



Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

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

JUN 20 2016

RE: SPA #16-0033
Non-Institutional Services

Dear Mr. Melendez:

The State requests approval of the enclosed amendment #16-0033 to the Title XIX (Medicaid) State Plan for non-institutional services to be effective April 1, 2016 (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.

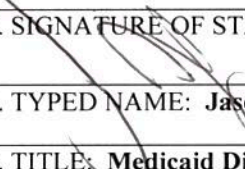
Copies of pertinent sections of enacted State statute are enclosed for your information (Appendix III). A copy of the public notice of this plan amendment, which was given in the New York State Register on March 30, 2016, is also enclosed for your information (Appendix IV).

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

Sincerely,

Jason A. Helgeson
Medicaid Director
Office of Health Insurance Programs

Enclosures

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: HEALTH CARE FINANCING ADMINISTRATION		1. TRANSMITTAL NUMBER: 16-0033	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, 2016	
5. TYPE OF PLAN MATERIAL (<i>Check One</i>): <input type="checkbox"/> NEW STATE PLAN <input type="checkbox"/> AMENDMENT TO BE CONSIDERED AS NEW PLAN <input checked="" type="checkbox"/> AMENDMENT COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (<i>Separate Transmittal for each amendment</i>)			
6. FEDERAL STATUTE/REGULATION CITATION: §1902(r)(5) of the Social Security Act, and 42 CFR 447		7. FEDERAL BUDGET IMPACT: (<i>in thousands</i>) a. FFY 04/01/16-09/30/16 \$ (11.87) b. FFY 10/01/16-09/30/17 \$ (23.75)	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A Supplement: Page 2(b.1) Attachment 3.1-B Supplement: Page 2(b.1)		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>): Attachment 3.1-A Supplement: 2(b.1) Attachment 3.1-B Supplement: 2(b.1)	
10. SUBJECT OF AMENDMENT: Generic CPI Penalty (FMAP = 50%)			
11. GOVERNOR'S REVIEW (<i>Check One</i>): <input checked="" type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="checkbox"/> OTHER, AS SPECIFIED: <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
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 1460 Albany, NY 12210	
13. TYPED NAME: Jason A. Helgerson			
14. TITLE: Medicaid Director Department of Health			
15. DATE SUBMITTED: JUN 20 2016			
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
2016 Title XIX State Plan
Second Quarter Amendment
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. The Department may require manufacturers to provide rebates for generic prescription drugs which have increased more than three hundred percent of its State maximum acquisition cost (SMAC). The rebate shall be limited to the amount by which the current amount exceeds three hundred percent of the SMAC. Such rebates shall be in addition to any rebates payable to the Department pursuant to any other provision of Federal or State law. For NY State Fiscal Year 2016-2017, in the event CMS has adopted a final methodology for determining the amount of additional rebates under the federal generic drug price increase program, pursuant to 42 U.S.C. § 1396r-8 (c)(3), as amended by section 602 of the Bipartisan Budget Act of 2015, the State may collect for a given drug the portion of the rebate determined to be in excess of the rebate required by such federal rebate program.
- [4]5. 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]6. 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.

TN #16-0033 _____

Approval Date _____

Supersedes TN #13-0029 _____

Effective Date _____

**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. The Department may require manufacturers to provide rebates for generic prescription drugs which have increased more than three hundred percent of its State maximum acquisition cost (SMAC). The rebate shall be limited to the amount by which the current amount exceeds three hundred percent of the SMAC. Such rebates shall be in addition to any rebates payable to the Department pursuant to any other provision of Federal or State law. For NY State Fiscal Year 2016-2017, in the event CMS has adopted a final methodology for determining the amount of additional rebates under the federal generic drug price increase program, pursuant to 42 U.S.C. § 1396r-8 (c)(3), as amended by section 602 of the Bipartisan Budget Act of 2015, the State may collect for a given drug the portion of the rebate determined to be in excess of the rebate required by such federal rebate program.
- [4]5. 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]6. 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.

TN #16-0033 _____

Supersedes TN #13-0029 _____

Approval Date _____

Effective Date _____

Appendix II
2016 Title XIX State Plan
Second Quarter Amendment
Summary

SUMMARY
SPA #16-0033

This State Plan Amendment proposes to require the drug manufacturer to provide rebates to the Department, when the price of a generic prescription drug dispensed to a NYS Medicaid enrollee increases at a rate greater than three hundred percent of its State Maximum Acquisition Cost (SMAC) in comparison to its SMAC at any time during the course of the preceding twelve months.

The Federal Budget Impact for the time period 04/01/17 through 09/30/17 is contingent upon the enactment of this provision for the State Fiscal Year (SFY) 17-18 budget, or the enactment of the generic CPI penalty at the Federal level, yielding the same savings.

Appendix III
2016 Title XIX State Plan
Second Quarter Amendment
Authorizing Provisions

SPA #16-0033
Chapter 59 of the Laws of 2016

§ 11. Subdivision 7 of section 367-a of the social services law is amended by adding a new paragraph (f) to read as follows:

(f) (1) The department may require manufacturers of drugs other than single source drugs and innovator multiple source drugs, as such terms are defined in 42 U.S.C. § 1396r-8(k), to provide rebates to the department for any drug that has increased more than three hundred percent of its state maximum acquisition cost (SMAC), on or after April 1, 2016, in comparison to its SMAC at any time during the course of the preceding twelve months. The required rebate shall be limited to the amount by which the current SMAC for the drug exceeds three hundred percent of the SMAC for the same drug at any time during the course of the preceding twelve months. Such rebates shall be in addition to any rebates payable to the department pursuant to any other provision of federal or state law. Nothing herein shall affect the department's obligation to reimburse for covered outpatient drugs pursuant to paragraph (d) of this subdivision.

(2) Except as provided in subparagraph three of this paragraph, the commissioner shall not determine any further rebates to be payable pursuant to this paragraph once the Centers for Medicare and Medicaid
S. 6407--C 5 A. 9007--C

Services has adopted a final methodology for determining the amount of additional rebates under the federal generic drug price increase rebate program pursuant to 42 U.S.C. § 1396r-8 (c) (3), as amended by section 602 of the Bipartisan Budget Act of 2015.

(3) During state fiscal year 2016-2017, if the Centers for Medicare and Medicaid Services has adopted a final methodology for determining the amount of additional rebates under the federal generic drug price increase rebate program pursuant to 42 U.S.C. § 1396r-8 (c) (3), as amended by section 602 of the Bipartisan Budget Act of 2015, the department may collect for a given drug the portion of the rebate determined under this paragraph that is in excess of the rebate required by such federal rebate program.

(4) The additional rebates authorized pursuant to this paragraph shall apply to generic prescription drugs dispensed to enrollees of managed care providers pursuant to section three hundred sixty-four-j of this title and to generic prescription drugs dispensed to Medicaid recipients who are not enrollees of such providers.

(5) Beginning in two thousand seventeen, the department shall provide an annual report to the legislature no later than February first setting forth:

(i) The number of drugs that exceeded the ceiling price established in this paragraph during the preceding year in comparison to the number of drugs that experienced at least a three hundred percent price increase during two thousand fourteen and two thousand fifteen;

(ii) The average percent amount above the ceiling price of drugs that exceeded the ceiling price in the preceding year in comparison to the number of drugs that experienced a price increase more than three hundred percent during two thousand fourteen and two thousand fifteen;

(iii) The number of generic drugs available to enrollees in Medicaid fee for service or Medicaid managed care, by fiscal quarter, in the preceding year in comparison to the drugs available, by fiscal quarter, during two thousand fourteen and two thousand fifteen; and

(iv) The total drug spend on generic drugs for the preceding year in comparison to the total drug spend on generic drugs during two thousand fourteen and two thousand fifteen.

**Appendix IV
2016 Title XIX State Plan
Second Quarter Amendment
Public Notice**

addition to any rebates payable to the Department pursuant any other provision of federal or state law.

The estimated annual net aggregate decrease in gross Medicaid expenditures attributable to this initiative contained in the budget for state fiscal year 2016/2017 is (\$12 million).

- Effective October 1, 2016, fee-for-service reimbursement for a pharmacy prescription drug designated as a specialty drug by one or more Medicaid managed care providers will not exceed the amount such providers pay for the drug, as determined by the commissioner based on managed care providers' claim encounter data for the drug.

The estimated annual net aggregate decrease in gross Medicaid expenditures attributable to this initiative contained in the budget for state fiscal year 2016/2017 is (\$3.7 million).

- Effective April 1, 2016, when the price of a generic prescription drug dispensed to a NYS Medicaid enrollee (managed care or fee-for-service) increases at a rate greater than the rate of inflation, the commissioner of health is authorized to require the drug manufacturer to provide rebates to the Department, in addition to any rebates payable to the Department pursuant any other provision of federal or state law.

The estimated annual net aggregate decrease in gross Medicaid expenditures attributable to this initiative contained in the budget for state fiscal year 2016/2017 is (\$47.5 million) and state fiscal year 2017/2018 (\$47.5 million).

The overall estimated annual net aggregate decrease in gross Medicaid expenditures attributable to reform and other initiatives contained in the budget for state fiscal year 2016/2017 is (\$107.4 million); and the estimated annual net aggregate increase in gross Medicaid expenditures attributable to an extension of upper payment limit (UPL) payments for state fiscal year 2016/2017 in \$2.2 billion.

The public is invited to review and comment on this proposed State Plan Amendment. Copies of which will be available for public review on the Department's website at http://www.health.ny.gov/regulations/state_plans/status.

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

For further information and to review and comment, please contact: Department of Health, Division of Finance and Rate Setting, 99 Washington Ave. – One Commerce Plaza, Suite 1460, Albany, NY 12210, e-mail: spa_inquiries@health.ny.gov

PUBLIC NOTICE

Office for People with Developmental Disabilities and Department of Health

Pursuant to 42 CFR Section 447.205, the New York State Office for People with Developmental Disabilities (OPWDD) and the New York State Department of Health hereby gives public notice of the following:

OPWDD and the Department of Health proposes to amend the Title XIX (Medicaid) State Plan for non-institutional services related to the qualifications for OPWDD covered services to comply with proposed regulatory provisions. The following changes are proposed:

Effective on and after April 1, 2016, OPWDD will outline the qualifications for Independent Practitioner Services for Individuals with Developmental Disabilities (IPSIDD) that will be covered through the preventive services: Occupational Therapy; Physical Therapy; Speech and Language Pathology; and Psychotherapy. Additionally, OPWDD will show the Current Procedural Terminology (CPT) codes that will be covered and include a clarification that the Applied Behavioral Science Specialist (ABSS) title will not be limited to the treatment of individuals with an autism spectrum diagnosis.

The public is invited to review and comment on this proposed State Plan Amendment. Copies of which will be available for public review on the Department's website at http://www.health.ny.gov/regulations/state_plans/status.

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

For further information and to review and comment, please contact: Department of Health, Division of Finance and Rate Setting, 99 Washington Ave. – One Commerce Plaza, Suite 1460, Albany, NY 12210, e-mail: spa_inquiries@health.ny.gov

PUBLIC NOTICE

Department of State
F-2016-0033

Date of Issuance – March 30, 2016

The New York State Department of State (DOS) is required by Federal regulations to provide timely public notice for the activities described below, which are subject to the consistency provisions of the Federal Coastal Zone Management Act of 1972, as amended.

The applicant has certified that the proposed activity complies with and will be conducted in a manner consistent with the approved New

proved services rendered on or after April 1, 2016 to be increased by one percent was not included in the budget for state fiscal year 2016/2017, and will not be pursued at this time.

- The proposal regarding eligibility procedures for streamlining infants and toddlers referred to the Early Intervention Program (EIP) was not included in the budget for state fiscal year 2016/2017, and will not be pursued at this time.

- The proposal regarding cost-sharing limits applied to Medicare Part C (Medicare Advantage or Medicare managed care) claims is being amended to reflect the enacted provisions of the budget for state fiscal year 2016/2017. Under the enacted budget, Medicaid payment will now be limited to eighty-five percent of the amount of any co-payment or co-insurance liability. The provider would be required to accept the Medicare Part C health plan payment and any Medicaid payment as payment in full for the service and the member could not be billed for any co-payment/co-insurance amount that was not reimbursed by Medicaid.

The estimated annual net aggregate decrease in Medicaid expenditures attributable to this initiative contained in the budget for state fiscal year 2016/2017 is (\$11.45 million) gross.

Prescription Drugs:

- The proposal regarding establishing price ceilings on critical prescription drugs for which there is a significant public interest in ensuring rational pricing by drug manufacturers, was not included in the budget for state fiscal year 2016/2017, and will not be pursued at this time.

- The proposal that would have limited fee-for-service reimbursement for a pharmacy prescription drug designated as a specialty drug by one or more Medicaid managed care providers to the amount such providers pay for the drug was not included in the budget for state fiscal year 2016/2017, and will not be pursued at this time.

- Clarifies the initiative previously noticed March 30, 2016, regarding the price of a generic prescription drug dispensed to a NYS Medicaid enrollee (managed care or fee-for-service) increases at a rate greater than three hundred percent of its State maximum acquisition cost (SMAC) in comparison to its SMAC at any time during the course of the preceding twelve months, the commissioner of health is authorized to require the drug manufacturer to provide rebates to the Department, limited to the amount by which the current SMAC for the drug exceeds three hundred percent. Such rebates shall be in addition to any rebates payable to the Department pursuant any other provision of federal or state law. During State fiscal year 2016-2017, if the Centers for Medicare and Medicaid Services has adopted a final methodology for determining the amount of additional rebates under the federal generic drug price increase rebate program pursuant to 42 U.S.C. § 1396r-8(c)(3), as amended by section 602 of the Bipartisan Budget Act of 2015, the department may collect for a given drug the portion of the rebate determined under this paragraph that is in excess of the rebate required by such federal rebate program.

The estimated annual net aggregate decrease in gross Medicaid expenditures attributable to this initiative contained in the budget for state fiscal year 2016/2017 is (\$47.5 million) and state fiscal year 2017/2018 (\$47.5 million).

The public is invited to review and comment on this proposed State Plan Amendment. Copies of which will be available for public review on the Department's website at http://www.health.ny.gov/regulations/state_plans/status.

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

For further information and to review and comment, please contact:
Department of Health, Division of Finance and Rate Setting, 99 Washington Ave., One Commerce Plaza, Suite 1460, Albany, NY 12210, e-mail: spa_inquiries@health.ny.gov

PUBLIC NOTICE

Department of State

A meeting of the New York State Board of Real Estate Appraisal will be held on May 23, 2016 at 10:30 a.m. at the Department of State, 99 Washington Ave., Rm. 505, Albany; 65 Court St., Rm. 208, Buffalo; and 123 William St., Rm. 231, New York City.

Should you wish to attend or require further information, please contact Sharon Charland, Board Coordinator, at sharon.charland@dos.ny.gov or (518) 473-2733.

PUBLIC NOTICE

Department of State

F-2015-1065

Date of Issuance – May 11, 2016

The New York State Department of State (DOS) is required by Federal regulations to provide timely public notice for the activities described below, which are subject to the consistency provisions of the Federal Coastal Zone Management Act of 1972, as amended.

The applicant has certified that the proposed activity complies with and will be conducted in a manner consistent with the approved New York State Coastal Management Program. The applicant's consistency certification and accompanying public information and data are available for inspection at the New York State Department of State offices located at One Commerce Plaza, 99 Washington Avenue, in Albany, New York.

In F-2015-1065, Selkirk Lighthouse & Marina, is proposing to repair the existing erosion and protect the shoreline by adding a large rip-rap along the eastern shore of Salmon River near the mouth to Lake Ontario, in the Town of Richland. Selkirk Lighthouse & Marina proposes to construct approximately 170-feet of machined placed rip-rap wall to repair and provide erosion protection of the existing shoreline. The rip-rap will be placed at a max of 2H:1V slope. Rip-rap will be placed to re-align the shoreline where areas have been eroded. Some vegetative shoreline stabilization may be used as well, particularly in front of the one-story building in the northern portion of the project area. The total amount of fill placed below the mean high water line is a minimum of 48 CYS. Approximately 30 CYS will be removed and live loaded/removed offsite to allow the placement of the setting stone prior to placing the large machined place rip-rap. A turbidity curtain will be installed and a tracked excavator will be used from upland to prepare and place the large rip-rap. The stated purpose of the proposed action is the "Protection/restoration of shoreline and property."

Any interested parties and/or agencies desiring to express their views concerning any of the above proposed activities may do so by filing their comments, in writing, no later than 4:30 p.m., 15 days from the date of publication of this notice, or, May 26, 2016.