NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

MARY T. BASSETT, M.D., M.P.H.
Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

June 30, 2022

James G. Scott, Director
Division of Program Operations
Centers for Medicare & Medicaid Services
601 E. 12th St., Room 355
Kansas City, Missouri 64106

RE: SPA #22-0036
Non-Institutional Services

Dear Mr. Scott:

The State requests approval of the enclosed amendment #22-0036 to the Title XIX (Medicaid) State Plan for non-institutional services to be effective April 1, 2022 (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 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.

A copy of pertinent sections of enacted legislation is 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, 2022, 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 Regina Deyette, Medicaid State Plan Coordinator, Division of Finance and Rate Setting, Office of Health Insurance Programs at (518) 473-3658.

Sincerely,

Amir Bassiri
Acting Medicaid Director
Office of Health Insurance Programs

Enclosures

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB No. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES

1. TRANSMITTAL NUMBER: 22-0036

2. STATE: NY

3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT: (●) XIX ( ) XXI

TO: CENTER DIRECTOR
CENTERS FOR MEDICAID & CHIP SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
April 1, 2022

5. FEDERAL STATUTE/REGULATION CITATION
42 CFR 447 Subpart I; 42 CFR § 447.502

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 04/01/22-09/30/22 $ (500,000)
b. FFY 10/01/22-09/30/23 $ (1,000,000)

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Attachment 3.1-A Supp-Page 2(b)
Attachment 3.1-B Supp-Page 2(b)

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*
Attachment 3.1-A Supp-Page 2(b)
Attachment 3.1-B Supp-Page 2(b)

9. SUBJECT OF AMENDMENT
Value Based Outcomes Arrangements

10. 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:

11. SIGNATURE OF STATE AGENCY OFFICIAL
[redacted]

12. TYPED NAME
Amir Bassiri

13. TITLE
Acting Medicaid Director

14. DATE SUBMITTED
June 30, 2022

15. RETURN TO
New York State Department of Health
Division of Finance and Rate Setting
99 Washington Ave – One Commerce Plaza
Suite 1432
Albany, NY 12210

FOR CMS USE ONLY

16. DATE RECEIVED

17. DATE APPROVED

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL

19. SIGNATURE OF APPROVING OFFICIAL

20. TYPED NAME OF APPROVING OFFICIAL

21. TITLE OF APPROVING OFFICIAL

22. REMARKS

Instructions on Back

Appendix I
2022 Title XIX State Plan
Second Quarter Amendment
Amended SPA Pages

New York
2(b)

10. Prior approval is required for all dental care except preventive prophylactic and other routine dental care services and supplies.

1905(a)(12) Prescribed Drugs, Dentures, and Prosthetic Devices; and eyeglasses.

12a. Prior authorization or dispensing validation is required for some prescription drugs. The State has established a preferred drug program with prior authorization for drugs not included on the preferred drug list. The prior authorization complies with the requirements of Section 1927(d)(5) of the Social Security Act and provides for a 24-hour turnaround by either telephone or other telecommunications device from receipt of request and provides for a 72-hour supply of drugs in emergency circumstances. In addition, brand-name drugs that have a FDA approved, A-rated generic equivalent must be prior authorized unless exempted by the Commissioner of Health. Prior authorization is required for a generic equivalent of a brand name drug, including a generic equivalent that is on the preferred drug list or the clinical drug review program, when the net cost of the brand name drug, after consideration of all rebates, is less than the cost of the generic equivalent.

Drugs for which Medical Assistance reimbursement is available are limited to the following:

1. Outpatient drugs of any manufacturer which has entered into and complies with a rebate agreement under Sections 1902(a)(54) and 1927(a) of the Act with the Centers for Medicare and Medicaid Services (CMS) which are prescribed for a medically accepted indication. All drugs covered by the National Drug Rebate Agreements remain available to Medicaid beneficiaries, although some may require prior authorization. Drugs for the treatment of erectile dysfunction, as set forth in 42 U.S.C. §1396r-8(d)(2)(K), are not a covered service, on and after April 1, 2006, unless such drugs are used to treat conditions other than sexual or erectile dysfunction and these uses have been approved by the Food and Drug Administration.

2. Supplemental Rebate Programs

   The State is in compliance with Section 1927 of the Social Security Act. The State has the following policies for the Supplemental Rebate Programs for the Medicaid population.

   a) CMS has authorized the State of New York to enter into the National Medicaid Pooling Initiative (NMPI) for drugs provided to Medicaid beneficiaries. The NMPI Supplemental Rebate Agreement (SRA) and the Amendment to the SRA submitted to CMS on March 30, 2006 have been authorized for pharmaceutical manufacturers' existing agreements through their current expiration dates. The updated NMPI SRA submitted to CMS on June 30, 2013 has been authorized for renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid beneficiaries.

      i. Effective on or after July 1, 2020, the Department will implement a single statewide formulary for opioid dependence agents and opioid antagonists for all Medicaid participating managed care organizations (MCO's) and for Medicaid fee for service, under the prescribed conditions in Attachment A-2 of the NMPI Supplemental Rebate Agreement.

   b) CMS has authorized the State of New York to enter into Medicaid State-specific Supplemental Rebate Agreement directly with manufacturers to receive supplemental rebates of covered outpatient drugs for Medicaid beneficiaries. The State-specific Supplemental Rebate Agreement was submitted to CMS on December 31, 2014 and has been authorized by CMS.

   c)CMS has authorized the State of New York to enter into outcomes-based contract arrangements with drug manufacturers for drugs provided to Medicaid beneficiaries. These contracts will be executed on the contract template titled "Value-Based Supplemental Rebate Agreement" submitted to CMS and authorized for use beginning April 1, 2022.

New York
2(b)

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Appendix II
2022 Title XIX State Plan
Second Quarter Amendment
Summary

SUMMARY
SPA #22-0036

This amendment proposes to revise the State Plan to allow the State to enter into outcomes-based contract arrangements with drug manufacturers through supplemental rebate agreements.

Appendix III
2022 Title XIX State Plan
Second Quarter Amendment
Authorizing Provisions

42 CFR § 447.502 - Definitions.

§ 447.502 Definitions.

For the purpose of this subpart, the following definitions apply:

Actual acquisition cost (AAC) means the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers.

Authorized generic drug means any drug sold, licensed, or marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA) under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand name drug.

Bona fide service fee means a fee paid by a manufacturer to an entity that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. The fee includes, but is not limited to, distribution service fees, inventory management fees,

product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs).

Brand name drug means a single source or innovator multiple source drug.

Bundled sale means any arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit national drug code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.

(1) The discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement.

(2) For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle.

(3) Value-based purchasing (VBP) arrangements may qualify as a bundled sale.

Clotting factor means a hemophilia clotting factor 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 CMS and posted on the CMS Web site.

CMS-authorized supplemental rebate agreement means an agreement that is approved through a state plan amendment (SPA) by CMS, which allows a state to enter into single and/or multi-state supplemental drug rebate arrangements that generate rebates that are at least as large as the rebates set forth in the Secretary's national rebate agreement with drug manufacturers. Revenue from these rebates must be paid directly to the state and be used by the state to offset a state's drug expenditures resulting in shared savings with the Federal Government.

Consumer Price Index - Urban (CPI-U) means the index of consumer prices developed and updated by the U.S. Department of Labor. It is the CPI for all urban consumers (U.S. average) for the month before the beginning of the calendar quarter for which the rebate is paid.

Covered outpatient drug means, of those drugs which are treated as a prescribed drug for the purposes of section 1905(a)(12) of the Act, a drug which may be dispensed only upon a prescription (except as provided in paragraphs (2) and (3) of this definition).

(1) A drug can only be considered a covered outpatient drug if it:

(i) Is approved for safety and effectiveness as a prescription drug by the FDA under section 505 or 507 of the FFDCA or under section 505(j) of the FFDCA;

(ii) Was commercially used or sold in the United States before the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug, and which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the FFDCA) or an action brought by the Secretary under sections 301, 302(a), or 304(a) of FFDCA to enforce section 502(f) or 505(a) of the FFDCA;

(iii) Is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need or is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug or for which the Secretary has not issued a notice for an opportunity for a hearing under section 505(e) of the FFDCA on a proposed order of the Secretary to withdraw approval of an application for such drug under section 505(e) of the FFDCA because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling;

(iv) Is a biological product other than a vaccine that may only be dispensed upon a prescription and is licensed under section 351 of the Public Health Service Act (PHSA) and is produced at an establishment licensed under section 351 of the PHSA to produce such product; or

(v) Is insulin certified under section 506 of the FFDCA.

(2) A covered outpatient drug does not include any drug, biological product, or insulin provided as part of or incident to and in the same setting as any of the following services (and for which payment may be made as part of that service instead of as a direct reimbursement for the drug):

(i) Inpatient Services;

(ii) Hospice Services;

(iii) Dental Services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;

(iv) Physician services;

(v) Outpatient hospital services;

(vi) Nursing facility and services provided by an intermediate care facility for individuals with intellectual disabilities;

(vii) Other laboratory and x-ray services; or

(viii) Renal dialysis.

(3) A covered outpatient drug does not include:

(i) Any drug product, prescription or over-the-counter (OTC), for which an NDC number is not required by the FDA;

(ii) Any drug product for which a manufacturer has not submitted to CMS evidence to demonstrate that the drug product satisfies the criteria in paragraph (1) of this definition;

(iii) Any drug product or biological used for a medical indication which is not a medically accepted indication; or

(iv) Over-the-counter products that are not drugs.

Customary prompt pay discount means any discount off of the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified timeframe and consistent with customary business practices for payment.

Innovator multiple source drug means a multiple source drug, including an authorized generic drug, that is marketed under a new drug application (NDA) approved by FDA, unless the Secretary determines that a narrow exception applies (as described in this section). It also includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA) or antibiotic drug application (ADA).

Lagged price concession means any discount or rebate that is realized after the sale of the drug, but does not include customary prompt pay discounts.

Line extension means, for a drug, a new formulation of the drug, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary).

Manufacturer means any entity that holds the NDC for a covered outpatient drug or biological product and meets the following criteria:

(1) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

(2) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(3) For authorized generic products, the term "manufacturer" will also include the original holder of the NDA.

(4) For drugs subject to private labeling arrangements, the term "manufacturer" will also include the entity under whose own label or trade name the product will be distributed.

Multiple source drug means, for a rebate period, a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act, for which there is at least 1 other drug product which meets all of the following criteria:

(1) Is rated as therapeutically equivalent (under the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" which is available at *http://www.accessdata.fda.gov/scripts/cder/ob/*).

(2) Except as provided at section 1927(k)(7)(B) of the Act, is pharmaceutically equivalent and bioequivalent, as defined at section 1927(k)(7)(C) of the Act and as determined by FDA.

(3) Is sold or marketed in the United States during the period.

National drug code (NDC) means the numerical code maintained by the FDA that includes the labeler code, product code, and package code. For purposes of this subpart, the NDC is considered to be an 11-digit code, unless otherwise specified in this subpart as being without regard to package size (that is, the 9-digit numerical code).

National rebate agreement means the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his or her designee and a manufacturer to implement section 1927 of the Act.

New formulation means, for a drug, a change to the drug, including, but not limited to: an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients.

Nominal price means a price that is less than 10 percent of the average manufacturer price (AMP) in the same quarter for which the AMP is computed.

Noninnovator multiple source drug means:

(1) A multiple source drug that is not an innovator multiple source drug or a single source drug;

(2) A multiple source drug that is marketed under an ANDA or an abbreviated antibiotic drug application;

(3) A covered outpatient drug that entered the market before 1962 that was not originally marketed under an NDA;

(4) Any drug that has not gone through an FDA approval process, but otherwise meets the definition of covered outpatient drug; or

(5) If any of the drug products listed in this definition of a noninnovator multiple source drug subsequently receives an NDA or ANDA approval from FDA, the product's drug category changes to correlate with the new product application type.

Oral solid dosage form means, an orally administered dosage form that is not a liquid or gas at the time the drug enters the oral cavity.

Over-the-counter (OTC) drug means a drug that is appropriate for use without the supervision of a health care professional such as a physician, and which can be purchased by a consumer without a prescription.

Pediatric indication means a specifically stated indication for use by the pediatric age group meaning from birth through 16 years of age, or a subset of this group as specified in the "Indication and Usage" section of the FDA approved labeling, or in an explanation elsewhere in the labeling that makes it clear that the drug is for use only in a pediatric age group, or a subset of this group.

Professional dispensing fee means the professional fee which:

(1) Is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

Rebate period means a calendar quarter.

Single source drug means a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act, which is produced or distributed under a new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies (as described in this section), and includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA.

States means the 50 States and the District of Columbia and, beginning January 1, 2023, also includes the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa.

United States means the 50 States and the District of Columbia and, beginning January 1, 2023, also includes the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa.

Value-based purchasing (VBP) arrangement means an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a select population and includes, but is not limited to:

(1) Evidence-based measures, which substantially link the cost of a covered outpatient drug to existing evidence of effectiveness and potential value for specific uses of that product; and/or

(2) Outcomes-based measures, which substantially link payment for the covered outpatient drug to that of the drug's actual performance in patient or a population, or a reduction in other medical expenses.

Wholesaler means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

[81 FR 5347, Feb. 1, 2016, as amended at 81 FR 80005, Nov. 15, 2016; 84 FR 64786, Nov. 25, 2019; 85 FR 87101, Dec. 31, 2020; 86 FR 64825, Nov. 19, 2021]

42 CFR Subpart I - Payment for Drugs

CFR

S. URCE:
81 FR 5347, Feb. 1, 2016, unless otherwise noted.

Appendix IV
2022 Title XIX State Plan
Second Quarter Amendment
Public Notice

Effective on or after April 1, 2022, this notice proposes to establish Medical Assistance coverage and rates of payment for crisis intervention services to stabilize and treat mental health and substance use disorder conditions, provided by mobile crisis teams and residential crisis settings for adults, as well as crisis stabilization centers for adults and children.

More specifically, crisis intervention services provided by multidisciplinary mobile crisis teams in accordance with Section 9813 of the American Rescue Plan Act provide an array of crisis intervention services, including telephonic triage for both adults and children, mobile crisis response, and mobile or telephonic follow-up services, in a variety of settings in the community.

Crisis intervention services provided in crisis stabilization centers will provide urgently needed immediate evaluation, treatment, and support services, including coordination with other mental health and substance use services, for children and adults experiencing or at risk of a mental health or substance use disorder crisis.

Crisis intervention services will also be provided in residential crisis settings, which are short-term, voluntary, non-IMD, sub-acute settings, and address a spectrum of acuity levels in which an individual may present in a mental health or substance use disorder crisis. Services stabilize crisis symptoms and restore functionality to enable transition back to the community and to prevent or reduce future psychiatric crises.

The estimated annual net aggregate increase in gross Medicaid expenditures related to this State Plan Amendment for State Fiscal Year 2023 is $16M and for State Fiscal Year 2024 is $44.5 million.

Effective on or after April 1, 2022, and for each State Fiscal Year thereafter, the State proposes to revise the method of distributing the funding for the Clinic Safety Net (CSN) distribution for comprehensive diagnostic and treatment centers that are other than Federally Qualified Health Centers (referred to as the non-FQHC CSN distribution).

There is no change to the annual gross Medicaid expenditures as a result of this proposed amendment.

Effective on or after April 1, 2022, the State proposes to enter into outcomes-based contract arrangements with drug manufacturers for drugs provided to Medicaid beneficiaries through supplemental rebate agreements.

The estimated annual net aggregate decrease in gross Medicaid expenditures attributable to this initiative contained in the budget for State Fiscal Year 2023 is ($5 million).

Effective on or after April 1, 2022, this notice proposes to enhance (increase) state established reimbursement rates as follows:

Contingent upon CMS approval of the Spending Plan submitted by the state, established rates will be enhanced for state-plan approved private duty nursing (PDN) services for members 23 years of age and older by an additional 30 percent for the medically fragile training and experience and 45 percent for the private duty nursing directory starting April 1, 2022.

The estimated annual net aggregate increase in gross Medicaid expenditures as a result of the proposed amendments for PDN services for State Fiscal Year 2023 is $38.9 million.

Effective on or after April 1, 2022, pursuant to the Centers for Medicare and Medicaid Services, Medicaid coverage must include routine patient costs for items and services furnished in connection with participation by beneficiaries in qualifying clinical trials. The Department will submit a State Plan Amendment for Medicaid to formalize federal approval of existing coverage in accordance with the requirements. Routine patient costs and qualifying clinical trials are defined in Section 1905(a)30 and Section 1905(gg) of the Social Security Act (the Act), respectively. This includes clinical trials in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition and is described in any of clauses (i)-(iii) of section 1905(gg) of the Act. Routine patient costs do not include any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project.

There is no estimated annual change to gross Medicaid expenditures as a result of this proposed amendment, since these benefits are already covered under long-standing NYS Medicaid policy.

Effective on or after April 1, 2022, pursuant to the Centers for Medicare and Medicaid Services, Alternative Benefit Plans (ABP) coverage must include routine patient costs for items and services furnished in connection with participation by beneficiaries in qualifying clinical trials. The Department will submit a State Plan Amendment for ABP to formalize federal approval of existing coverage in accordance with the requirements. Routine patient costs and qualifying clinical trials are defined in Section 1905(a)30 and Section 1905(gg) of the Social Security Act (the Act), respectively. This includes clinical trials in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition and is described in any of clauses (i)-(iii) of section 1905(gg) of the Act. Routine patient costs do not include any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project.

There is no estimated annual change to gross Medicaid expenditures as a result of this proposed amendment, since these benefits are already covered under long-standing NYS Medicaid policy.

Effective April 1, 2022, the Medicaid Program is proposing to incentivize ABA provider enrollment and participation by increasing Medicaid reimbursement amounts, aligning fees with those paid by the Child Health Plus program. ‘‘Applied behavior analysis’’ or ‘‘ABA’’ is the design, implementation, and evaluation of environmental modifications, using behavioral stimuli and consequences, to produce socially significant improvement in human behavior, including the use of direct observation, measurement, and functional analysis of the relationship between environment and behavior. ABA services are provided to individuals who have a diagnosis of autism spectrum or related disorder. As of August 1, 2021, Medicaid began accepting enrollment of Licensed Behavior Analysts as independent practitioners to provide ABA to Medicaid members under age 21 with a diagnosis of Autism Spectrum Disorder or Rhett’s Syndrome. However, Medicaid Managed Care Plans (MMC) and ABA providers indicated that the Medicaid reimbursement rate is below rates paid by CHP and commercial plans. Subsequently, very few ABA providers have been willing to enroll as Medicaid managed care and/or fee-for-service providers.

The estimated annual net aggregate increase in gross Medicaid expenditures as a result of the proposed amendment for State Fiscal Year 2023 is $73.2 million.

Effective on or after April 1, 2022, this proposal to amend the State Plan to align with Subdivision 2 of section 365-a of the social services law, that authorizes clinical social workers, licensed pursuant to Article 154 of the Education law, to bill Medicaid directly for their services within their scope of practice, effective April 1, 2022.

The estimated annual net aggregate increase in gross Medicaid expenditures attributable to this initiative contained in the budget for State Fiscal Year 2023 is $24.2 million.

Effective on or after April 1, 2022, this proposal to amend the State Plan to align with Subdivision 2 of section 365-a of the social services law, that authorizes licensed mental health counselors and marriage and family therapists, licensed pursuant to Article 163 of the Education law, to bill Medicaid directly for their services within their scope of practice, effective April 1, 2022.

The estimated annual net aggregate increase in gross Medicaid expenditures attributable to this initiative contained in the budget for State Fiscal Year 2023 is $4.2 million.

Effective on or after July 1, 2022, Medicaid reimbursement rates for non-facility physician services will be updated to 70% of current Medicare rates. This update will apply to Evaluation & Management (E&M) and Medicine procedure codes. Most Medicaid physician reimbursement rates have not been updated since 2009 and New York Medicaid is currently reimbursing physicians, on average, at 45% of Medicare for E&M codes and 58% of Medicare for Medicine codes. Updating the Medicaid physician fee schedule is intended to increase the use of primary care and preventative services and reduced utilization of costlier downstream care.