NY MRT 1115 Waiver Extension Request FAQs

General Waiver Extension

The following summarizes and addresses comments received by the New York State Department of Health (NYSDOH) in response to the **General Waiver Extension** within the three-year extension of the existing Section 1115 Medicaid Redesign Team (MRT) waiver.

The below themes were expressed by commenters through the public comment process:

Q: How will New York State avoid a significant change or termination in Substance Use Disorder (SUD) services for Medicaid members?

A: This 1115 waiver extension request is designed as a continuation of all current programmatic authorities, including SUD services under the current Medicaid Redesign Team (MRT) Waiver.

Q: Can New York State authorize an expansion of Cardiovascular Technologists' (CVTs) scope of practice to administer contrast materials under the direct supervision of a physician?

A: No. An 1115 waiver demonstration does not apply to this type of expansion. Policies and standards concerning scope of practice, including those applicable to CVTs, are a function of how New York State Education Department licenses and regulates the professions.

Q: Does the request for the extension of all current programs and authorities include the Delivery System Reform Incentive Payment (DSRIP) Program?

A: No. This 1115 waiver extension request does not include DSRIP, which was a demonstration program that CMS declined to renew following its expiration on March 31, 2020. New York State will build on the successful work accomplished through DSRIP when it seeks a new programmatic 1115 waiver demonstration, in light of pandemic-related health equity needs and increased support from community-based organizations (CBOs).

Q: How will New York State approach future waiver amendments and waiver design?

A: As New York designs its next 1115 waiver demonstration, the experience and knowledge gained during DSRIP and the COVID-19 pandemic will have a beneficial impact on prospective waiver requests. Further, all comments received related to future waiver amendments and design will be considered as we continue to work with CMS and stakeholders to draft a larger renewal package.

Q: Will New York State engage in additional oversight of health plans to ensure that services are being provided adequately, particularly to high needs Managed Long Term Care (MLTC) members?

A: Yes. New York State will continue to provide oversight to plans through the terms of model contracts with MLTCs, as approved by CMS, and rigorous plan oversight functions.

Q: Is New York State changing eligibility standards for MLTC enrollment?

A: No. This particular waiver extension request does not propose changes to eligibility standards for any of the existing programs authorized under the current 1115 waiver. However, on November 10, 2020, following a public comment period, a waiver amendment application was submitted to CMS, which imposes new enrollment eligibility criteria as recommended by the Medicaid Redesign Team II and enacted in the State Fiscal Year 2020-21 budget. This waiver amendment application remains under review by CMS.

Q: How will New York State ensure that community perspectives are included in waiver design?

A: Ensuring the incorporation of all perspectives, including community perspectives, into current and future waiver design efforts is a priority. A new 1115 waiver demonstration is anticipated for the near future, which will include elements of community-based organization (CBO) participation, pandemic response and health equity. During the development and submission of this new demonstration, we will engage in public comment processes to ensure community perspectives are considered

NY MRT 1115 Waiver Extension Request FAQs

Managed Long-Term Care (MLTC) Transportation Carveout

The following summarizes and addresses comments received by the New York State Department of Health (NYSDOH) in response to the **Managed Long-Term Care (MLTC) Transportation Carveout** within the three-year extension of the existing Section 1115 Medicaid Redesign Team (MRT) waiver.

The below themes were expressed by commenters through the public comment process:

Q: Why is the Department carving the transportation benefit out of MLTC plan coverage?

A: Moving the transportation benefit out of MLTC plan coverage will streamline and standardize the administration of the transportation benefit while improving access to transportation for MLTC members. In addition, the Department is changing the current fee-for-service transportation benefit into a risk-based model with a competitively procured broker. The carveout and risk-based model will create a larger member pool, lower cost, incentivize the medically appropriate match to mode, and encourage efficiencies.

Q: How will the MLTC population be transitioned?

A: The MLTC population will be transitioned in phases later in 2021 by geographic region after the broker has effectively transitioned the non-MLTC populations. The Department will oversee stakeholder engagement before and during the transition. Every phase will include ample education and training efforts as well as collaboration with the plans to ensure continuity of services.

Q: How will the broker handle the needs of high-acuity MLTC members?

A: The Department recognizes that the MLTC population includes high-acuity and medically fragile members. The Department will collaborate with the plans to the ensure a seamless transition of services and that members understand how to use the benefit. The current transportation managers already handle high acuity, medically fragile members in both FFS and the mainstream managed care program which covers long term care services and supports.

Q: Will the Department procure one or multiple brokers?

A: In the development of the Request for Proposals, the Department is assessing the various regional transportation needs and may procure one or more brokers best suited to meet those needs.

Q: Will the broker(s) use existing transportation networks?

A: The Department will encourage the broker(s) to use existing transportation networks, including those used by health plans, which can deliver high-quality and cost-effective services.

Q: What is the Department's oversight plan?

A: The Department will monitor access to ensure that the network has sufficient capacity across all modes of transportation. The broker(s) will be required to resolve complaints promptly and share complaint data with the Department. Additionally, the Department will impose financial penalties and corrective action planning for incorrect denials, unresolved complaint rates, and unfulfilled trips. The Department will require the broker(s) to submit reports demonstrating their performance in these areas.

NY MRT 1115 Waiver Extension Request FAQs

Carveout of Pharmacy Benefit from Medicaid Managed Care to Fee-For-Service

The following summarizes and addresses comments received by the New York State Department of Health (NYSDOH) in response to the **Carveout of Pharmacy Benefit from Medicaid Managed Care to Fee-For-Service** (the Carve-Out) within the three-year extension of the existing Section 1115 Medicaid Redesign Team (MRT) waiver.

The below themes were expressed by commenters through the public comment process:

340B:

Comment(s):

NYSDOH received numerous comments that expressed concern, citing that the Carve-Out will result in the removal of critical funding from the healthcare safety net including community health centers, Ryan White providers, and Disproportionate Share Hospitals (DSH). Commenters contended that the Carve-Out will prohibit safety net providers from provisioning uncompensated care and care expansion to impoverished communities due to not having access to the benefits of the Federal 340B program.

Commenters asserted that the projected $87M in State savings will result in approximately $245M annual loss to healthcare providers, Federally Qualified Health Centers (FQHCs), and Ryan White clinics serving the most vulnerable populations of New York. Commenters further asserted that no methodology for reinvestment of 340B savings has been shared.

Several commenters cited how the HIV epidemic and COVID-19 pandemic have disproportionately impacted poor, Black, Indigenous and people of color (BIPOC) and that the Carve-Out will prevent health care safety net providers and covered entities from providing essential services to their patients that represent the LGBTQ community, homeless and/or undocumented. Commenters cite that the services that are at risk from the Carve-Out include: patient navigation, care coordination for patients living with HIV/AIDs, mental health services, general care coordination, triage nursing lines, access for uninsured or under-insured patients, sliding-scale pharmacy benefits, community outreach, removal of contract pharmacies, and others. Lastly commenters cite that the Carve-Out presents the risk that patients will no longer be able to obtain their medications.

Response:

NYSDOH recognizes the importance of the 340B program to safety-net providers, which is reflected in the State's commitment to reinvest $102M, in State Fiscal Year ("SFY") 2021-22 (subject to federal approval), to directly support covered entities and preserve critical services that are currently funded with 340B revenue. Specifically, the proposed SFY 2021-22 Executive Budget establishes a 340B Reimbursement Fund to offset losses to certain 340B entities as a result of the Carve-Out. Eligible 340B providers, which will include non-hospital 340B providers in New York, will receive a proportionate distribution from a methodology that considers each providers 340B revenue and volume of Medicaid members served. NYSDOH intentionally limited the provider eligibility to safety net clinics and Medicaid dependent providers to ensure minimal financial disruption for these

providers and the Medicaid members they serve. Annual distributions from the 340B Reimbursement Fund will equal the amount of $102 million for the upcoming fiscal year and continue for each fiscal year thereafter, however the statutory language allows for additional funding in future years.

After the Carve-Out, 340B covered entities will continue to be able to purchase drugs at reduced prices and receive margin on 340B drugs associated with other payors (e.g., Medicare and Commercial Insurers) and Medicaid covered physician administered drugs. Furthermore, drugs covered under the Medicaid Fee-For-Service (FFS) program will not change as a result of the carve-out. 340B claims and medications will continue to be covered when the benefit is transitioned to FFS, effective April 1, 2021. The State's commitment to a multi-year reinvestment demonstrates the State's continued support of services for populations who struggle to get access to care and medications due to social determinants of health.

In response to comments received regarding 340B, NYSDOH directs commenters to review the following Pharmacy Carve-Out Frequently Asked Questions (FAQs): 013, 040, 043, 067, 068, 079, 080, 081, 082, 096, 097

Impact on Waiver Budget Neutrality:

Comment(s):

NYSDOH also received a comment regarding the Pharmacy Carveout amendment's impact on budget neutrality calculations and that the cost projections may not have accurately captured the savings that would be generated from the Carve-Out.

Response:

The Budget Neutrality requirement for 1115 waivers does not function as expressed in the comment. Budget Neutrality in the 1115 waiver is based on the comparison of actual expenditures vs. a set per-member per-month (PMPM) without waiver baseline, which is calculated based on the cost of administering the same benefits through an alternative authority and without the flexibilities granted through an 1115 demonstration. It is important to note that this calculation accounts for only those services and benefits included in the 1115 waiver and does not speculate about benefits and services that could be included in the 1115 waiver but are not. Tax revenue and other statewide budgetary considerations are likewise outside of the scope of the budget neutrality calculation.

Additionally, because the Carve-Out and New York State's 1115 MRT waiver renewal are planned with concurrent start dates, pharmacy benefits will not be factored into the initial rebased without wavier PMPM and will therefore no longer be a factor at all in cost and savings determinations from the Budget Neutrality perspective.

Threat to Care Management & Impediment to Value Based Payment Arrangements:

Comment(s):

Additional comments regarding the Pharmacy Carve-Out amendment received were concerned with NYSDOH's ability to accurately capture real-time pharmacy data, which could have a negative impact on care management and the ability of Managed Care Organizations (MCOs) to report on existing Value-Based Payment (VBP) arrangements.

Response:

NYSDOH is providing the MCOs with a daily pharmacy claims file that includes pharmacy claims activity for the prior day. Furthermore, DOH will be providing a set of on-demand reports that support integrated care management and disease management activities, including but not limited to managing members' chronic diseases, promoting medication adherence, and monitoring adverse reactions. These reports will provide for timely access to critical data, given that there is a lag for some of the MCOs when loading the daily pharmacy claims file to their data warehouse, and ensure that existing VBP arrangements between MCOs and providers continue post transition.

In response to comments received regarding threat to care management and impediment to VBP arrangements, NYSDOH directs commenters to review the following Pharmacy Carve-Out Frequently Asked Questions (FAQs): 018, 020, 056, 073, and 104

Cystic Fibrosis Therapy Access:

Comment(s):

NYSDOH received comments regarding the continuity of care and access to cystic fibrosis therapy. Commenters requested that NYSDOH ensure:

a. the preferred drug list reflects the FDA label for all CFTR modulators and does not place restrictions on access;
b. coverage to hypertonic saline and dornase afla without step therapy;
c. the preferred drug list continues to include access to aztreonam for inhalation solution (Cayston) and tobramycin product; and
d. ensure patients and providers have the ability to choose the most appropriate enzyme needed for care based on the patient's health profile.

Response:

a. The Medicaid FFS Pharmacy Program provides access to CFTR modulators when prescribed in accordance with FDA labeling and/or the Official Compendia.
b. Both hypertonic saline & dornase afla are available on the Medicaid FFS formulary, without restriction.
c. The Medicaid FFS preferred drug list will apply, with continued access to aztreonam for inhalation solution (Cayston) and tobramycin.
d. Prescribers will be able to select pancreatic enzymes from the Medicaid FFS Preferred Drug List, as they do today for their Medicaid FFS patients.

Menges Report Concerns:

Comment(s):

NYSDOH received comments expressing concern regarding the findings contained within the Menges Group report *Why New York Should Maintain its Medicaid Pharmacy Carve-In Approach.*

Response:

The Health Plans Association (HPA) contracted with the Menges Group to evaluate the MRT II-enacted budget proposal requiring the transition of the pharmacy benefit to Medicaid FFS. The Menges Group claims that NYSDOH administrative savings estimates are overstated and that the Carve-Out will diminish the ability of MCOs to provide integrated care coordination. Most notably, the Menges report claims that the transition will cost the State $154 million during FY22 and will ultimately cost the State $1.5 billion over 5 years. NYSDOH strongly disagrees with the Menges report findings for the following reasons:

- The report's conclusion that costs will increase under a 'carve out' model is based solely on assumptions that compare New York to aggregate results from other states, but not the actual costs when comparing Managed Care claims to FFS claims in New York Medicaid -- only NYSDOH has access to the actual cost information (e.g., administrative costs, federal and supplemental rebates at the drug level, 340B prices, etc.) that enables an accurate and comprehensive fiscal analysis. Neither Menges nor the MCOs have access to this data and are basing their analysis on flawed assumptions.

- Menges compares the New York State Medicaid program to the Medicaid programs of Delaware, Illinois, Indiana, Iowa, Nebraska, Ohio, Texas, and Utah. These states are not operating comparable Medicaid pharmacy programs, so comparing New York's drug spend and utilization with these states is inaccurate, misleading and not based on facts.

- Menges has been commissioned by Health plans in other states that have implemented a pharmacy carve-out, like West Virginia, where the results proved that the State realized greater than anticipated savings with no negative health impacts for Medicaid members (counter to what Menges estimated). A Navigant report determined the State saved $54 million from the carve-out in SFY 2018. The State originally projected $30 million in savings for SFY 2018 in a study they conducted before the carve-out. Menges Group critique of Navigant report and West Virginia savings and Navigant rebuttal to critique.

- The State has implemented budget actions in prior years, including the elimination of spread pricing in managed care, that would suggest the findings of the Menges report are inaccurate. Moreover, the Menges report bases much of its findings on an assumption that a higher generic effective rate results in lower net drug costs in Medicaid, which is not true. The Medicaid FFS program has programs that prefer dispensing certain brand name drugs over generic drugs because the net cost to state is lower.

- The report specifically states that NYSDOH has eliminated all health plan administrative reimbursement associated with the pharmacy benefit and should not reduce the administrative portion of the pharmacy premiums by more than 5% -- this statement is simply untrue and further confirms that the report does not accurately articulate how NYSDOH has calculated the savings (DOH has assumed a 3% reduction to the admin component of the pharmacy premium).

- Menges argues that the FFS transition will jeopardize patient access to necessary pharmaceuticals. However, NYSDOH compared the FFS formulary to health plan formularies and found that FFS is less restrictive and covers more products in all therapeutic classes than health plans currently cover. As the State Medicaid program operates a preferred drug list, enrollees should find their access to medically necessary drugs improved and at lower costs.