STATE OF NEW YORK
DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237
www.health.ny.gov

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

March 31, 2011

Mr. Michael Melendez
Acting Associate Regional Administrator
Department of Health & Human Services
Centers for Medicare & Medicaid Services
New York Regional Office
Division of Medicaid & Children's Health
26 Federal Plaza – Room 3800
New York, NY 10278

Dear Mr. Melendez:

Re: SPA #11-01 Non-Institutional Services

The State requests approval of the enclosed amendment #11-01 to the Title XIX (Medicaid) State Plan to reflect the additional coverage by New York Medicaid of select active pharmaceutical ingredients (APIs) to the list of 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, to be effective January 1, 2011 (Appendix I). This amendment is being submitted based upon federal guidelines. A summary of the proposed 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 state statute are enclosed for your information (Appendix III). A copy of the public notice of this plan amendment, which was given in the New York State Register on December 22, 2010, is also enclosed for your information (Appendix IV). In addition, responses to the five standard funding questions are also enclosed (Appendix V).

If you have any questions regarding this State Plan submission, please do not hesitate to contact John E. Ulberg Jr., Director, Division of Health Care Financing at (518) 474-6350.

Sincerely,

Jason A. Helgerson
Medicaid Director
Deputy Commissioner
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: **11-01**	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, 2011**	

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: **NYS Public Health Law, Article 2-A** **Social Security Act, Section 1927**	7. FEDERAL BUDGET IMPACT: a. FFY **04/01/10-09/30/10 $0** b. FFY **10/01/10-09/30/11 $0**
8. 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**

10. SUBJECT OF AMENDMENT:
Active Pharmaceutical Ingredients (APIs)
(FMAP = 58.77% effective 1/1/11; 56.88% effective 4/1/11; 50% effective 7/1/11 forward)

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** **Corning Tower** **Empire State Plaza** **Albany, New York 12237**
13. TYPED NAME: **Jason Helgerson**	
14. TITLE: **Medicaid Director & Deputy Commissioner Department of Health**	
15. DATE SUBMITTED: March 31, 2011	

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
2011 Title XIX State Plan
First Quarter Amendment
Non-Institutional Services
Amended SPA Pages

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.

X **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
X (d) agents when used for the symptomatic relief cough and colds: Some - benzonatate only
X (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
X (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
X (h) barbiturates: All
X (i) benzodiazepines: All
X (j) smoking cessation for non-dual eligibles as Part D will cover: All
X (k) active pharmaceutical ingredients: Some - select

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.
13b. Screening Services.
13c. Preventive Services.
13d. Rehabilitative Services

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.

X **The following excluded drugs are covered:**
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X (h) barbiturates: All
X (i) benzodiazepines: All
X (j) smoking cessation for non-dual eligibles as Part D will cover: All
X (k) active pharmaceutical ingredients: Some - select

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13b. Screening Services.
13c. Preventive Services.
13d. Rehabilitative Services

Appendix II
2011 Title XIX State Plan
First Quarter Amendment
Non-Institutional Services
Summary

Summary
SPA #11-01

This state plan amendment proposes to seek federal approval to reflect the additional coverage by New York Medicaid of select active pharmaceutical ingredients (APIs) to the list of 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), effective January 1, 2011.

The Federal public notice stated that the estimated annual net aggregate increase in gross Medicaid expenditures is $91,000, which has been determined to be incorrect. In 2010, APIs qualified as outpatient drugs, thereby eligible for FFP. APIs have since been determined by CMS as not meeting the definition of outpatient drugs as defined in section 1927(k)(2) of the Social Security Act. In accordance with direction by CMS, the State plan is being amended effective January 1, 2011 to include coverage of these products, thereby assuring continued FFP, with no change in coverage and no annual net increase in gross Medicaid expenditures.

Appendix III
2011 Title XIX State Plan
First Quarter Amendment
Non-Institutional Services
Authorizing Provisions

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid , CHIP, and Survey & Certification

August 11, 2010

MEDICAID DRUG REBATE PROGRAM **Release No. 155**

For State Medicaid Directors

AFFORDABLE CARE ACT OPERATIONAL GUIDANCE & FIRST QUARTER 2010 REBATE INFORMATION

In an effort to expedite this guidance, we previously provided interim guidance via email on May 24, 2010; however, we have since received questions requesting clarification on some of the provisions. Therefore, we have updated the language on the new rebate calculation for Single Source (S)/ Innovator Multiple Source (I) line extension drugs in an oral solid dosage form and on the limit of the rebate amount for S/I drugs under this section. We will continue to provide additional guidance as soon as it becomes available.

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA), P.L. 111-148, and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (HCERA), P.L. 111-152, together called the Affordable Care Act (ACA). Section 2501 of ACA, as amended by section 1206 of HCERA, include changes to certain Medicaid Drug Rebate (MDR) provisions, effective first quarter 2010. Several of these changes impact the Unit Rebate Amount (URA) calculation for all drugs covered under the MDR Program. Specifically, these sections increase the rebate percentages for S, I, and Non-Innovator (N) drugs and establish new requirements for calculating rebates for reformulated S/I drugs in oral solid dosage form. Additional details about these revised calculations may be found below.

In accordance with the national rebate agreement, labelers are responsible for calculating URAs. However, CMS usually provides States with calculated URAs for use on rebate invoices so that States can verify these URAs with any labeler-adjusted URAs that States may receive. CMS was not able to calculate a URA using the new rebate percentages or requirements for reformulated drugs in time for first quarter 2010 rebate processing. Therefore, until CMS' MDR systems (i.e.,

Drug Data Reporting for Medicaid (DDR) and MDR) are modified to reflect the URA changes implemented by ACA, CMS does not expect to be calculating these URAs.

In order to facilitate the data exchange between CMS and States, CMS did not send updated URAs to States on the first quarter 2010 tapes, along with the usual labeler contact and drug product data files. As a result, State invoices will not contain updated URAs, and labelers remain responsible for calculating these amounts. These uncalculated URAs will also be reflected in DDR beginning with the URAs for the first quarter of 2010 until system modifications are made. (Please note that this does not affect any prior period adjustments (PPAs) which are based on percentages in effect prior to ACA.) Therefore, labelers should update and submit their URAs to States using the OMB-approved Reconciliation of State Invoice (ROSI) form (Form CMS-304) that reflects the ACA amendments beginning with the first quarter 2010 drug rebate reporting period. A copy of the ROSI can be found in the MDR Data Guide for Labelers which is posted on the DDR website.

The URA calculation changes are summarized below:

Changes to the Basic URA Calculation

--Innovator (S/I Drug Category) drugs are subject to an increase in the minimum rebate percentage used to perform the basic rebate calculation. The Basic URA of these products is now the greater of AMP minus best price or the product's AMP multiplied by 23.1 percent.

--Innovator (S/I Drug Category) clotting factor drugs for which a separate furnishing payment is made under section 1842(o)(5) of the Social Security Act are subject to an increase in the minimum rebate percentage used to perform the basic rebate calculation. The Basic URA of these products is now the greater of AMP minus best price or the product's AMP multiplied by 17.1 percent. A list of these NDCs will be posted and updated in DDR in the near future for State and labeler use.

--Innovator (S/I Drug Category) drugs approved by the Food and Drug Administration (FDA) for exclusively pediatric indications are subject to an increase in the minimum rebate percentage used to perform the basic rebate calculation. The Basic URA of these products is now the greater of AMP minus best price or the product's AMP multiplied by 17.1 percent.

--Non-innovator (N Drug Category) drugs are subject to an increase in the minimum rebate percentage used to calculate rebates. To calculate the Basic URA of these products, the product's AMP is now multiplied by 13 percent.

New Rebate Calculation for S/I Line Extension (i.e., New Formulations) Drugs in Oral Solid Dosage Forms

For a drug that is a line extension (new formulation) of an S/I drug that is an oral solid dosage form, the rebate is the amount computed under section 1927 of the Act or, if greater, the product of:

- the AMP for the line extension drug,
- the highest additional rebate for any strength of the original S/I drug, and

- the total number of units of each dosage form and strength of the line extension drug (section 1206 of HCERA, which replaced section 1927(c)(2)(C) as added by section 2501(d) of PPACA).

Limit on Rebate Amount for S/I Drugs

--The total rebate obligation for all innovator drugs (S/I Drug Category) is capped at 100% of AMP.

Labelers are responsible for calculating rebates and URAs in accordance with the statute. CMS is currently working on systems updates and will promptly notify labelers and States when the changes are in place. At that time, States will receive PPAs retroactive, if applicable, to the first quarter 2010.

(Contact: mdroperations@cms.hhs.gov)

LIST OF PEDIATRIC AND CLOTTING FACTOR DRUGS AVAILABLE SOON IN DDR

The Affordable Care Act (ACA) establishes several new rebate calculations for those National Drug Codes (NDCs) covered under the Medicaid Drug Rebate Program, effective January 1, 2010. Under section 2501 of the ACA, most single source and innovator multiple source drugs are subject to a minimum rebate of 23.1 percent. Section 2501(a)(1)(B) of the ACA added a new section 1927(c)(1)(B)(iii) to the Social Security Act (the Act) to require a new minimum rebate of 17.1 percent of the average manufacturer price (AMP), effective January 1, 2010 for a drug approved by the Food and Drug Administration (FDA) exclusively for pediatric indications.

We plan to interpret this provision in accordance with Federal regulations published by the FDA regarding pediatric labeling requirements for prescription drugs, and plan to interpret in light of the FDA labeling and as the indications for pediatric use on the labeling. In accordance with regulations at 21 CFR 201.57, and 21 CFR 201.80, the FDA defines pediatric use for drugs use as for pediatric populations and pediatric patients. The FDA defines pediatric populations and pediatric patients as the pediatric age group from birth to 16 years. Accordingly, we plan to apply the 17.1 percent minimum rebate to those single source or innovator multiple source drugs approved by the FDA exclusively for pediatric indications meeting this FDA definition. Drugs that are not approved, or labeled, exclusively with indications for pediatric use will not qualify for the minimum rebate provisions in section 1927(c)(1)(B)(iii of the Act.

Until CMS's systems can be updated to include an identifier for these drugs and others specified in ACA, we have compiled an initial draft list of those pediatric drugs we have been able to identify that we believe to meet the above-mentioned definition. This list will be posted on the Bulletin Page in the Drug Data Reporting for Medicaid (DDR) application for State and labeler use. Additionally, this list will be posted on the Policy & Reimbursement's Spotlight web page at http://www.cms.gov/Reimbursement/02_Spotlight.asp. If you have concerns or are aware of other drugs that meet the pediatric definition specified above, please contact the policy email resource box at RxDrugPolicy@cms.hhs.gov and specify the drug(s) for which you have concerns or that you believe meet this definition as well as supporting documentation, including the FDA labeling, so that CMS can review this and, if appropriate, update the list accordingly.

Additionally, the ACA added a new section 1927(c)(1)(B)(iii) establishing a minimum rebate of 17.1 percent for clotting factors for which a separate furnishing payment is made under section 1842(o)(5) of the Act and which is included on a list of such factors specified and updated regularly by the Secretary. We expect that when products are included on the list, the minimum rebate of 17.1 percent of AMP will be used as a basis for rebate calculation. CMS has obtained this data from Medicare Part B and will post the list of clotting factor NDCs on the Bulletin Page in DDR for State and labeler use. This list will also be posted on the Policy & Reimbursement's Spotlight web page. If you have any questions or corrections to this list, please contact the policy email resource box at RxDrugPolicy@cms.hhs.gov so that we can review this submission and, if appropriate, update the list accordingly.

CMS will issue additional guidance regarding changes to the Medicaid Drug Rebate Program as it becomes available.

REMOVAL OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs) AND EXCIPIENTS AS COVERED OUTPATIENT DRUGS

We are providing policy clarification regarding the inclusion of APIs and excipients in the drug rebate program. An API is a bulk drug substance, which is defined by the FDA as any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient of the drug product. 21 C.F.R. § 207.3(a)(4). APIs may be included in extemporaneously compounded prescriptions and may serve as the active drug component in a compounded formulation.

In accordance with the foregoing, APIs do not meet the definition of a covered outpatient drug as defined in section 1927(k)(2) of the Social Security Act (Act). As such, APIs are not subject to the requirements of the MDR program. In addition, excipient products used in compounds (*e.g.*, aquaphor, petrolatum, etc.) are non-drug products and, as a result, should not be reported to the MDR program. However, FFP may be available for these products if the State plan allows for their coverage as incident to another service category (*e.g.* Home Health, Nursing, Other Practitioner).

To the extent possible, CMS has identified the APIs and excipients that are listed in the MDR system. We are notifying manufacturers that the NDCs do not qualify as covered outpatient drugs and, as a result, will be deleted from the MDR product file of covered outpatient drugs effective January 1, 2011. As with all deletions, we will notify the States regarding the removal of these products. The list of identified API and excipient NDCs can be found on the Policy & Reimbursement's Spotlight Webpage. Please note that this is not a definitive list. If additional API and/or excipient NDCs are identified, please notify MDROperations@cms.hhs.gov to have them removed from the MDR Program.

The State Medicaid agency should also review their State plan to assure that to the extent that it wishes to continue coverage of these products, the plan allows for such coverage. Where the plan does not allow for such coverage, a State plan amendment should be submitted.

If you have any questions, please contact Joseph Fine at 410-786-2128.

Appendix IV
2011 Title XIX State Plan
First Quarter Amendment
Non-Institutional Services
Public Notice

MISCELLANEOUS NOTICES/HEARINGS

Notice of Abandoned Property Received by the State Comptroller

Pursuant to provisions of the Abandoned Property Law and related laws, the Office of the State Comptroller receives unclaimed monies and other property deemed abandoned. A list of the names and last known addresses of the entitled owners of this abandoned property is maintained by the office in accordance with Section 1401 of the Abandoned Property Law. Interested parties may inquire if they appear on the Abandoned Property Listing by contacting the Office of Unclaimed Funds, Monday through Friday from 8:00 a.m. to 4:30 p.m., at:

1-800-221-9311
or visit our web site at:
www.osc.state.ny.us

Claims for abandoned property must be filed with the New York State Comptroller's Office of Unclaimed Funds as provided in Section 1406 of the Abandoned Property Law. For further information contact: Office of the State Comptroller, Office of Unclaimed Funds, 110 State St., Albany, NY 12236.

PUBLIC NOTICE

Department of Health

Pursuant to 42 CFR Section 447.205, the Department of Health hereby gives public notice of the following:

The Department of Health proposes to amend the Title XIX Medicaid State Plan, based on Federal recommendations, to reflect the additional coverage of select active pharmaceutical ingredients to the list of 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, effective January 1, 2011.

The estimated annual net aggregate increase in gross Medicaid expenditures attributable to this proposed initiative for state fiscal year 2010/2011 is $91,000.

Copies of the proposed state plan amendments will be on file in each local (county) social services district and available for public review.

For the New York City district, copies will be available at the following places:

New York County
250 Church Street
New York, New York 10018

Queens County, Queens Center
3220 Northern Boulevard
Long Island City, New York 11101

Kings County, Fulton Center
114 Willoughby Street
Brooklyn, New York 11201

Bronx County, Tremont Center
1916 Monterey Avenue
Bronx, New York 10457

Richmond County, Richmond Center
95 Central Avenue, St. George
Staten Island, New York 10301

The public is invited to review and comment on this proposed state plan amendment.

For further information and to review and comment, please contact: Patricia Keller, Department of Health, One Commerce Plaza, Suite 720, Albany, NY 12210, (518) 486-3209, (518) 473-5508 (fax), e-mail: PPNO@health.state.ny.us

PUBLIC NOTICE

Uniform Code Regional Boards of Review

Pursuant to 19 NYCRR 1205, the petitions below have been received by the Department of State for action by the Uniform Code Regional Boards of Review. Unless otherwise indicated, they involve requests for relief from provisions of the New York State Uniform Fire Prevention and Building Code. Persons wishing to review any petitions, provide comments, or receive actual notices of any subsequent proceeding may contact Steven Rocklin, Codes Division, Department of State, One Commerce Plaza, 99 Washington Ave., Albany, NY 12231, (518) 474-4073 to make appropriate arrangements.

2010-0268 Matter of Richard Regan, Eight Heston Road, Shirley, NY 11967 for an appeal and or variances concerning safety requirements, including the ceiling height within an existing basement space.

Involved is a one-family dwelling, located at Eight Heston Road, Town of Brookhaven, Suffolk County, State of New York.

2010-0466 Matter of Thomas FitzSimmons, 556 Middle Neck Road, Great Neck, NY 11023 for an appeal and or variances concerning safety requirements, including the number of required exits.

Involved is an existing underground assembly building, located at 1350 Union Turnpike, Town of North Hempstead, Nassau County, State of New York.

2010-0471 Matter of Jason & Francine Barnes, One Matlock Place, Pittsford, NY 14523 for a variance concerning requirements for ceiling height in basement of a one-family dwelling.

Involved is the alteration to a two-story with basement one-family dwelling of wood frame construction, located at One Matlock Place, Town of Perinton, County of Monroe, State of New York.

2010-0489 Matter of Eli Elbaum, 333 Earle Ovington Blvd., Uniondale, NY 11553 for an appeal and or variances concerning safety requirements, including flood construction.

Involved is a new a one-family dwelling, located at 55 Island Parkway, Town of Hempstead, Nassau County, State of New York.

2010-0533 Matter of Rebecca Johnson, 535 No. Pearl Street, Albany, NY 12204 for a variance concerning fire safety issues including the requirement for a cellar ceiling in a multiple dwelling.

Involved is a routine inspection of an existing multiple dwelling using the Multiple Dwelling Law and a citation for lack of a cellar