NEW YORK
state department of
HEALTH

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

Sue Kelly
Executive Deputy Commissioner

January 6, 2014

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 #13-72
Non-Institutional Services

Dear Mr. Melendez:

The State requests approval of the enclosed amendment #13-72 to the Title XIX (Medicaid) State Plan for non-institutional services to be effective January 1, 2014 (Appendix I). This amendment is being submitted based on revisions to section 2502 of the Affordable Care Act. 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 proposed 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 24, 2013, is also enclosed for your information (Appendix IV).

If you have any questions regarding this State Plan submission, please do not hesitate to contact John E. Ulberg, Jr., Medicaid Chief Financial Officer, Division of Finance and Rate Setting 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<br><br>FOR: HEALTH CARE FINANCING ADMINISTRATION | 1. TRANSMITTAL NUMBER: **13-72** | 2. STATE<br>**New York** |
|---|---|---|
| | 3. PROGRAM IDENTIFICATION: **TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)** | |
| TO: REGIONAL ADMINISTRATOR<br>HEALTH CARE FINANCING ADMINISTRATION<br>DEPARTMENT OF HEALTH AND HUMAN SERVICES | 4. PROPOSED EFFECTIVE DATE<br>**January 1, 2014** | |

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:<br>**Section 2502 of the Affordable Care Act** | 7. FEDERAL BUDGET IMPACT:<br>**a. FFY 01/01/14-09/30/14 $ 12,255**<br>**b. FFY 10/01/14-09/30/15 $ 12,255** |
|---|---|
| 8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:<br><br>**Attachment 3.1-A Supplement: Page 2c**<br>**Attachment 3.1-B Supplement: Page 2c** | 9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:<br><br>**Attachment 3.1-A Supplement: Page 2c**<br>**Attachment 3.1-B Supplement: Page 2c** |

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
☐ 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:<br>**New York State Department of Health**<br>**Bureau of Federal Relations & Provider Assessments**<br>**99 Washington Ave – One Commerce Plaza**<br>**Suite 1430**<br>**Albany, NY 12210** |
|---|---|
| 13. TYPED NAME: **Jason A. Helgerson** | |
| 14. TITLE: **Medicaid Director**<br>**Department of Health** | |
| 15. DATE SUBMITTED: January 6, 2014 | |

**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**
**2014 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.

☒ **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
- [☒ (h) barbiturates: All (Except for dual eligible individuals, effective January 1, 2013, when used in the treatment of epilepsy, cancer or a chronic mental health disorder, as Part D will cover those indications.)
- ☒ (i) benzodiazepines: All (Except for dual eligible individuals, effective January 1, 2013, as Part D will cover all indications.)
- ☒ (j) smoking cessation for non-dual eligibles as Part D will cover: All]

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.

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
- [☒ (h) barbiturates: All (Except for dual eligible individuals, effective January 1, 2013, when used in the treatment of epilepsy, cancer or a chronic mental health disorder, as Part D will cover those indications.)
- ☒ (i) benzodiazepines: All (Except for dual eligible individuals effective January 1, 2013, as Part D will cover all indications.)
- ☒ (j) smoking cessation for non-dual eligibles as Part D will cover: All]

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

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

13d. Rehabilitative Services

# Appendix II
# 2014 Title XIX State Plan
# First Quarter Amendment
# Non-Institutional Services
# Summary

**SUMMARY**
**SPA #13-72**

Effective January 1, 2014, Section 1927(d)(7) of the Act prohibits states from excluding the following drugs or their medical uses from coverage: benzodiazepines, barbiturates, and agents used to promote smoking cessation, (including OTC agents approved by the FDA). States were instructed by CMS to submit a SPA to remove benzodiazepines, barbiturates, and smoking cessation drugs from the list of drugs a State can exclude from coverage or restrict. If the language appears on the state plan they cannot just uncheck the box, the language on the state plan needs to be removed, and also, revise the assigned numbering and/or lettering on the plan page(s).

Currently, NYS Medicaid provides coverage for these excludable drugs for all full benefit non-dual eligible Medicaid beneficiaries; therefore, this technical change will not have a fiscal impact on the full benefit non-dual eligible Medicaid beneficiaries.

For the full benefit dual eligible population, NYS Medicaid currently provides coverage for barbiturates when used in the treatment of conditions other than epilepsy, cancer or a chronic mental health disorder, as Part D does not cover barbiturates when used in the treatment of these other conditions. Effective 1/1/2014, barbiturates qualify as Part D drugs for all medically accepted indications and are no longer covered under Medicaid. Therefore, this coverage by NYS Medicaid will discontinue. The fiscal impact reflects the discontinuance of this coverage for the full-benefit dual eligible population.

# Appendix III
# 2014 Title XIX State Plan
# First Quarter Amendment
# Non-Institutional Services
# Authorizing Provisions

"(B) subject to discounts under section 340B of the Public Health Service Act.".

(d) ADDITIONAL REBATE FOR NEW FORMULATIONS OF EXISTING DRUGS.—

(1) IN GENERAL.—Section 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)) is amended by adding at the end the following new subparagraph:

"(C) TREATMENT OF NEW FORMULATIONS.—[*Replaced by section 1206(a) of HCERA*] In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation with respect to such drug under this section shall be the amount computed under this section for such new drug or, if greater, the product of—

"(i) the average manufacturer price of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form;

"(ii) the highest additional rebate (calculated as a percentage of average manufacturer price) under this section for any strength of the original single source drug or innovator multiple source drug; and

"(iii) the total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

In this subparagraph, the term 'line extension' means, with respect to a drug, a new formulation of the drug, such as an extended release formulation.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to drugs that are paid for by a State after December 31, 2009.

(e) MAXIMUM REBATE AMOUNT.—Section 1927(c)(2) of such Act (42 U.S.C. 1396r–8(c)(2)), as amended by subsection (d), is amended by adding at the end the following new subparagraph:

"(D) MAXIMUM REBATE AMOUNT.—In no case shall the sum of the amounts applied under paragraph (1)(A)(ii) and this paragraph with respect to each dosage form and strength of a single source drug or an innovator multiple source drug for a rebate period beginning after December 31, 2009, exceed 100 percent of the average manufacturer price of the drug.".

(f) CONFORMING AMENDMENTS.—

(1) IN GENERAL.—Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended—

(A) in subsection (a)(2)(B)(i), by striking "1927(c)(4)" and inserting "1927(c)(3)"; and

(B) by striking subsection (c); and

(C) redesignating subsection (d) as subsection (c).

(2) EFFECTIVE DATE.—The amendments made by this subsection take effect on January 1, 2010.

**SEC. 2502. ELIMINATION OF EXCLUSION OF COVERAGE OF CERTAIN DRUGS.**

(a) IN GENERAL.—Section 1927(d) of the Social Security Act (42 U.S.C. 1397r–8(d)) is amended—

(1) in paragraph (2)—

(A) by striking subparagraphs (E), (I), and (J), respectively; and

(B) by redesignating subparagraphs (F), (G), (H), and (K) as subparagraphs (E), (F), (G), and (H), respectively; and

(2) by adding at the end the following new paragraph:

"(7) NON-EXCLUDABLE DRUGS.—The following drugs or classes of drugs, or their medical uses, shall not be excluded from coverage:

"(A) Agents when used to promote smoking cessation, including agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

"(B) Barbiturates.

"(C) Benzodiazepines.".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2014.

**SEC. 2503. PROVIDING ADEQUATE PHARMACY REIMBURSEMENT.**

(a) PHARMACY REIMBURSEMENT LIMITS.—

(1) IN GENERAL.—Section 1927(e) of the Social Security Act (42 U.S.C. 1396r–8(e)) is amended—

(A) in paragraph (4), by striking "(or, effective January 1, 2007, two or more)"; and

(B) by striking paragraph (5) and inserting the following:

"(5) USE OF AMP IN UPPER PAYMENT LIMITS.—The Secretary shall calculate the Federal upper reimbursement limit established under paragraph (4) as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. The Secretary shall implement a smoothing process for average manufacturer prices. Such process shall be similar to the smoothing process used in determining the average sales price of a drug or biological under section 1847A.".

(2) DEFINITION OF AMP.—Section 1927(k)(1) of such Act (42 U.S.C. 1396r–8(k)(1)) is amended—

(A) in subparagraph (A), by striking "by" and all that follows through the period and inserting "by—

"(i) wholesalers for drugs distributed to retail community pharmacies; and

"(ii) retail community pharmacies that purchase drugs directly from the manufacturer."; and

(B) by striking subparagraph (B) and inserting the following:

"(B) EXCLUSION OF CUSTOMARY PROMPT PAY DISCOUNTS AND OTHER PAYMENTS.—

"(i) IN GENERAL.—The average manufacturer price for a covered outpatient drug shall exclude—

**Appendix IV**
**2014 Title XIX State Plan**
**First Quarter Amendment**
**Non-Institutional Services**
**Public Notice**

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, Bureau of Federal Relations & Provider Assessments, 99 Washington Ave. – One Commerce Plaza, Suite 1430, Albany, NY 12210, (518) 474-1673, (518) 473-8825 (FAX), e-mail: spa_inquiries@health.state.ny.us

## 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 to remove coverage of barbiturates used in all medically accepted indications for dual eligible beneficiaries effective January 1, 2014.

Section 1927(d)(2) of the Act has been amended effective January 1, 2014, to remove barbiturates from the list of excludable drugs, thereby qualifying barbiturates as a covered Part D drug for all medically accepted indications. Currently, barbiturates are covered for dual eligible beneficiaries when used for indications other than epilepsy, cancer, and chronic mental health disorders.

Since the coverage of barbiturates under Part D is inclusive of all indications, New York State proposes to provide coverage for only non-dual eligible beneficiaries.

The estimated annual net aggregate decrease in gross Medicaid expenditures attributable to this initiative contained in the budget for state fiscal year 2013/14 is up to $22,000.

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

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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*: Department of Health, Bureau of Federal Relations & Provider Assessments, 99 Washington Ave. – One Commerce Plaza, Suite 1430, Albany, NY 12210, (518) 474-1673, (518) 473-8825 (FAX), e-mail: spa_inquiries@health.state.ny.us