NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

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

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

JUN 15 2017

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

RE: SPA #17-0005
Non-Institutional Services

Dear Mr. Melendez:

The State requests approval of the enclosed amendment #17-0005 to the Title XIX (Medicaid) State Plan for non-institutional services to be effective April 1, 2017 (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 legislation 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 29, 2017, 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. Helgerson
Medicaid Director
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: **17-0005**	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, 2017**	
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: **§1902(r)(5) of the Social Security Act, and 42 CFR 447**	7. FEDERAL BUDGET IMPACT: **(in thousands)** **a. FFY 04/01/17-09/30/17 $2,750.00** **b. FFY 10/01/17-09/01/18 $5,500.00**	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: **Attachment 4.19-B: Page 4(d); 4(d)(1); 4(d)(2); 4(e)**	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: **Attachment 4.19-B: Page 4(d); 4(e)**	
10. SUBJECT OF AMENDMENT: **Pharmacy Drug Reimbursement** **(FMAP = 50%)**		
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: 13. TYPED NAME: **Jason A. Helgerson** 14. TITLE: **Medicaid Director** **Department of Health** 15. DATE SUBMITTED: JUN 15 2017	16. RETURN TO: **New York State Department of Health** **Bureau of Federal Relations & Provider Assessments** **99 Washington Ave – One Commerce Plaza** **Suite 1432** **Albany, NY 12210**	
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:		

FORM HCFA-179 (07-92)

Appendix I
2017 Title XIX State Plan
Second Quarter Amendment
Amended SPA Pages

New York
4(d)

Reimbursement for Prescribed Drugs (including specialty drugs) dispensed by a retail pharmacy, an institutional or long term care pharmacy or any other pharmacy enrolled in the NYS Medicaid FFS Program is the lower of:

1) Ingredient cost (plus a professional dispensing fee when a covered outpatient drug); or
2) the billing pharmacy's usual and customary price charged to the general public.

Ingredient cost is as follows:

Brand Name Drugs:

Ingredient cost is the National Average Drug Acquisition Cost (NADAC); or, in the event of no NADAC pricing available, Wholesale Acquisition Cost (WAC) less 3.3%.

Generic Drugs:

Ingredient cost is the lower of:

1) NADAC; or
2) the upper limit if established by the Federal Government for specific multiple source drugs; or
3) the State Maximum Acquisition Cost (SMAC)

New York
4(d)(1)

In the event of no NADAC pricing available, Ingredient cost is the lower of:

1) WAC less 17.5%; or
2) the upper limit if established by the Federal Government for specific multiple source drugs; or
3) the SMAC

Over-the Counter (OTC) Drugs:

Ingredient cost is the lower of:

1) NADAC; or
2) the upper limit if established by the Federal Government for specific multiple source drugs; or
3) the SMAC

In the event of no NADAC pricing available, Ingredient cost is the lower of:

4) WAC;
5) the upper limit if established by the Federal Government for specific multiple source drugs; or
6) the SMAC

Ingredient cost for drugs dispensed by pharmacies that are acquired at a nominal price as referenced in 42 CFR § 447.502 or via the Federal Supply Schedule is at actual acquisition cost.

Ingredient Cost for 340B-purchased drugs is at actual acquisition cost when dispensed by the following:

- A covered entity as described in section 1927(a)(5)(B) of the Act. (340B covered entity pharmacy).

New York
4(d)(2)

- A contract pharmacy under contract with a 340B covered entity as described in section 1927(a)(5)(B) of the Act.
- An Indian Health Service, tribal and urban Indian pharmacy.

The professional dispensing fee for brand name, generic, and OTC covered outpatient drugs, including 340B-purchased drugs, when dispensed by a retail pharmacy, an institutional or long term care pharmacy or any other pharmacy enrolled in the NYS Medicaid FFS Program, is $10.00.

Payment for clotting factor dispensed by a pharmacy enrolled in the NYS Medicaid FFS Program will include the drug ingredient cost plus a $10.00 professional dispensing fee. The drug ingredient cost shall be the lower of usual and customary or SMAC.

Physician administered drugs submitted under the medical benefit are reimbursed at actual acquisition cost by invoice. Covered entities using drugs purchased at the prices authorized under Section 340B of the Public Health Services Act for Medicaid members must bill Medicaid their actual acquisition cost.

Reimbursement for Investigational Drugs (if/when approved by a Medical Director) shall be actual acquisition cost by invoice.

New York
4(e)

Compound Drugs: Reimbursement is determined by the State Department of Health at the cost of ingredients plus the current dispensing fee.

Exception: Physician Override: Reimbursement for those brand name drugs for which there are generic equivalent drugs for which reimbursement is not to exceed the aggregate of the specified upper limit for the particular drug established by the Centers for Medicare and Medicaid Services, plus a dispensing fee, will be paid at the lower of the estimated acquisition cost, plus a dispensing fee, or at the provider's usual and customary price charged to the general public when the prescriber has obtained a prior authorization when required for the brand-name drug, indicated that the brand name drug is required by placing "daw" (dispense as written) in the box located on prescription form and by writing "brand necessary" or "brand medically necessary" in his/her own handwriting on the face of the prescription.

Where it has been determined that reimbursement plus a dispensing fee does not exceed the aggregate for all drugs under the Federal Upper Limit (FUL) program , the writing by the prescriber of "brand necessary" or "brand medically necessary" will not be required. Prior authorization will not be required for these select drugs.

Indian Health Clinics and tribal clinics which have licensed pharmacies, may submit fee-for-service claims for pharmacy services provided to Native Americans and will be reimbursed at the net acquisition cost for those drugs purchased through the Federal Supply Schedule or at an amount determined by the reimbursement methodology indicated above for all other purchased drugs.

Appendix II
2017 Title XIX State Plan
Second Quarter Amendment
Summary

SUMMARY
SPA #17-0005

This State Plan Amendment proposes to allow the Department of Health to move to actual acquisition cost (AAC) using the National Average Drug Acquisition Cost (NADAC) as the primary basis for its lower of reimbursement methodology for prescription drugs submitted for payment to the medical assistance program, along with a professional dispensing fee, effective April 1, 2017.

Appendix III
2017 Title XIX State Plan
Second Quarter Amendment
Authorizing Provisions

Subdivision 9 of Section 367-a of the Social Services Law:

9. Notwithstanding any inconsistent provision of law or regulation to the contrary, for those drugs which may not be dispensed without a prescription as required by section sixty-eight hundred ten of the education law and for which payment is authorized pursuant to paragraph (g) of subdivision two of section three hundred sixty-five-a of this title, and for those drugs that are available without a prescription as required by section sixty-eight hundred ten of the education law but are reimbursed as items of medical assistance pursuant to paragraph (a) of subdivision four of section three hundred sixty-five-a of this title, payments under this title shall be made at the following amounts:
(a) for drugs provided by medical practitioners and claimed separately by the practitioners, the actual cost of the drugs to the practitioners; and
(b) for drugs dispensed by pharmacies:
(i) (A) if the drug dispensed is a generic prescription drug, the lower of: (1) an amount equal to the national average drug acquisition cost set by the federal centers for medicare and medicaid services for the drug, if any, or if such amount if not available, the wholesale acquisition cost of the drug based on the package size dispensed from, as reported by the prescription drug pricing service used by the department, less seventeen and one-half percent thereof; (2) the federal upper limit, if any, established by the federal centers for medicare and medicaid services; (3) the state maximum acquisition cost, if any, established pursuant to paragraph (e) of this subdivision; or (4) the dispensing pharmacy's usual and customary price charged to the general public; (B) if the drug dispensed is available without a prescription as required by section sixty-eight hundred ten of the education law but is reimbursed as an item of medical assistance pursuant to paragraph (a) of subdivision four of section three hundred sixty-five-a of this title, the lower of (1) an amount equal to the national average drug acquisition cost set by the federal centers for medicare and medicaid services for the drug, if any, or if such amount is not available, the wholesale acquisition cost of the drug based on the package size dispensed from, as reported by the prescription drug pricing service used by the department, (2) the federal upper limit, if any, established by the federal centers for medicare and medicaid services; (3) the state maximum acquisition cost if any, established pursuant to paragraph (e) of this subdivision; or (4) the dispensing pharmacy's usual and customary price charged to the general public;
(ii) if the drug dispensed is a brand-name prescription drug, the lower of:
(A) an amount equal to the national average drug acquisition cost set by the federal centers for medicare and medicaid services for the drug, if any, or if such amount is not available, the wholesale acquisition cost of the drug based on the package size dispensed from, as reported by the prescription drug pricing service used by the department, less three and three-tenths percent thereof; or (B) the dispensing pharmacy's usual and customary price charged to the general public; and
(iii) notwithstanding subparagraphs (i) and (ii) of this paragraph and paragraphs (d) and (e) of this subdivision, if the drug dispensed is a drug that has been purchased from a manufacturer by a covered entity pursuant to section 340B of the federal public health service act (42 USCA § 256b), the actual amount paid by such covered entity pursuant to such section, plus the reasonable administrative costs, as determined by the commissioner, incurred by the covered entity or by an authorized

contract pharmacy in connection with the purchase and dispensing of such drug and the tracking of such transactions. For purposes of this subparagraph, a "covered entity" is an entity that meets the requirements of paragraph four of subsection (a) of such section, that elects to participate in the program established by such section, and that causes claims for payment for drugs covered by this subparagraph to be submitted to the medical assistance program, either directly or through an authorized contract pharmacy. No medical assistance payments may be made to a covered entity or to an authorized contract pharmacy of a covered entity for drugs that are eligible for purchase under the section 340B program and are dispensed on an outpatient basis to patients of the covered entity, other than under the provisions of this subparagraph. Pharmacies submitting claims for reimbursement of drugs purchased pursuant to section 340B of the public health service act shall notify the department that the claim is eligible for purchase under the 340B program, consistent with claiming instructions issued by the department to identify such claims.

(c) Notwithstanding subparagraph (i) of paragraph (b) of this subdivision, if a qualified prescriber certifies "brand medically necessary" or "brand necessary" in his or her own handwriting directly on the face of a prescription for a multiple source drug for which a specific upper limit of reimbursement has been established by the federal agency, in addition to writing "d a w" in the box provided for such purpose on the prescription form, payment under this title for such drug must be made under the provisions of subparagraph (ii) of such paragraph.

(d) In addition to the amounts paid pursuant to paragraph (b) of this subdivision, the department shall pay a professional pharmacy dispensing fee for each such drug dispensed in the amount of ten dollars per prescription or written order of a practitioner; provided, however that this professional dispensing fee will not apply to drugs that are available without a prescription as required by section sixty-eight hundred ten of the education law but do not meet the definition of a covered outpatient drug pursuant to Section 1927K of the Social Security Act.

Appendix IV
2017 Title XIX State Plan
Second Quarter Amendment
Public Notice

provided by a county operated freestanding mental health or substance abuse DTC. Distributions shall be based on each eligible facility's proportionate share of the sum of all DTC and clinic visits for all eligible facilities receiving payments for the base year two years prior to the rate year. The proportionate share payments may be added to rates of payment or made as aggregate payments to eligible facilities.

• Effective on or after April 1, 2017, eliminates supplemental medical assistance payments of up to $6 million annually made to providers of emergency medical transportation.

• Continues, effective for periods on and after April 1, 2017, funds to certified home health agencies, AIDS home care providers, and hospice service providers for the purpose of improving recruitment, training, and retention of home health aides or other personnel with direct patient care responsibility.

The estimated annual net aggregate increase in gross Medicaid expenditures attributable to this initiative contained in the budget for state fiscal year 2017/2018 is $26 million.

• Extends current provisions to services on and after April 1, 2017 through March 30, 2020, the reimbursable operating cost component for general hospital outpatient rates and adult day health care services provided by RHCFs rates will be established with the final 2006 trend factor equal to the final consumer price index (CPI) for all urban consumers less 0.25%.

• Extends current provisions for certified home health agency administrative and general cost reimbursement limits for the periods April 1, 2017 through March 31, 2020.

• Effective April 1, 2017, continues the supplemental upper payment limit payments made to general hospitals, other than major public general hospitals under non-institutional services of $339 million annually.

• Capital related costs of a general hospital excluding 44% of the major movable costs and excluding staff housing costs will continue effective April 1, 2017 through March 31, 2020.

The estimated gross annual decrease in Medicaid expenditures for state fiscal year 2017/2018 for this initiative is ($35.1) million.

Prescription Drugs:

• Effective April 1, 2017, in an effort to mitigate high drug costs, the Department proposes to establish requirements for manufacturers to pay a penalty in the form of a rebate, as well as impose a surcharge on wholesalers and manufacturers for certain high priced drugs.

o The Department will collect confidential information from drug manufacturers related to drug costs and prices, and with the assistance of the drug utilization review board (DURB), identify for review drugs which: are first introduced to market at prohibitively expensive prices, experience a large increase in price not explained by a relevant factor, or are priced disproportionally given limited therapeutic benefits. If a manufacturer's price exceeds the reasonable value of the drug, as determined by the DURB, the Board would recommend that a benchmark price be established and the excess amount would be subject to a Medicaid rebate and a surcharge.

o A list of such designated high priced drugs shall be published on the Department's website, along with the date on which each drug first appeared on the list, and its associated benchmark price.

o A surcharge of 60% shall be imposed on the excess charge amount of the gross receipt from the first in-state sale of a high priced drug. The surcharge shall be deposited into a designated High Priced Drug Reimbursement Fund, and paid out through the Department of Financial Services to health insurers and the Medicaid program in proportion to their respective costs attributable to the drug.

The estimated annual aggregate decrease in Medicaid expenditures for state fiscal year 2017/2018 for this initiative is $110 million.

• The Department proposes to amend the reimbursement for prescription drugs dispensed, effective April 1, 2017. These changes will bring the reimbursement methodology into compliance with Federal regulations.

o Reimbursement for prescribed drugs will be the lower of ingredient cost (plus a professional dispensing fee when a covered outpatient drug), or the billing pharmacy's usual and customary charge.

o For brand name drugs, the ingredient cost will be the National Average Drug Acquisition Cost (NADAC); or, in the event of no NADAC pricing available, Wholesale Acquisition Cost (WAC) less 3.3%.

o For generic drugs, ingredient cost will be the lower of NADAC; or the Federal Upper Limit (FUL); or the State Maximum Acquisition Cost (SMAC). In the event of no NADAC pricing available, ingredient cost is the lower of WAC less 17.5%; or the FUL; or SMAC.

o For over-the-counter drugs, ingredient cost will be the lower of NADAC; or FUL; or SMAC. In the event of no NADAC pricing available, ingredient cost is the lower of WAC; FUL; or SMAC.

o The professional dispensing fee for brand name, generic, and OTC covered outpatient drugs will be $10.00.

The estimated annual aggregate increase in Medicaid expenditures for state fiscal year 2017/2018 for this initiative is $11 million.

• Effective July 1, 2017, the co-pay for over-the-counter (OTC) non-prescription drug/items will be increased from $0.50 to $1.00. In addition, modifications to the list of covered drug/items in this category may be filed as regulations by the commissioner of health without prior notice and comment.

The estimated annual aggregate decrease in Medicaid expenditures for state fiscal year 2017/2018 for this initiative is $12.6 million.

• Effective July 1, 2017, the Department proposes to amend the copayment for brand name prescription drugs dispensed in order to eliminate the difference in co-pay between a preferred drug and a non-preferred drug, in accordance with federal requirements:

o The co-pay for brand-name prescription drugs will be changed to $2.50, regardless of their status on or off the preferred drug list; provided, however, that the copayments for brand name prescriptions drugs in the Fee-for-Service Brand Less Than Generic program will continue to be $1.00.

There is no additional estimated annual change to gross Medicaid expenditures as a result of the clarifying proposed amendments.

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 2017/2018 is $282,506,637 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 2017/2018 in $2.5 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