includes any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under state law, for maximum reduction of physical or mental disability and restoration of a recipient to his best possible functional level." We are unclear how DOT is actually a rehabilitative service that comports with the definition of rehabilitative services at 42 CFR 440.130(d) to reduce disability and restore function. Please add a service description for DOT in the state plan that comports with the definition of rehabilitative services. Please include each of the

component services of DOT, as applicable, the definitions of those component services, and the practitioners who furnish the services along with their practitioner qualifications. Practitioner qualifications should summarize the state's requirements for education, experience and training, as well as any licensure, credentialing or registration required.

2. Regulations at 42 CFR 440.230 require state plans to specify the amount, duration and scope of each service that is covered. Each covered service must be sufficient in amount, duration and scope to reasonably achieve its purpose. Please include in the state plan the state's limitations on amount, duration and scope of DOT services. Are any of the limitations "maximum" limitations? If so, can they be exceeded based on medical necessity?

"Off-Site" Services: Attachment 3.1-B Supplement page 2d

3. It is unclear what is meant by "off-site" services and whether they are coverable rehabilitative services pursuant to 42 CFR 440.130(d). For each "off-site" rehabilitative service, please include a service description in the state plan, along with their component services and the definitions of those component services, the practitioners who furnish the services, and the practitioner qualifications.
4. Pursuant to 42 CFR 440.230, please include in the state plan the state's limitations on amount, duration and scope of services of each of the "off-site" services in the state plan. Are any of the limitations "maximum" limitations? If so, can they be exceeded based on medical necessity?
5. The state indicates that the "off-site" services are provided only to children with developmental disabilities or delays. Section 1902(a)(10) of the Act and federal regulations at 42 CFR 440.240 require that services to members of a categorically needy group must be comparable. It is unclear how the state ensures that all children who meet the medical necessity criteria for receipt of "off-site" services may receive them. Please explain.

Early Intervention Services: Attachment 3.1-B Supplement page 2d

6. It is unclear whether each of the 14 early intervention services listed on the page meet the definition of rehabilitative services at 42 CFR 440.130(d) to reduce disability and restore function. For example, these services do not appear to be rehabilitative services: Screening, Assistive Technology Services, Vision Services, Nutrition Services, and Anticipatory Guidance. Please remove the services from the plan page that do not comport with the definition of rehabilitative services, and clarify in the plan how these services and activities are covered pursuant to the EPSDT benefit at section 1905(r) of the Social Security Act or other benefit categories.

issues identified above in a timely manner. Failure to respond within the 90 days will result in the initiation of a formal compliance process. During the 90-day period, CMS will provide any required technical assistance to assist you in resolving these issues. If you have any additional questions or require any further assistance, please contact Ivelisse Salce at (212) 616-2411 or Ivelisse.Salce@cms.hhs.gov.

Sincerely,

/s/

John Guhl
Acting Associate Regional Administrator
Division of Medicaid & Children's Health Operations

cc: Ilene E Matthews, DHCF
Delaine Deardorff-Beck, Health Insurance Specialist, Division of Pharmacy

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: HEALTH CARE FINANCING ADMINISTRATION	1. TRANSMITTAL NUMBER: 13-72	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 January 1, 2014	

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)

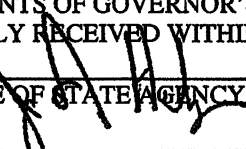
FEDERAL STATUTE/REGULATION CITATION: Section 2502 of the Affordable Care Act	7. FEDERAL BUDGET IMPACT: a. FFY 01/01/14-09/30/14 \$ 12,255 b. FFY 10/01/14-09/30/15 \$ 12,255
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PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A Supplement: Page 2c Attachment 3.1-B Supplement: Page 2c	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Attachment 3.1-A Supplement: Page 2c Attachment 3.1-B Supplement: Page 2c
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10. SUBJECT OF AMENDMENT:
Medicaid Excludable Drug List for Medicare Part D
FMAP = 50%

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

2. 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 1430 Albany, NY 12210
3. TYPED NAME: Jason A. Helgerson	
4. TITLE: Medicaid Director Department of Health	
5. DATE SUBMITTED: January 6, 2014	

FOR REGIONAL OFFICE USE ONLY

7. DATE RECEIVED:	18. DATE APPROVED: MAY 05, 2014
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PLAN APPROVED - ONE COPY ATTACHED

9. EFFECTIVE DATE OF APPROVED MATERIAL: JANUARY 01, 2014	20. SIGNATURE OF REGIONAL OFFICIAL: /s/
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11. TYPED NAME: JOHN GUHL	22. TITLE: ACTING ASSOCIATE REGIONAL ADMINISTRATOR DIVISION OF MEDICALS & CHILDREN'S HEALTH OPERATIONS
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13. REMARKS:

[REDACTED]

OFFICIAL

6. Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.
7. The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit –Part D.

The following excluded drugs are covered:

- (a) agents when used for anorexia, weight loss, weight gain
- (b) agents when used to promote fertility
- (c) agents when used for cosmetic purposes or hair growth
- (d) agents when used for the symptomatic relief cough and colds: Some - benzonatate only
- (e) prescription vitamins and mineral products, except prenatal vitamins and fluoride: Some - select B Vitamins (niacin, pyridoxine, thiamine, cyanocobalamin); Folic Acid; Vitamin K; Vitamin D (ergocalciferol, cholecalciferol); Iron (including polysaccharide iron complex); Iodine
- (f) nonprescription drugs: Some - select allergy, asthma and sinus products; analgesics; cough and cold preparations; digestive products; insulin; feminine products; topical products; smoking cessation products, minerals and vitamin combinations
- (g) covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee

12b. Prior approval is required for all dentures.

12c. Prior approval is required for prosthetic and orthotic devices over a dollar amount established by the State Department of Health and Identified for providers in the MMIS DME Provider Manual.

Prior approval is required for artificial eyes as specified in the MMIS Ophthalmic Provider Manual.

Program also includes coverage of orthotic appliances including hearing aids. All hearing aids require prior approval.

12d. Prior approval is required for certain special lenses and unlisted eye services as specified for providers in the MMIS Ophthalmic Provider Manual.

13a. Diagnostic Services (see 13.d Rehabilitative Services – Early Intervention).

13b. Screening Services (see 13.d Rehabilitative Services – Early Intervention).

13c. Preventive Services (see 13.d Rehabilitative Services – Early Intervention).

13d. Rehabilitative Services

(1) Directly Observed Therapy (DOT) – Clients must be assessed as medically appropriate for DOT based upon the client's risk of non adherence to a medication regimen necessary to cure an active, infectious, potentially fatal disease process and to prevent the development and spread of an infectious, potentially fatal disease which may not respond to conventional therapies.

TN#: #13-72

Approval Date: MAY 08 2014

Supersedes TN#: #12-35

Effective Date: JAN 01 2014

OFFICIAL

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 - (f) nonprescription drugs: Some - select allergy, asthma and sinus products; analgesics; cough and cold preparations; digestive products; insulin; feminine products; topical products; smoking cessation products, minerals and vitamin combinations
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