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

March 23, 2022

Brett Friedman
Acting State Medicaid Director
Office of Health Insurance Programs
New York Department of Health
Empire State Plaza
Corning Tower
Albany, NY 12237

Dear Mr. Friedman:

The Centers for Medicare & Medicaid Services (CMS) is approving New York's request to extend its section 1115(a) demonstration project, titled "Medicaid Redesign Team (MRT)" (Project Number 11-W-00114/2), in accordance with section 1115(a) of the Social Security Act ("the Act"). This approval is effective April 1, 2022 through March 31, 2027, upon which date, unless extended or otherwise amended, all authorities granted to operate this demonstration will expire. CMS's approval of this demonstration extension is conditioned upon compliance with the enclosed list of waiver and expenditure authorities and the Special Terms and Conditions (STCs) defining the nature, character and extent of anticipated federal involvement in the project.

On November 10, 2020, New York submitted an application for an amendment to its section 1115(a) demonstration. This amendment consisted of two parts. The first part would make changes to the Managed Long-Term Care (MLTC) plan eligibility criteria so that, in addition to being assessed for the need of Community-Based Long-Term Care Services (CBLTCS) for a continuous period of at least 120 days, the beneficiary must also need assistance with at least two activities of daily living (ADL). Or, if a person has Dementia or Alzheimer's, then that person needs supervision with more than one ADL. This amendment remains under review until the end of the American Rescue Plan Act (ARP) maintenance of effort (MOE) period, because section 9817 of the ARP requires that states must not impose stricter eligibility standards, methodologies, or procedures for home and community-based services (HCBS) programs and services than were in place on April 1, 2021 in order to receive the enhanced federal funding available under that provision.[1]

The second part of the amendment request is to permit dually eligible Medicare/Medicaid members who do not need CBLTCS (i.e., "well duals"), and who voluntarily sign up for a Medicare Dual Eligible Special Needs Plan (D-SNP) with a qualified Mainstream Medicaid

[1] State Medicaid Director Letter #21-003, Implementation of American Rescue Plan Act of 2021 Section 9817: Additional Support for Medicaid HCBS during the COVID-19 Emergency, May 13, 2021, available at: https://www.medicaid.gov/federal-policy-guidance/downloads/smd21003.pdf.

Managed Care (MMMC) plan, to stay enrolled in that MMMC plan. Previously, beneficiaries who became dually eligible were required to disenroll from the MMMC plan. This change allows a dually eligible beneficiary to stay in the MMMC plan if the MMMC plan also operates a Medicare D-SNP. CMS is approving this amendment request as part of this 5-year extension.

On March 5, 2021, New York submitted a request to extend its section 1115 demonstration. In this extension the state proposed two changes to its demonstration. The first change was to carve out non-emergency medical transportation (NEMT) from coverage through managed care contracts and, instead, to cover NEMT on a fee for service (FFS) basis, based on state plan payment rates. The second change was a proposal to similarly carve-out pharmacy benefits from managed care contracts so that all covered outpatient drugs are also paid for on an FFS basis. On March 18, 2021, CMS approved a temporary extension of New York's demonstration for one year until March 31, 2022 with no changes.

No section 1115 demonstration authority is required for a state to remove coverage of any Medicaid state plan service from managed care contracts and cover instead on an FFS basis outside the contract for managed care plan enrollees. The vehicle for making this change is an amendment to New York's managed care contracts. Therefore, CMS is not acting on the proposed carve-outs via this extension approval. Rather, New York will document these operational changes in its managed care contracts, which are reviewed and approved by CMS.

Monitoring and Evaluation

Consistent with CMS's requirements for section 1115 demonstrations, and as outlined in the demonstration extension STCs, the state is required to conduct systematic monitoring of the various demonstration components, per applicable CMS guidance and technical assistance. Such monitoring will support tracking the state's progress with the demonstration components towards their corresponding milestones and/or goals. Furthermore, in alignment with CMS guidance and STC requirements, New York will develop a rigorous evaluation design using robust data sources and analytic approaches that will support a comprehensive evaluation of the demonstration to assess whether the demonstration initiatives are effective in producing the desired outcomes for its beneficiaries and providers as well as for the state's overall Medicaid program.

The evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact on beneficiary coverage, access to and quality of care, and health outcomes, as well as its effectiveness in achieving the policy goals and objectives. Additionally, the state's monitoring and evaluation will be required to accommodate data collection and analyses stratified by key subpopulations of interest to inform a fuller understanding of existing disparities in access and health outcomes, and how the demonstration's various policies might support reducing or eliminating any such disparities.

Consideration of Public Comments

To increase the transparency of demonstration projects, sections 1115(d)(1) and (2) of the Act direct the Secretary to issue regulations providing for two periods of public comment on a state's

application for a section 1115 demonstration that would result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing. The first comment period occurs at the state level before submission of the section 1115(a) application, and the second comment period occurs at the federal level after the Secretary receives the application.

As required under section 1115(d)(2)(A) and (C) of the Act, comment periods should be "sufficient to ensure a meaningful level of public input," but the statute imposed no additional requirement on the states or the Secretary to provide individualized responses to address those comments, as might otherwise be required under a general rulemaking. Accordingly, the implementing regulations issued in 2012 provide that CMS will review and consider all comments received by the deadline, but will not provide individualized written responses to public comments.

The federal comment period for the extension was open from March 24, 2021 through April 23, 2021, and CMS received 99 comments, 96 of which were considered complete. Almost 97 percent of these comments expressed concern over how the pharmacy carve-out would impact 340B providers and the vulnerable clients they serve. Eighty-two percent of commenters voiced concerns about the overall financial impact on 340B providers, and some further indicated such financial impact may lead to poor health outcomes for low-income and traditionally underserved communities. We understand the state plans to make additional funding ($102 million annually) available to the 340B providers to address potential financial issues in these organizations. Other commenters expressed concern with the state's savings projections and budget neutrality. CMS has reviewed New York's budget neutrality worksheets for the demonstration extension and has determined that the demonstration extension is expected to be budget neutral. Approximately 60 percent said they had concerns with the proposal's impact on health outcomes, while 54 percent were concerned with its impact on equity. This demonstration extension is not authorizing any changes to Medicaid state plan benefits and the state is required to ensure appropriate access to providers and services.

Another commenter shared concerns that people receiving HIV medication would receive fewer services which would adversely affect their health. Again, the state is not making changes to Medicaid state plan benefits and has not indicated any intent to reduce services to persons receiving HIV medication. About 66 percent of respondents were in support of the demonstration extension's attempt to contain costs, but they believed the carve-out would not help this. One commenter had recommendations on how the state could propose to receive additional funding to address the needs of the long-term care delivery system.

States have the authority under the Medicaid statute to decide which state plan services to cover under managed care contracts, and which services to cover exclusively on an FFS basis so, as a legal matter, the comments objecting to the state's decision to carve-out pharmacy benefits from its managed care contracts and cover them exclusively on an FFS basis are not germane to this demonstration approval. However, CMS acknowledges the concerns expressed by the commenters and has discussed with the state its plans to address them.

One person expressed support for the NEMT carve-out, saying that having the NEMT benefit provided centrally would reduce waste, fraud, and abuse. The commenter also said the carve-

out would promote quality. Another person expressed concern that use of a centralized vendor could affect access to services for vulnerable people. The state explained that it will work closely with the MLTC plans during the transition period to ensure the transportation network meets the needs of the beneficiaries.

The federal comment period for the amendment request was from November 27, 2020 through December 27, 2020. CMS received eleven comments; one of which did not actually address the proposal. Seven comments expressed concerns with the first component of the amendment request which would impose more restrictive eligibility criteria to receive MLTC benefits. CMS is not approving the first component at this time. Three comments expressed some concerns and questions with the second component of the amendment request – i.e., allowing beneficiaries to remain in an MMMC plan when they become eligible for Medicare if the MMMC plan operates a Duals-Special Needs Plan.

For example, one commenter supported the integration of Medicare/Medicaid in the second component, while sharing concerns related to the amendment and implementation of the proposal. The commenter recommended that the state properly define "qualified MMMC plan," address concerns with passive enrollment, and ensure that an adequate educational campaign is implemented for those beneficiaries affected.

The state is required to follow all Medicaid managed care regulations to ensure appropriate state oversight of managed care plans. MMMC plans must follow all required beneficiary notice requirements. CMS believes allowing Medicaid enrollees, who become eligible for Medicare, to remain in their same managed care plan promotes continuity of care and integrated care. The state will be required to report on all aspects of the managed care delivery system, including the enrollment of dual eligibles, in the monitoring reports.

After carefully reviewing and considering the public comments submitted during the federal comment period, CMS has concluded that the demonstration is likely to advance the objectives of Medicaid.

Other Information

The award of this approval is subject to our receiving your written acknowledgement of the award and acceptance of these STCs within 30 days of the date of this letter. Your project officer for this demonstration is Jonathan Morancy. He is available to answer any questions concerning your amendment. Mr. Morancy's contact information is below:

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7500 Security Boulevard
Baltimore, MD 21244-1850
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E-mail: Jonathan.Morancy@cms.hhs.gov

If you have any questions regarding this approval, please contact Ms. Judith Cash, Director, State Demonstrations Group, Center for Medicaid and CHIP Services at (410) 786-9686.

Sincerely,

[redacted]

Daniel Tsai
Deputy Administrator and Director

Enclosure

cc: Frankeena McGuire, State Monitoring Lead, Medicaid and CHIP Operations Group