

ANDREW M. CUOMO GOVERNOR

March 4, 2021

Norris Cochran Acting Secretary U.S. Department of Health & Human Services 200 Independent Avenue, S.W. Washington, D.C. 20201

Dear Acting Secretary Cochran:

Pursuant to the terms of the New York State Medicaid Section 1115 Demonstration Medicaid Redesign Team (MRT) Waiver (11-W-00114/2), New York State (the State) is pleased to submit the enclosed waiver extension proposal to the Centers for Medicare and Medicaid Services (CMS) for its approval.

Waiver Extension Proposal

Without question, the MRT Waiver has been a resounding success. Together with CMS, we have expanded coverage to uninsured New Yorkers, improved care for the over six million New Yorkers who rely on the Medicaid program for comprehensive health coverage, shifted to paying for value rather than volume, and made substantial progress in reshaping our health care delivery system with the Delivery System Reform Incentive Payment (DSRIP) program. Since the inception of the MRT Waiver, the State has generated over \$65 billion in State and federal savings. To ensure that this progress can be sustained, the State is requesting a three-year extension of the MRT Waiver, which is set to expire on March 31, 2021.

This proposal seeks an extension of all current programs and authorities in the MRT Waiver, along with technical amendments to align with planned programmatic changes to the transition of Medicaid managed care benefits to the fee-for-service program as well as the expiration of the DSRIP program. This waiver extension proposal contains no changes to eligibility, scope of benefits, or cost-sharing requirements.

New York has fully complied with federal transparency requirements in preparation for formally submitting this waiver extension proposal. The State transmitted tribal and public notices referencing the preliminary proposal draft (December 1, 2020), conducted virtual public hearings (January 21, 2021 and January 27, 2021), and received over 720 comments. The State's engagement with stakeholders informed the structure and substance of this submission and have been addressed in the attached extension application. Upon review of a previous draft of this waiver, CMS determined that the application structure meets its technical and notice



requirements.

Forthcoming Demonstration Proposal

The COVID-19 pandemic has drastically impacted the health care delivery landscape. Responding to the COVID-19 pandemic has required the State to learn many lessons about coordinating an effective and massive response within the existing health care system, while at the same time exposing systemic issues that have created gaps in care among underserved and vulnerable populations. Accordingly, the State has necessarily been identifying new and larger programmatic changes to its Medicaid program in response.

The State anticipates submitting a new demonstration proposal and concept paper to CMS designed to address the inextricably linked health disparities and systemic health care delivery issues that have been both highlighted and intensified by the COVID-19 pandemic. In New York, the COVID-19 pandemic has been particularly detrimental to vulnerable populations. Achieving an equitable recovery from the COVID-19 pandemic requires a massive effort across all sectors of the health care delivery system. The State looks forward to engaging with CMS on this important proposal when submitted.

The cooperation between CMS and the State continues to be critical to the success of the MRT Waiver. We look forward to working closely with CMS during the review of our waiver extension request and the forthcoming demonstration proposal. If you have any questions, please contact Donna Frescatore, New York's Medicaid Director, at 518-474-3018.

Sincerely

ANDREW M. CUOMO

Enclosures

cc: Liz Richter, Acting Administrator, Centers for Medicare and Medicaid Services Howard Zucker, M.D., J.D., Commissioner of Health, New York State Anne Marie Costello, Acting Director, Center for Medicaid and CHIP Services Donna Frescatore, Medicaid Director, New York State

NEW YORK STATE MEDICAID REDESIGN TEAM (MRT) WAIVER

1115 Research and Demonstration Waiver #11-W-00114/2

MRT Waiver Extension Request

New York State Department of Health Office of Health Insurance Programs

One Commerce Plaza Albany, NY 12207

March 5, 2021



Department of Health

Office of Health Insurance Programs

Table of Contents

IntroductionIntroduction	3
Historical Context	3
Extending the Existing Waiver	8
Goals and Objectives of the Extension	
Eligibility, Benefits and Cost Sharing Requirements of the Extension	
Delivery System Implications of the Extension	
Implementation Timeline of the Extension	
Fiscal Implications of the Extension	
Requested Amendments to the Existing Demonstration	
A Transition (Carveout) of MLTC Non-Emergency Medical Transportation Serv	
FFS Amendment	
Goals and Objectives of the MLTC Transportation Carveout Amendment	
Eligibility, Benefits, and Cost-Sharing Requirements of the MLTC Transportation Carveout Amenda	
Waiver and Expenditure Authorities of the MLTC Transportation Carveout Amendment	12
Delivery System Implications of the MLTC Transportation Carveout AmendmentImplementation Timeline of the MLTC Transportation Carveout Amendment	
Fiscal Implications of the MLTC Transportation Carveout Amendment	
Public Notice Compliance and Documentation of the MLTC Transportation Carveout Amendment.	
Tribal Notification of the MLTC Transportation Carveout Amendment	
A Transition (Carveout) of the Pharmacy Benefit from Managed Care to FFS Amendment	
Goals and Objectives of the Pharmacy Carveout Amendment	13
Eligibility, Benefits, and Cost-Sharing Requirements of the Pharmacy Carveout Amendment	
Waiver and Expenditure Authorities of the Pharmacy Carveout Amendment	
Delivery System Implications of the Pharmacy Carveout Amendment	
Implementation Timeline of the Pharmacy Carveout Amendment	20
Fiscal Implications of the Pharmacy Carveout Amendment	
Public Notice Compliance and Documentation of the Pharmacy Carveout Amendment	
Tribal Notification of the Pharmacy Carveout Amendment	
Waiver and Expenditure Authorities	24
Budget Neutrality	28
Considerations Impacting Caseloads & Costs	28
Anticipated Waiver Cost & Caseloads	29
Demonstration Evaluations To-Date	30
Summaries of External Quality Review Organization Reports (EQROs)	30
Preliminary Interim Evaluation Reports	31
Public Notice Compliance and Documentation	33
Public Comment Overview	34

Public Comment Themes and State Responses	34
General Waiver Extension Comments	34
Pharmacy Carveout Amendment Comments	
MLTC Transportation Carveout Amendment Comments	36
Tribal Notification	36
Appendix A— Compliance with Public Comment Circulation Requirements	37
Appendix B– Tribal Letter	41
Attachments	47
Attachment A–Children's Design Preliminary Interim Evaluation	47
Attachment B-HARP Preliminary Interim Evaluation	47
Attachment C-SDC Preliminary Interim Evaluation	47
Attachment D–1115 Demonstration Preliminary Interim Evaluation	47
Attachment E– Budget Neutrality Workbooks	47

Introduction

The State of New York ("New York" or the "State") is requesting a three-year extension of the existing Section 1115 Medicaid Redesign Team ("MRT") waiver demonstration, which is set to expire on March 31, 2021. This extension proposal seeks a continuation of all current programs and authorities in State's current waiver demonstration, and the following two programmatic amendments:

- A Transition (Carveout) of the Non-Emergency Medical Transportation (NEMT)
 Benefit from Managed Long-Term Care to Fee-For-Service; and
- A Transition (Carveout) of Pharmacy Benefits from Medicaid Managed Care to Fee-For-Service.¹

These amendments were developed by the State's Medicaid Redesign Team II ("MRT II"), and are part of a larger, more comprehensive set of reforms that the State is planning to innovate and improve the Medicaid program. MRT II built on the work of the first MRT (and for which New York's 1115 Waiver was renamed) and brought together a comprehensive set of stakeholders to collectively find solutions that improve the delivery of care and outcomes for Medicaid members and contain spending growth in the Medicaid program.

Although the State began planning for a larger renewal effort for the MRT waiver, these efforts have been *significantly impacted* by the COVID-19 pandemic and associated federally declared public health emergency ("COVID-19"). It is essential for the stability of the State's Medicaid program that the current MRT waiver be extended without delay to give the State and its stakeholders time to consider the long-term impacts of the pandemic on its health care delivery system and identify redesign efforts that will best position the State to respond effectively to both COVID-19 and future public health emergencies. *As it is critical for the State to extend the MRT waiver for the continuity and stability of the Managed Care program, the State is willing to entertain a non-programmatic extension should CMS require additional time to consider the programmatic amendments.*

The State intends to follow this extension request with a comprehensive programmatic 1115 demonstration package that supports the evolution of the delivery systems to respond to emergency preparedness needs. Critically, COVID-19 will not be the last pandemic or public health emergency that New York or the country will face, and future diseases, catastrophic weather events, or acts of terrorism, among other potential causes of public health emergencies, may pose an even greater strain to the State's health care infrastructure.

Historical Context

The State's goal in implementing the MRT Section 1115(a) demonstration was to improve access to health services and outcomes for low-income New Yorkers by:

- Improving access to health care for the Medicaid population;
- Improving the quality of health services delivered; and

¹ This proposal does not include an extension of the Delivery System Reform Incentive Payment (DSRIP) program, which was the subject of our waiver request dated November 27, 2019 or the Designated State Health Program (DSHP), which has been precluded pursuant to State Medicaid Director Letter #17-005, Phase-out of expenditure authority for Designated State Health Programs (DSHP) in Section 1115 Demonstrations (December 15, 2017).

• Expanding coverage with resources generated through managed care efficiencies to additional low-income New Yorkers.

The demonstration is designed to permit New York to use a managed care delivery system to deliver benefits to Medicaid recipients, create efficiencies in the Medicaid program, and enable the extension of coverage to certain individuals who need long term care and supports. It was originally approved in 1997 to enroll most Medicaid recipients into a Managed Care Organization ("MCO"). As part of the demonstration's renewal in 2006, authority to require some disabled and aged populations to enroll in mandatory managed care was transferred to a new demonstration, the Federal-State Health Reform Partnership ("F-SHRP"). Effective April 1, 2014, this authority was restored to this demonstration as F-SHRP was phased out.

In 2001, the Family Health Plus ("FHPlus") program was implemented as an amendment to the demonstration, providing comprehensive health coverage to low-income uninsured adults, with and without dependent children, who have income greater than Medicaid State Plan eligibility standards. FHPlus was further amended in 2007 to implement an employer sponsored health insurance ("ESHI") component. Individuals eligible for FHPlus who have access to cost-effective ESHI are required to enroll in that coverage, with FHPlus providing any wrap-around services necessary to ensure that members get all FHPlus benefits. FHPlus expired on December 31, 2013 and became a State-only program, but federal matching funding for State expenditures for FHPlus will continue to be available as a Designated State Health Program through December 31, 2014.

In 2002, the demonstration was expanded to incorporate a family planning benefit under which family planning and family planning related services were provided to women losing Medicaid eligibility and to certain other adults of childbearing age (family planning expansion program). The family planning expansion program expired on December 31, 2013 and became a State plan benefit.

In 2010, the Home and Community Based Services Expansion program (HCBS Expansion program) was added to the demonstration. It covers cost-effective home and community-based services to certain adults with significant medical needs as an alternative to institutional care in a nursing facility. The benefits and program structure mirrors those of existing section 1915(c) waiver programs and aims to cover quality services for individuals in the community, ensure the well-being and safety of the participants and increase opportunities for self-advocacy and self-reliance.

As part of the 2011 extension, the State was authorized to develop and implement two new initiatives designed to improve the quality of care rendered to Partnership Plan recipients. The first, the Hospital-Medical Home ("H-MH") project, provided funding and performance incentives to hospital teaching programs in order to improve the coordination, continuity and quality of care for individuals receiving primary care in outpatient hospital settings and facilitate certification of such programs by the National Committee for Quality Assurance as patient-centered medical homes. This demonstration initiative ended on December 31, 2014.

Under the second 2011 initiative, the State would have provided funding, on a competitive basis, to hospitals and/or collaborations or hospitals and other providers for the purpose of developing and implementing strategies to reduce the rate of Potentially Preventable Readmissions for the Medicaid population. The demonstration initiative was never implemented.

Finally, in 2011 The Centers for Medicare & Medicaid ("CMS") began providing matching funding for the State's program to address clinic uncompensated care through its Indigent Care Pool ("ICP"). This pool expired on December 31, 2014, and as such, these changes are no longer in effect.

In 2012, New York added to the demonstration an initiative to improve service delivery and coordination of long-term care services and supports for individuals through a managed care model. Under the Managed Long-Term Care ("MLTC") program, eligible individuals in need of more than 120 days of community-based long-term care are enrolled with managed care providers to receive long term services and supports as well as other ancillary services. Other covered services are available on a fee-for-service basis to the extent that New York has not exercised its option to include the individual in the Mainstream Medicaid Managed Care Program ("MMMC"). Enrollment in MLTC was phased in geographically and by group.

The State's goals specific to MLTC are as follows:

- Expanding access to managed long-term care for Medicaid members who are in need of long-term services and supports ("LTSS");
- Improving patient safety and quality of care for members in MLTC plans;
- Reducing preventable inpatient and nursing home admissions; and
- Improving satisfaction, safety and quality of life.

In April 2013, New York had three amendments approved. The first amendment was a continuation of the State's goal for transitioning more Medicaid members into managed care. Under this amendment, the Long-Term Home Health Care Program ("LTHHCP") participants began transitioning, on a geographic basis, from New York's 1915(c) waiver into the 1115 demonstration and into managed care. Second, this amendment eliminated the exclusion from MMMC of both foster care children placed by local social service agencies and individuals participating in the Medicaid buy-in program for the working disabled.

Additionally, the April 2013 amendment approved expenditure authority for New York to claim Federal Financial Participation ("FFP") for expenditures made for certain Designated State Health Programs ("DSHP") beginning April 1, 2013 through March 31, 2014. These DSHPs were aimed to improve health outcomes for Medicaid and other low-income individuals, and the federal funding was linked to requirements for the State to submit deliverables to demonstrate successful efforts to transform its health system for individuals with developmental disabilities.

A December 2013 amendment was approved to ensure that the demonstration made changes that were necessary in order to coordinate its programs with the Medicaid expansion and other changes made under the Affordable Care Act ("ACA") implementation beginning January 1, 2014.

Effective April 1, 2014, CMS approved an amendment to extend several authorities that expired in calendar year 2014. As part of the amendment CMS extended authorities related to the transitioning of parents into State Plan coverage and other authorities that provide administrative ease to the State's programs and continuing to provide services to vulnerable populations, i.e., HCBS Expansion program and individuals moved from institutional settings into community-based settings.

Also, effective April 1, 2014, populations receiving managed care or managed long-term care in the 14 counties that encompassed the F-SHRP demonstration were moved into this demonstration.

An amendment approved on April 14, 2014 allowed New York to take the first steps toward a major delivery system reform through a Delivery System Reform Incentive Payment ("DSRIP") program. This amendment to the Partnership Plan demonstration provided for an Interim Access Assurance Fund to ensure that sufficient numbers and types of providers were available in the community to participate in the transformation activities contemplated by the DSRIP Program. The DSRIP program incentivized providers through additional payments beginning in 2015. The amendment also included expenditure authority for DSHPs to allow the State to concentrate resources on the investments necessary to implement its DSRIP program. Savings from the DSRIP program were anticipated to exceed the cost of the DSHP program.

On December 31, 2014, CMS amended the demonstration to enable New York to extend long term nursing facility services to members of New York's MMMC and MLTC populations.

Enrollment in MMMC and MLTC was extended to individuals entering residential health care facilities ("RHCF") for stays that are classified as permanent. As part of the agreement, the State also instituted an independent LTSS assessment process via an enrollment broker and implemented its Independent Consumer Support Program in areas of the State where services and enrollment were being instituted.

In August 2015, CMS approved New York's request to implement Health and Recovery Plans ("HARP") to integrate physical, behavioral health and BH HCBS for Medicaid members with diagnosed severe mental illness ("SMI") and/or substance use disorder ("SUD") to receive services in their own homes and communities. Under the demonstration, HARPs are a separate coverage product that is targeted to Medicaid members that meet need-based criteria for SMI and/or SUD established by the State. HIV Special Needs Plan ("SNP") under MMMC will also offer BH HCBS services to eligible individuals meeting targeting, risk, and functional needs criteria. All MMMC plans will offer BH benefits in integrated plans including four new demonstration services.

The demonstration was also amended to effectuate eligibility flexibilities for the Adult Group, including allowing adults enrolled in TANF to be enrolled as a demonstration population without a MAGI determination, extension of continuous eligibility for members of the Adult Group who turn 65 during their continuous eligibility period and temporary coverage for members of the Adult Group who are determined eligible to receive coverage through the Marketplace.

On November 30, 2016, CMS approved an extension of the demonstration, but in response to comments by the State, that extension was rescinded and superseded by a modified approval effective December 7, 2016. Under the most recent extension, the Partnership Plan was renamed New York Medicaid Redesign Team ("MRT") and references were changed throughout the Special Terms and Conditions ("STCs"). The extension included time-limited authorization to extend the DSRIP program first authorized in 2014, through March 31, 2020. The extension also included a new time limited DSHP authority to the extent that the State increases its Medicaid expenditures through its DSRIP program and achieves metrics that will result in anticipated cost savings that offset the DSHP expenditures. DSHP funding will be phased down over the demonstration period. The DSRIP and DSHP authorities are intended to be a one-time investment in system transformation that can be sustained through ongoing payment mechanisms and/or State and local initiatives.

The Behavioral Health Self-Direction Pilot was included as part of the renewal. This pilot makes self-direction services available to HARP and HIV SNP members receiving BH HCBS. The program is authorized to be in effect from January 1, 2017 through March 31, 2021.

On April 19, 2019, CMS approved an amendment to allow a waiver of comparability which permits managed care members to only be assessed a drug copay. The State will not assess the non-drug benefit cost sharing described in the Medicaid State Plan.

On August 2, 2019, CMS approved an amendment containing the following changes:

- Allow children with HCBS under the State's 1915(c) Children's Waiver and children placed in foster care through a Voluntary Foster Care Agency to enroll in Mainstream Managed Care or an HIV SNP.
- Continues Medicaid eligibility for Family of One ("Fo1") Non-1915 children who would have been eligible under the Children's Waiver had case management not been moved under the State Plan as a Health Home service or who were in a non-SSI category and receive HCBS or Health Home comprehensive case management.
- Include Children's Waiver HCBS and State Plan behavioral health services in the Medicaid managed care benefit package.
- Include children receiving HCBS under the Children's waiver in the Self Direction Pilot for Individual Directed Goods and Services.

On December 19, 2019, CMS approved an amendment with the following changes for Partially Capitated MLTC plans:

- Implement a lock-in policy for partially capitated MLTC plans, pursuant to which
 members of Partially Capitated MLTC plans are able to transfer to another Partially
 Capitated MLTC plan without cause during the first 90 days of a 12-month period and
 with good cause during the remainder of the period. A member of a Partially Capitated
 MLTC plan may transfer to another type of MLTC plan at any time.
- Limit the nursing home benefit in the Partially Capitated MLTC plan to three months for those members who have been designated as Long-Term Nursing Home Stays ("LTNHS") in a skilled nursing or residential health care facility, at which time the individual will be involuntarily disenrolled from the Partially Capitated MLTC plan and payment for nursing home services will be covered by Medicaid fee for service for individuals that qualify for institutional Medicaid coverage. Consistent with this Partially Capitated MLTC benefit change, individuals 21 years of age or older who are dually eligible for Medicare and Medicaid and LTNHS in a nursing home will be excluded from enrollment in a Partially Capitated MLTC plan.

Progress to Date

The MRT Waiver to date has realized measurable progress in achieving the following goals:

- Improving access to health care for the Medicaid population;
- Improving the quality of health services delivered; and
- Expanding coverage with resources generated through managed care efficiencies to additional low-income New Yorkers.

The State has made significant strides to transform Medicaid delivery systems to meet the myriad and evolving needs of Medicaid members today, while building infrastructure that

supports providers' ability to increase efficiencies in the delivery of care, engage in risk-contracting, and support population health. This transition has resulted in moving Medicaid provider contracts into early risk-based arrangements and testing models of collaboration to support providers and MCOs in addressing the social determinants of health ("SDOH"). Medicaid providers earned incentives for creating integrated, high-performing health care delivery systems that improve quality of care, support population heath, and reduce costs. Continuing this critical work while building a transition to even more integrated structures and reward pathways will be important to sustain gains made. Further developing these clinical network partnerships by deepening existing relationships and workflows, adding new partners, and engaging MCOs will further strengthen local continuums of care and increase efficiencies across delivery systems. While the current MRT waiver represented a crucial first step in the State's transition to value-based payment ("VBP") this extension request is the decisive bridge to the larger renewal that the State will pursue in light of COVID-19 and other MRT II reforms, on the State's journey to the full-realization of value-based care ("VBC").

Extending the Existing Waiver

Since New York's Section MRT waiver was approved in 1997, there have been several amendments, including those incorporating changes resulting from the recommendations of Governor Andrew Cuomo's Medicaid Redesign Team ("MRT"). New York remains well-positioned to lead the nation in Medicaid reform. Governor Cuomo's MRT and now the MRT II, which was established in early 2020, has developed an action plan, similar to the first MRT, that will build on the work of the MRT and, when fully implemented, will continue to improve health outcomes for more than six million New Yorkers, increase member satisfaction, and support the long-term fiscal sustainability of the Medicaid program. Significant federal savings were realized through New York's first MRT process and will also accrue from MRT II.

However, as COVID-19 spread across the United States, almost all states have been impacted—New York being no exception—as reflected both by the number of confirmed cases and resulting deaths. COVID-19 has laid bare the necessity for New York's healthcare system to be fundamentally reconfigured for scalability and flexibility, both for the near and long term.

While New York State recognizes this need, the outbreak of COVID-19 has proven that the original mission of ensuring coverage, access and quality health care to low-income New Yorkers, remains as much of an imperative today as it was in 1997. Despite the State's decisive response to the COVID-19 outbreak by providers, local departments of social services ("LDSS"), managed care organizations ("MCOs"), and communities—which has been extraordinary and involves taking swift action to approve private laboratories to test for the virus, standing up drive-through testing centers in outbreak hotspots to increase its testing capacity, and now rapidly building temporary hospital sites—COVID-19 revealed the limitations of the current delivery system to surge and redeploy resources rapidly during times of crisis.

It is with this strain on the system and increase in new members to the program, that the State is requesting a three-year extension. At present, according to the most recent monthly enrollment report, approximately 600,000 new members have been added to the program since the declaration of the Public Health Emergency.² The extension allows the continuation of the essential delivery of services to the Medicaid population in New York—including its authority to operate a comprehensive managed care program inclusive of long-term

² New York State Department of Health Enrollment by County, September 2020 https://www.health.ny.gov/health_care/medicaid/enrollment/docs/by_resident_co/2020/sept-2020.pdf

supports and services to the frail and elderly, support people with behavioral health diagnoses in managed care, and offer essential home and community based services to children, among other authorities—and affords the State sufficient time to comprehensively assess and incorporate into its strategy the impacts of COVID-19 and the systems changes that must occur in order to enhance its response to future public health crises and pandemics.

Goals and Objectives of the Extension

The goals and objectives of this waiver extension remain the same as the current goals and objectives set forth in the MRT Waiver at its onset (at initial approval known as "The Partnership Plan"). Those goals and objectives are:

- Improving access to health care for the Medicaid population;
- Improving the quality of health services delivered; and
- Expanding coverage with resources generated through managed care efficiencies to additional low-income New Yorkers.

New York State seeks to ensure that the State Medicaid program may continue meeting these goals throughout the COVID-19 pandemic and while the State and its stakeholders collectively develop a waiver renewal.

Eligibility, Benefits and Cost Sharing Requirements of the Extension

The State is not requesting any changes to eligibility, benefits, or cost-sharing requirements as part of this extension. However, the State is requesting to maintain all current eligibility categories, benefits, and co-payment standards that have already received approval from CMS, as outlined in the current STCs of the MRT waiver.

Delivery System Implications of the Extension

This extension application is not requesting any changes to the delivery system or payment rate for services beyond those following two amendments:

- The Transportation Carveout of Managed Long-Term Care to Fee-For-Service
- The Pharmacy Benefit Carveout from Managed Care to Fee-For-Service

For details on the changes proposed in these amendment requests, please see appropriate sections below.

Implementation Timeline of the Extension

This proposal is for a three-year 1115 waiver extension from April 1, 2021 to March 31, 2024, in order for the State to continue the vital programs authorized through the MRT Waiver and provide the necessary time to work with CMS and stakeholders to develop a full renewal in light of the COVID-19 pandemic.

Fiscal Implications of the Extension

This extension request is budget neutral to the federal government and does not impose any additional cost, nor request any additional federal funding. *The purpose of this extension request is to maintain existing programs and related waiver and expenditure authorities with minor modifications.* The State does not anticipate that, as a result of this extension proposal, caseload and costs will significantly change. The anticipated total caseload across the extension proposal to be 4.7M members for DY23, inclusive of the recent increases due to COVID-19. The anticipated total computable cost for this caseload is \$54B. These numbers are

subject to change depending on the minimum wage adjustment or other factors. For further details and additional cost and caseload projections, please see the Budget Neutrality section below.

Requested Amendments to the Existing Demonstration

The two requested amendments from the MRT II process seek to further stabilize our Medicaid program, enhancing the oversight and streamlining the administration of these two benefits so they can be provided to beneficiaries more effectively. The State has, and will, assess all elements of the requested changes for alignment with federal performance measurement approaches, programmatic approaches and promising practices, in order to promote better outcomes for the State's Medicaid members. The State seeks to build on the lessons learned from its current waiver and is requesting two concurrent amendments in this waiver extension, which were recommendations advanced by MRT II to improve health outcomes, increase member satisfaction, and support the long-term fiscal sustainability of the Medicaid program:

- A Transition ("Carveout") of MLTC Non-Emergency Medical Transportation Services Fee-For-Service ("FFS"); and
- A Transition ("Carveout") of the Pharmacy Benefit from Managed Care to FFS.

Each amendment is discussed in further detail below.

A Transition (Carveout) of MLTC Non-Emergency Medical Transportation Services to FFS Amendment

Medicaid transportation is a federally required State Plan-approved service managed and administered by the Department of Health ("DOH" or the "Department") to ensure that members have access to approved medical services. The Medicaid Non–Emergency Medical Transportation ("NEMT") benefit is authorized under the Social Security Act § 1902(a)(70) and 42 C.F.R. § 440.170, and requires that a Medicaid program:

- Ensure necessary transportation to and from providers;
- Use the most appropriate form of transportation; and
- Include coverage for transportation and related travel expenses necessary to secure medical examinations and treatment.

Since 2012, the 1115 MRT demonstration authorized MLTC plans to offer NEMT services to its members as part of the benefit package it manages. With the exception of Programs of All-Inclusive Care for the Elderly ("PACE") organizations, the State now seeks to move the authority for provision of NEMT services from the MRT waiver, into a State Plan Amendment ("SPA"). For additional information, CMS may review a forthcoming SPA, which will be submitted before the end of the calendar quarter in which it will take effect.

Goals and Objectives of the MLTC Transportation Carveout Amendment
While assuring access to care for over six million Medicaid members, and using the most medically appropriate, cost-effective level of service, the New York Medicaid Program spending on NEMT services continues to grow disproportionately, particularly at the taxi/livery level of service. Following a recommendation of MRT II, the State enacted a series of actions to help better manage the growth of NEMT spending and

align these benefits to member needs.³ In connection with these actions, this MRT waiver amendment proposal would carve out the Medicaid NEMT benefit from non-PACE, MLTC capitated rates to FFS management. The management of the trips (e.g., scheduling, assignment of the most appropriate mode, prior authorization) will be performed by a professional transportation management broker—either statewide or in certain regions of the State. Such broker(s) will be procured by the State in a risk-based arrangement(s). This change in transportation management streamlines and centralizes the benefit for Medicaid members, and adheres to the principles of value-based care -payment to improve outcomes. Presently, there are approximately 263,000 MTLC members, in 28 plans, whose NEMT transportation cost component of the capitated rates totals over \$400 million annually. The transportation benefit has previously and successfully been carved out of the MMMC benefit package and managed through the FFS program.

The carveout of the NEMT transportation benefit from MLTC enhances efficiencies by leveraging the contracted transportation management broker resources, including the broker's infrastructure and network. Hospitals, medical providers, and managed care organizations will also benefit from the efficiency of a single transportation management point of contact statewide or in their region, rather than multiple transportation organizations that vary by plan. Additional benefits of transportation broker management include:

- Medicaid per member cost savings
- Increased efficiency with limited resources
- Assignment of the most medically appropriate mode of transport
- Greater Medicaid program accountability
- Improved service quality
- Better coordination of services during inclement weather and catastrophes
- Expedited complaint investigation and resolution
- Early identification of transportation access issues
- Increased flexibility and sensitivity to individual member needs
- Improved fraud and abuse identification

The goals of this amendment request are as follows:

- Improve administrative simplification by creating a consistently managed transportation benefit and removing the benefit from the MRT waiver
- Reduce cost-risk by shifting the broker arrangement to a risk-based arrangement.
- Create a larger pool of members by combining all members, except PACE for which the transportation benefit must be managed by the PACE Organization under federal rules, for brokers to provide NEMT service to.

Eligibility, Benefits, and Cost-Sharing Requirements of the MLTC Transportation Carveout Amendment

The proposed amendment does not make any changes to program eligibility, benefits, or cost-sharing requirements. This proposed regulatory amendment should not have an impact on members' access to the transportation benefit; it instead shifts the delivery of

_

³ https://www.nysenate.gov/legislation/laws/SOS/365-H

the benefit from MLTC plans to FFS. Please see the New York Medicaid State Plan for additional eligibility, benefit and cost-sharing details.

Waiver and Expenditure Authorities of the MLTC Transportation Carveout Amendment

This amendment is carving out the management of transportation benefits for MLTC member lives from the MRT waiver, and therefore is not requesting any additional waiver or expenditure authorities.

<u>Delivery System Implications of the MLTC Transportation Carveout Amendment</u>

<u>Member Impact</u>: The MLTC Carveout will be phased-in upon implementation of the NEMT broker and transitions 292,000 enrollees from MLTC plans to a transportation "broker" model. This carveout is shifting the delivery system through which members receive the benefit but does not change the scope, or eligibility of the benefit itself, therefore there will be minimal member impact due to this amendment.

Plan Impact: The Department will transition the Medicaid transportation benefit from the MLTC plans, and its associated capitated premium calculation (excluding PACE), back to the FFS program. This impacts approximately 292,000 MLTC members. This change is intended to promote consistency and improve quality across the management of the transportation benefit and creates alignment with how transportation is already successfully managed for 6 million members enrolled in MMMC and the FFS program.

Broker Impact: Once the transportation benefit is transitioned back into the FFS program, the management of trips (e.g., scheduling, assignment of the most appropriate mode, prior authorization, etc.) will be performed by one or more professional transportation brokers ("Brokers") either statewide or in certain regions of the State—that will be procured by the State. Brokers will enter into a risk-based arrangement in order to drive value and lessen cost-risk of the NEMT program.

State Impact: The transition of the benefit will have consumer protections in place to ensure for the smoothest possible transition, including State responsibilities such as:

- Transitioning of member transformation information with limited disruptions in member transportation experience;
- Monitoring of member access;
- Developing mandatory corrective actions for any Medicaid enrolled provider who fails to meet quality performance standards; and
- regular auditing and oversight by the Department of Health and other State and federal agencies in order to ensure the quality of the transportation services provided and adequacy of Medicaid member access to medical care and services.

Implementation Timeline of the MLTC Transportation Carveout Amendment
This carveout is intended to take place upon implementation of the NEMT broker with a phased implementation approach over a six-month period.

Fiscal Implications of the MLTC Transportation Carveout Amendment

This amendment is seeking to carveout MLTC members from receiving transportation services under the waiver authority and transition them to receiving the services through FFS under the State Plan. The total caseload affected is approximately 292,000 members, with total computable cost projected to be approximately \$291.6M for DY23. Costs to administering agencies and the State associated with this amendment will be covered by existing State budget appropriations and anticipated federal financial participation. The proposed amendment does not have an impact on the budget neutrality of the MRT waiver. There are no costs imposed on local governments by these regulations because the amendments incorporate Medicaid transportation program changes related to implementation of the transportation management broker. With anticipated member impact is intended to be minimal.

<u>Public Notice Compliance and Documentation of the MLTC Transportation</u> Carveout Amendment

The State scheduled public hearings on January 21, 2021 and January 27, 2021, which were conducted through real-time, audio-visual webinars on WEBEX and recorded and provided an opportunity for the public to offer comment, consistent with flexibilities granted by CMS during the federal public health emergency period. This amendment was further provided to the public as part of the larger extension request on December 16, 2020.

<u>Tribal Notification of the MLTC Transportation Carveout Amendment</u>

The State provided tribal notification of this amendment as part of the larger extension request on December 16, 2020.

A Transition (Carveout) of the Pharmacy Benefit from Managed Care to FFS Amendment

As the policy landscape of providing pharmacy benefits in Medicaid shifts away from the "carve in" model, where pharmacy benefits are included in the managed care benefit package, to a "carve out" model, several large Medicaid programs (e.g., California, West Virginia, Wisconsin, Tennessee⁴) have decided to manage the pharmacy benefit for Medicaid members through the FFS benefit under the State's control. The State Plan currently authorizes FFS to deliver this benefit, from which MMMC members were carved out of in 2011. The transition *back* to FFS will leverage the existing State Plan authority for all Medicaid members. As such, CMS approval of the State's 1115 waiver is not a pre-condition to implementation of the pharmacy transition to Medicaid fee-for-service.

Goals and Objectives of the Pharmacy Carveout Amendment

The transition of the pharmacy benefit from MMMC to FFS is a result from growing concerns about the value of "carve-in" model and the ability to of the State to manage pharmacy spending, given the lack of transparency by MCOs and their Pharmacy Benefit Managers ("PBMs").¹ The use of "spread pricing" where managed care plans contract with PBMs to manage their prescription drug benefits, and the PBMs keep a portion of the amount paid to them by the health plans for prescription drugs has exposed the lack of transparency in managed care pharmacy reimbursement and the

⁴ https://www.kff.org/report-section/how-state-medicaid-programs-are-managing-prescription-drug-costs-pharmacy-benefit-administration/

potential for additional expenses borne by the Medicaid program. The pharmacy benefit carveout will address these concerns and achieve the following goals:

- Provide the State with full visibility into prescription drug costs;
- Centralize and leverage negotiation power;
- Realize economies of scale through centralized management and administration;
- Provide a single drug formulary with standardized utilization management protocols; and
- Address the growth of the 340B program and associated reductions in State rebate revenue.

Despite the State's efforts to control rising drug costs, Medicaid spending on prescription drugs has been growing faster than the rate of inflation. By moving the pharmacy benefit for the over 5 million Medicaid Managed Care ("MMC") members back to the FFS system, the State will have greater visibility into the underlying cost of prescription drugs and the ability to centralize the purchasing power for all 6.6 million Medicaid members as a single State purchaser of drugs. In addition to greater transparency and enhanced purchasing power, there will be a single, centralized formulary to ensure consistency in the pharmacy benefit across the Medicaid program. This will simplify the benefit for members and prescribers, easing administrative burden by eliminating multiple formularies and prior authorization contacts, remove conflicts of interest with intermediaries in the pharmaceutical supply chain, and improve the ability of the State to negotiate rebates with drug manufacturers.

This carveout is also intended to address growth in the State's 340B program and associated reductions in State rebate revenues. While 340B is an important program to safety-net providers, its rate of growth (averaging 47% on a compounded annual basis) has become unsustainable. This loss of rebates to the NY Medicaid program has totaled over \$800 million (gross) over the past four years and continues to increase year over year. In recognition of both the importance of the 340B program to safety-net providers in the State, but also the need to address revenue reductions, the State is committed to the reinvestment of \$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. A 340B Advisory Group, composed of key 340B stakeholders was established in State statute, to provide feedback to the State regarding how the \$102M will be distributed. To date, the 340B Advisory Group has not submitted recommendations regarding how the \$102M will be distributed. Therefore, the State has proposed, in the SFY 2021-22 Executive Budget, a methodology for the distribution of these funds. 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 pharmacy 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. The State 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 carveout, 340B covered entities will continue 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. Medicaid members will continue to access their medications regardless of whether 340B drug stock is used. The tagging of a claim as 340B vs. non-340B is not visible to the member and does not result in disruption at the counter when members pick up their medications.

Eligibility, Benefits, and Cost-Sharing Requirements of the Pharmacy Carveout Amendment

There are no changes to eligibility, scope of benefits, or co-payment standards as a result of this carveout. This amendment simply shifts the administration and delivery of the benefits by <u>carving out</u> these this benefit from the Medicaid Managed Care delivery systems to Fee-For-Service in the State Plan. This carveout is intended to generate savings, through greater transparency and enhanced purchasing power, with the goal of minimal provider and member disruption. The Pharmacy benefit carveout applies to all MMMCs, including HARP and HIV-SNP plans; however, this carveout does *not* apply to MLTC plans (e.g., PACE, MAP, partial capitation MLTC), the Essential Plan, or Child Health Plus ("CHP").

The State provided continuously updated charts on both an overview and detailed scope of benefits chart of which services are and are not subject to the carveout, as well as how these services will be handled in the post-transition phase of the carveout. These documents are as follows:

- The Overview of the Scope of Benefits provides a snapshot of what is changing and what is not in relation to pharmacy services in New York Medicaid's two delivery systems, managed care and FFS, in the current state (pre-transition) and future state (post-transition).
- The Detailed Scope of Benefits provides a comprehensive inventory of the NYS
 Medicaid's outpatient pharmacy benefit, and whether the benefit is subject to the
 carveout and whether the managed care plans are required to continue to
 provide the benefit available when provided by a non-pharmacy provider.

The Overview and Detailed Scope of Benefits documents can be accessed on the MRT website via this website:

https://health.ny.gov/health_care/medicaid/redesign/mrt2/pharmacy_carve_out/docs/rx_carve_out_scope.pdf.

A full list of Durable Medical Equipment ("DME") that are not subject to the carveout and are found within the Durable Medical Equipment, Prosthetics, Orthotics, Supplies and Procedure Codes and Coverage Guidelines can be accessed on the MRT website via this link

https://health.ny.gov/health_care/medicaid/redesign/mrt2/pharmacy_carve_out/docs/rx_carve_out_scope.pdf.

<u>Waiver and Expenditure Authorities of the Pharmacy Carveout Amendment</u>

New York State's MRT Waiver demonstration provides the current authority under which the pharmacy benefit is delivered by MCOs. This amendment is removing the pharmacy benefit for managed care plan enrolled members from the MRT Waiver and moving it

into the existing benefit structure vested by the State Plan. Therefore, the State is not requesting any additional waiver or expenditure authorities in regard to this amendment.

<u>Delivery System Implications of the Pharmacy Carveout Amendment</u>

A large consideration when comparing the impact of the current model (under MCOs) to an FFS model is the administrative costs associated with the delivery of prescription drug benefits. Under the MCO model, these costs are incurred by the MCO and their associated PBM, and reimbursed by the State through managed care premiums, and include services such as pharmacy network management, eligibility management, claims processing, preferred drug list ("PDL") development and maintenance, and drug utilization review and health plan surplus.

Under the FFS model, New York State Medicaid would bear these responsibilities and the associated costs directly, in addition to overhead for State staff, expenses for pharmacy claims and rebate processing vendors, PDL maintenance, as well as other consulting and administrative services costs. Other impacts on specific stakeholders and systems are listed below:

Member Impact: The intent of the previously mentioned transition period is to limit service disruption to the fullest extent possible. The communication of the benefit transition will be done so through use of social media, the distribution of easy-to-read tip sheets for members that that provide them with key information and links to guide them through the transition. Additionally, updates to providers and pharmacies will be done via Medicaid Update articles and targeted prescriber outreach to address member specific issues (e.g., use of non-preferred medications), through mail, email and other electronic methods. All members who upon transition are receiving non-preferred medications will be allowed a one-time fill within 90 days of the implementation, slated on or after April 1, 2021. Prescribers will also be alerted that their patients are on non-preferred medications so that they can switch to a preferred medication or request prior authorization, for fills beyond the transition fill. Medicaid members will continue to obtain their medications, regardless of whether 340B drug stock is used to fill their prescriptions.

Managed Care members without their Medicaid card will not experience disruption at the counter when picking up their medications at the pharmacy, as there will be a variety of methods in which pharmacies will be able to verify enrollment and process prescriptions including accessing the Medicaid Client Identification ("CIN") number from either the Medicaid Card or the MCO card, using the State's ePACES system or the pharmacy claim standard ("NCPDP") E1 eligibility transaction.

Children in foster care that are already enrolled in MCOs will begin to receive their outpatient pharmacy benefit through the FFS program effective on or after April 1, 2021. Foster care children that transition from FFS into an MCO July 1, 2021 will continue to receive their pharmacy benefit through the FFS program, resulting in a consistent pharmacy benefit for all children in foster care.

Additional information about the communication activities, strategy, and timeline to notify members, providers, and plans can be found on the New York MRT Website regarding the Pharmacy Carveout can be found at this website:

https://www.health.ny.gov/health_care/medicaid/redesign/mrt2/pharmacy_carve_out/docs/rx carve out activities timeline.pdf.

Provider Impact: Providers that are prescribing outpatient drugs (or other products covered under the outpatient pharmacy benefit), for MCO members, will access a single FFS formulary and the PDL to determine coverage parameters. Pharmacies that are billing for outpatient drugs for MCO members will submit claims to the eMedNY system. In doing so, this significantly reduces the burden on providers to check multiple formularies in order to determine preferred or non-preferred status of a drug, and instead streamlines this process by using the established FFS formulary.

The Pharmacy Carveout will have no impact to 340B Covered Entities' ability to use the 340B program for practitioner administered drugs provided to Medicaid members and non-Medicaid members (e.g., Medicare and Commercial Insurers). It also is important to note that the Pharmacy Carveout will not change the ability of a 340B Covered Entity to purchase medications at reduced 340B prices.

MCO Impact: MCOs will continue to be responsible for maintaining all activities necessary for their enrolled members' care coordination and claims payment for non-outpatient pharmacy services and related activities, consistent with contractual obligations. The MCOs will determine the personnel and resources that they need in order to continue to perform these functions in order and effectively transition the pharmacy benefit out of their scope.

DOH has worked closely with the MCOs to ensure that they receive timely pharmacy data and reports that will enable continued care management, pharmacy compliance programs and support value-based program (VBP) activities. As such, DOH will be 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 more 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 MCO's and providers continue post transition.

POS Pharmacy Impact: The impact to pharmacies underwent an extensive stakeholder engagement and feedback process throughout the development of this amendment during which they provided key input into the transition strategy. Upon transition of the pharmacy benefit to the FFS program, DOH will use the eMedNY system for point-of-sale claims adjudication. This is the claims adjudication system which is currently used for Medicaid members that access all their benefits through the FFS program. A comprehensive evaluation of the eMedNY system has been conducted, to ensure that the system contains adequate capacity for the increased claims volume. Pharmacies will have multiple modalities to quickly obtain member ID including accessing the CIN number from either the Medicaid Card or the MCO card, as well as the State's ePACES system, and finally the pharmacy claim standard (i.e., NCPDP) E1 eligibility transaction. Additionally, monitoring processes and reports have been refined to more quickly identify potential claim processing variances (e.g., monitoring of expected claim transactions vs. actual transactions, # of claim denials by reason vs. actual claim denials by reason). Lastly, post implementation monitoring will include recurring calls with call centers and

stakeholders to further identify and resolve questions and/or issues related to claims processing.

Drugs and Supplies Covered by the Carveout: The carveout will include covered outpatient drugs and other products covered under the Outpatient Pharmacy Program. This includes outpatient prescription and over-the-counter drugs, diabetic, incontinence and other supplies. It does not include physician administered (J-Code) drugs. The Scope of Benefits chart which can be found on the NY MRT website lists what drugs and products are included in the Outpatient Pharmacy Program, https://www.health.ny.gov/health_care/medicaid/redesign/mrt2/pharmacy_carve_out/rx_carve_out_scope.htm

Preferred Drug Program: The Medicaid FFS Preferred Drug Program ("PDP") promotes the use of less expensive, equally effective prescription drugs when medically appropriate. The determination of whether a drug is preferred or non-preferred drugs within the PDP, does not prohibit a prescriber from obtaining any of the drugs. To ensure a smooth transition, DOH conducted an analysis comparing the drugs currently being used by managed care members to the drugs in the PDP and determined that there is a 90% match to drugs that are preferred under the PDP. Furthermore, for the 10% that didn't match, half are for acute drugs, that would most likely, not be continued on or after April 1, 2021. The *one-time fill* and transition period in concert with the targeted communications to prescribers and members, as previously described, will mitigate transition issues.

State Program and Policy Staff: The Office of Health Insurance Programs ("OHIP") within DOH is responsible for policy and program management for the Medicaid pharmacy program. With the transition of the pharmacy benefit into the FFS program, there will be significant volume increases, as outlined in Table 1, for which additional capacity in distinct pharmacy roles, including pharmacist supervisors, pharmacy managers, and data analysts, are necessary for clinically based operations and processes within the program.

Clinical and subject matter expertise are essential to mitigate the risks associated with added claims and prior authorization volumes as well as critical transition activities including, but not limited to evaluating pharmacy claims data, drug utilization patterns, and comparing plan formularies to the FFS formulary to inform the development of transition strategies that ensure that members continue to get access to needed medications. As such, thirteen state positions have been added to support these activities.

A detailed overview of the extent of the pharmacy benefit categories that OHIP will be responsible for are outlined in the aforementioned Scope of Benefits Charts. Please note that all pharmacy categories except for one (physician administered drugs) will be under the responsibility of FFS effective on or after April 1, 2021.

Systems and Operations: In order to ensure a successful implementation and ongoing management of the pharmacy program additional infrastructure, staff and supports are necessary to facilitate and support such a transition. The OHIP systems role in the Pharmacy Carveout is arguably among the most crucial as the systems team within OHIP is responsible for paying all FFS claims through the eMedNY system, storing and managing all adjudicated claims data in the Medicaid Data Warehouse, and staff are

responsible for the prior approval for DME & Supplies that are subject to the carveout, all of which are integral to the ability to manage the additional pharmacy volume. Currently, OHIP systems staff is responsible for the oversight of information systems that support the New York Medicaid Program and DOH initiatives including the Medicaid Management Information System, Healthcare Benefit Exchange, and Medicaid Data Warehouse.

The increased volume that the FFS program will incur as a result of the transition from managed care is significant – there will be a 600% increase in the claims volume, \$7 billion dollars of additional payments made through the claims payment system (i.e., eMedNY), an additional 700,000 prior authorizations – and several system and operational enhancements are underway to ensure the appropriate application of clinical criteria and standards are embedded into the claims payment system to appropriately pay claims accordingly.

OHIP (and the contractors it directs and oversees) are effectively replacing all the functions that plans currently contract out to PBMs. Absent adequate system enhancements and additional State personnel with relevant expertise the risk of denied claims and/or inaccurate payment of approved claims is significant. The impact of these risks would be realized at the point of sale when a pharmacy submits a claim to the eMedNY system. Eliminating unnecessary claim rejections and ensuring that questions regarding claim denials are handled in an expeditious manner ensure that Medicaid members receive medications in a timely manner. Issues regarding coding logic specific to a drug with high utilization could impact thousands of times for Medicaid members. In addition, if claims are paid inaccurately due to a failure in coding, reimbursement logic, or payment edits, the Medicaid program would be liable for overpayment until such a time that issue was identified and corrected, both of which would be less likely to occur with the appropriate resources for claims, monitoring, quality assurance and oversight.

Furthermore, the additional staff will be responsible for the development of systems capability to monitor claims flow, logic, timeliness of payment, variations in submissions and related 'operational health of the program' activities. In addition, the staff will build system tools that support all areas of the pharmacy benefit in managing the program. This includes developing analytic dashboard, system views, supporting programmers and analysis with visibility into the claims adjudication system, conducting detailed reimbursement logic to support pricing efficiencies, thereby reducing waste and improving service delivery to providers and recipients. In addition, OHIP will be required to build out infrastructure so support data sharing with the MCOs so that they can continue to provide effective care management for their Medicaid members. As such twelve State positions have been added to support the Medicaid FFS Pharmacy systems and operational activities.

Finance and Rate Setting: Finance and Rate Setting within OHIP is responsible for projecting and monitoring the Medicaid Drug Cap. In addition, and important to the fiscal management of the pharmacy benefit, DFRS is responsible for administering the Pharmacy Rebate Program through which Medicaid currently receives over \$2 billion dollars in manufacturer rebates to offset program costs, an amount that is expected to increase with the Carveout as detailed in Table 1 below.

The transition of the pharmacy benefit to FFS means that the State, as opposed to the managed care plans, will bear full responsibility for the financial management of the

Medicaid pharmacy program. As such, four positions will be added to DFRS and a dedicated unit will be created, charged with overseeing and leading financially based operations and processes within the Medicaid Pharmacy program. This will ensure adequate resources are in place to conduct timely analyses of spending and rebates.

Implementation Timeline of the Pharmacy Carveout Amendment

Communication about the transition of the pharmacy benefit to FFS will be done by both NYS DOH and the MCOs and will be accomplished through a variety of methods including recurring stakeholder meetings letters and Medicaid Update articles. Additional details regarding the stakeholder meetings can be found in the "Public Notice, Compliance and Documentation Section" of this document.

The State has provided detailed and continuously updated charts to give additional context and information related to the New York State Department of Health's (NYS DOH) transition and communication activities of the Pharmacy Carveout from Managed Care to Fee-For-Service as well as the roles and responsibilities of the State (Department of Health, Office of Health Insurance Programs), MCOs, and FFS Pharmacy Contractors in the post-transition phase of the carveout. These transition and communication activities and roles and responsibilities can be found at https://health.ny.gov/health_care/medicaid/redesign/mrt2/pharmacy_carve_out/docs/rx_carve_out_roles.pdf, respectively.

Transition Strategy: SFY 2019-20 has been established as the year for planning and implementation, guided by the following principles:

- <u>Continuity</u>: Ensure members are provided with continued access to needed medications and supplies with minimal impact. Comparison of FFS pharmacy claims and Medicaid Managed Care pharmacy claim encounters will inform transition strategy.
- <u>Communication</u>: Maintain communication with stakeholders (e.g. providers, patient advocates, and MCOs) through recurring stakeholder meetings and the posting of pertinent information on the Carveout on the DOH website, which may be accessed at the following website:
 https://www.health.ny.gov/health_care/medicaid/redesign/mrt2/pharmacy_carveout/
- Oversight: Utilize post-implementation processes that ensure appropriate oversight, issue identification, tracking and resolution.

DOH has worked closely with MCOs and other stakeholders including agencies such as the Office of the Medicaid Inspector General (OMIG) concerning implementation-related decisions and activities such as provider and pharmacy communications and data sharing specifications for health plans so that they can continue to maintain all activities necessary for their members' care coordination as well as activities to identify Fraud Waste and Abuse. The focus has been to limit member and provider impact through a comprehensive analysis of current utilization of pharmacy services and the implementation of transition and communication strategies that will smooth the transition. DOH has established several stakeholder groups including Managed Care Plans, a

340B advisory group, and all-stakeholder meetings, that meet on a recurring basis (further discussed below), and whose feedback has informed the implementation.

All individuals currently receiving pharmacy benefits provided by 16 managed care organizations will continue to have access to needed medications when the benefit is transitioned to FFS on or after April 1, 2021. This will be accomplished through a data driven transition strategy that addresses formulary differences ahead of the effective date through targeted communication and outreach activities. There will also be a transition period from on or after April 1, 2021 through June 30, 2021. During this period, members will be provided with a one-time, temporary fill for medications that would normally require prior authorization under the FFS Preferred Drug Program (PDP). This allows additional time for prescription-related alerts and communication to prescribers to either seek prior authorization or change to a drug, which does not require prior authorization. Additionally, NY State will honor prior authorizations already provided by the MCOs.

Fiscal Implications of the Pharmacy Carveout Amendment

The approximate caseload impact is 4.4 million members currently receiving this benefit through Managed Care that will be carved out to Fee-For-Service. The projected impact of this carveout for DY23 is approximately \$6.3B. The transition of the pharmacy benefit from managed care to FFS is projected to save the State approximately \$87.3M annually beginning in State Fiscal Year (SFY) 2021-22. The elements of the projected savings in SFY 2021-22, include but are not limited to the following factors:

- Additional federal and State supplemental drug rebates resulting from a shift of drug utilization from the Managed Care (MC) delivery system to the Fee-For-Service (FFS) delivery system under a uniform preferred drug list, which will increase leverage when negotiating with drug manufacturers.
- Reduction of administrative costs and non-claim components of spending, including the costs associated to administrative functions of multiple pharmacy benefits managers used by MCOs as well as taxes and surplus funded in MC premiums; and
- Savings on 340B drugs from reimbursement of actual acquisition cost, which is the federally required reimbursement for 340B drugs in FFS. The \$87.3M in State share savings assumes that less than 50% of the 340B savings will be realized in the SFY 2021-22.
- In addition, the State share savings projection is based on current FFS reimbursement methodology, which includes a \$10.08 professional dispensing fee.

OHIP required one year (that being the current state fiscal year) to prepare for the transition due to the scope of the programmatic and operational activities that need to take place to transition the pharmacy benefits for over 5 million Medicaid Managed Care members to FFS. Investments in staffing and systems as previously explained, are necessary to accommodate the influx of managed care pharmacy utilization, which is five times the size of the current FFS utilization. Table 1 below illustrates the expected volume increases associated with the transition to FFS that will occur on or after April 1, 2021, Table 2 depicts the fiscal summary of the carveout, and savings generated, which are the results of net investments in staffing and systems.

Additionally, administrative costs are a critical component to financial plan budget savings. Administrative costs that are included within the current managed care capitation rates along with the level of spread pricing included within the managed care reimbursement allows for MCOs and PBMs to realize a profit when administering the pharmacy benefit. Administrative costs paid to managed care plans to administer the Medicaid pharmacy benefit were \$285 million in 2019. By comparison, the Department administration of the functions, including the cost of the additional staff, is \$43 million (of which \$22.5M are State only costs) Although the number of Medicaid members currently served by the Medicaid FFS pharmacy program is relatively small compared to the number of members receiving their pharmacy benefits through a managed care plan, some portion of the administrative overhead cost associated with running the FFS program are already being incurred by the Medicaid program, which enables DOH to replicate this function and manage this benefit for over 6 million additional Medicaid beneficiaries at a relatively minimal marginal cost. Details on the administrative savings associated with the FFS Pharmacy Carveout are shown in the table below.

Table 1: Projected Volume Increases – Pharmacy Transition to FFS

Projected Volume Increases – Pharmacy Transition from Managed Care to FFS	FFS Today	FFS 4/1/2021	Percentage Increase
Members	1.5M	6.6M ¹	340%
Total Annual Gross Spend	\$785M	\$7.4B	843%
Annual Claims Transactions	26.6M	150M	464%
Annual Paid Claims	12M	90M	650%
Annual Prior Authorizations	120,876	906,570 ²	650%
Federal and Supplemental Rebates	\$700M	\$3.6B	429%
Rebates as a % of Total Pharmacy Spend	50.92%	57.92% ³	7%

Notes

- 1: Source: September 2020 NYS OHIP Medicaid Monthly Enrollment Report
- 2: Based on current ratio of prior authorizations to paid claims
- 3: Based on SFY 2021-22 Savings Target of \$87.3M (State Share)

Table 2: Pharmacy Carveout Fiscal Summary (SFY 2020-21 Enacted Budget)

Key Drivers / Component	Managed Care	FFS	Cost/(Savings)
Claims Repricing (includes rebates)			

Key Drivers / Component	Managed Care	FFS	Cost/(Savings)
Ingredient Cost 5	\$6,066M	\$5,558M	(\$508M)
Dispensing Fee ⁶	\$32M	\$637M	\$605M
Net Change in Reimbursement Cost	\$6,098M	\$6,195M	\$97M
Administrative Costs			
Current Admin (Including Taxes & Surplus) ⁷	\$285M	-	(\$285M)
New Admin (Including New Staff & Contract Costs) ⁸	-	\$43M	\$43M
Net Change in Admin Spend	\$285M	\$43M	(\$242M)
<u>Rebates</u>			
Current Federal & Supplemental Rebates 9	(\$3,357M)	(\$3,219M)	\$138M
New Federal & Supplemental Rebates 10	-	(\$419M)	(\$419M)
Net Change in Rebates	(\$3,357M)	(\$3,638M)	(\$281M)
Other Adjustments			
340B Reinvestment ¹¹	-	\$102M	\$102M
Risk Margin ¹²	-	\$89M	\$89M

⁵ Assumes FFS Reimbursement logic to reprice ingredient cost for managed care claims (Source: MDW SFY 2018-19 claims). Incremental trend of 4% applied to both MC and FFS spend to account for SFY 2020-21 Benefit Period (Source: Deloitte). The repricing of Managed Care claims using the FFS reimbursement logic includes \$166 million in savings (gross) associated with 340B reimbursement. In addition, the repricing assumes increased FFS utilization of non-preferred drugs due to the impact of prescriber prevails; and applies the savings from the SFY 2019-20 budget action to eliminate spread pricing in MC as a cost to FFS (because these savings were achieved prior to 4/1/21 carveout).

⁶ Assumes \$.50 Dispensing Fee for Managed Care claims (Source: Plan Contracts); and the current \$10.08 Dispensing for FFS. Includes dispensing fee associated with 340B claims.

⁷ Assumes MMC Admin reduction (3.07%), as well as relevant taxes (.84%) and surplus (1%) in managed care premiums. Does not include the ACA tax. (Source: Deloitte)

⁸ New FFS Admin costs assumes 29 new FTE's (\$4M) and additional funding for existing pharmacy vendor contracts (\$39M) (Source: DOH).

Assumes the same federal rebate dollars for Managed Care and FFS; Also, assumes reduced supplemental rebates in FFS compared to MC due to drug mix of current FFS SR agreements. These rebates assumptions do not factor drug mix or rebate changes associated with a Statewide PDL.

¹⁰ Includes a 6% increase in federal rebates due to drug mix changes under the FFS Preferred Drug List (PDL). Also assumes that FFS can achieve a 1% increase in supplemental rebates due to additional negotiating leverage under the NPMI and Medicaid Drug Cap. (Source: Magellan)

¹¹ The value of the 340B reinvestment will be permanently reinvested to 340B Covered Entities beginning in SFY 2021-22 and each

year thereafter.

12 Assumes a 1.5% risk margin (on repriced FFS spend) to account for the transfer of risk from Managed Care to FFS where the State would bear the risk for blockbuster drugs in the pipeline.

Key Drivers / Component	Managed Care	FFS	Cost/(Savings)
Net Change in Other Adjustments	-	\$201M	\$201M
Net Spend (Gross)	\$3,026M	\$2,792M	(\$235M)
Net Spend (State Share) ¹³	\$1,123M	\$1,036M	(\$87M)

<u>Public Notice Compliance and Documentation of the Pharmacy Carveout Amendment</u>

The State scheduled public hearings on January 21, 2021 and January 27, 2021, which were conducted through real-time, audio-visual webinars on WEBEX and recorded and provided an opportunity for the public to offer comment, consistent with flexibilities granted by CMS during the COVID-19 federal public health emergency period. This amendment was further provided to the public as part of the larger extension request on December 16, 2020.

The State has also conducted extensive stakeholder engagement efforts throughout the amendment process across three different groups. First, monthly stakeholder meetings were held in service of providing all interested stakeholders with updates, facilitate a Q&A session, and incorporate feedback into the workplan as needed. Second, bi-weekly meetings with the MCOs were held to a provide a recurring forum for DOH and the Medicaid Managed Care plans to address specific topics that require consensus or clarification, in order to progress with the transition. Finally, as part of the legislation to transition the pharmacy benefit out of MMMC to FFS, the State convened a 340B Advisory Group in order to develop non-binding recommendations to achieve savings and align with the goals of the carveout amendment.

In addition, the State has established a <u>web page</u> specific to the Pharmacy Carveout, to keep stakeholders informed of the discussion topics at the various stakeholder meetings, and it also contains a comprehensive FAQ document which can be accessed using this link

https://health.ny.gov/health_care/medicaid/redesign/mrt2/pharmacy_carve_out/docs/pharm_carve_out_faq.pdf.

Tribal Notification of the Pharmacy Carveout Amendment

The State provided tribal notification of this amendment as part of the larger extension request on December 16, 2020.

Waiver and Expenditure Authorities

The State requests to continue following waivers and expenditure authorities to operate the demonstration, as outlined below.

Waiver Authorities Requested

¹³ Assumes State Share costs @ 37.10% of Gross costs.

Waiver Authority	Reason and Use of Waiver Authority
Extension of Existing Demonstration Section 1115(a)	a. To the extent necessary to enable the State to extend the existing waiver for an additional three years.
2. Statewideness Section 1902(a)(1)	a. To permit New York to geographically phase in the Managed Long-Term Care (MLTC) program and the Health and Recovery Plans (HARP) and to phase in Behavioral Health (BH) Home and Community Based Services (HCBS) into HIV Special Needs Plans (HIV SNP).
3. Comparability Section 1902(a)(10), section 1902(a)(17)	 a. To enable New York to apply a more liberal income standard for individuals who are deinstitutionalized and receive HCBS through the managed long-term care program than for other individuals receiving community-based long-term care. b. To the extent necessary to permit New York to waive cost sharing for non-drug benefit cost sharing imposed under the Medicaid State Plan for members enrolled in the Mainstream Medicaid Managed Care Plan (MMMC) – including Health and Recovery Plans (HARP) and HIV SNPs – and who are not otherwise exempt from cost sharing in §447.56(a)(1). c. Family of One Non-1915 Children, or "Fo1 Children" – To allow the State to target eligibility to, and impose a participation capacity limit on, medically needy children under age 21 who are otherwise described in 42 CFR §435.308 of the regulations who: 1) receive Health Home Comprehensive Care Management under the State Plan in replacement of the case management services such individuals formerly received through participation in New York's NY #.4125 1915(c) waiver and who no longer participate in such waiver due to the elimination of the case management services, but who continue to meet the targeting criteria, risk factors, and clinical eligibility standard for such waiver; and 2) receive HCBS 1915(c) services who meet the risk factors, targeting criteria, and clinical eligibility standard for the above-identified 1915(c) waiver. Individuals who meet either targeting classification will have excluded from their financial eligibility determination the income and resources of third parties whose income and resources could otherwise be deemed available under 42 CFR § 435.602(a)(2)(i). Such individuals will also have their income and resources compared to the medically needy income level (MNIL) and resource standard for a single individual, as described in New York's State Medicaid Plan.

	Waiver Authority	Reason and Use of Waiver Authority			
4.	Amount, Duration & Scope Section 1902(a)(10)(B)	a. To enable New York to provide behavioral health (BH) HCBS services, whether furnished as a State Plan benefit or as a demonstration benefit to targeted populations that may not be consistent with the targeting authorized under the approved State Plan, in amount, duration and scope that exceeds those available to eligible individuals not in those targeted populations.			
5.	Freedom of Choice Section 1902(a)(23)(A)	a. To the extent necessary to enable New York to require members to enroll in Managed Care Organizations, including the Mainstream Medicaid Managed Care (MMMC), and MLTC (excluding individuals designated as "Long-Term Nursing Home Stays") and HARPs programs in order to obtain benefits offered by those plans. Members shall retain freedom of choice of family planning providers.			
6.	Reasonable Promptness Section 1902(a)(8)	 a. To enable the State to limit the number of medically needy Fo1 Children not otherwise enrolled in the Children's 1915(c) waiver. 			
	Title XIX Requirements Not Applicable to Self-Direction Pilot Program (see Expenditure Authority 6, "Self-Direction Pilot")				
7.	Direct Payment to Providers Section 1902(a)(32)	a. To the extent necessary to permit the State to make payments to members enrolled in the Self Direction Pilot Program to the extent that such funds are used to obtain self-directed HCBS LTC services and supports.			

The State is also requesting the use of the same expenditure authorities as approved in the existing 1115 demonstration, except for expenditure authority to provide incentive payments and planning grants for the previously numbered Expenditure Authority 7, Delivery System Incentive Reform Payment (DSRIP) program, which are expiring in March of 2020, or previously numbered Expenditure Authority 6, Designated State Health Program Funding, which expired in 2020.

While the State is not requesting the use of the DSRIP Expenditure Authority, CMS provided additional authority to provide DSRIP administration and a schedule of PPS payments until 2021. This additional authority is not part of this extension request.

The State requests the continuation of the remaining expenditure authorities and are as follows:

Expenditure Authorities Requested

	Expenditure Authority	Reason and Use of Expenditure Authority
1.	Demonstration-Eligible	Expenditures for healthcare related costs for the following
	Populations.	populations that are not otherwise eligible under the Medicaid State Plan:
		 a. Demonstration Population 2 (TANF Adult). Temporary Assistance for Needy Families (TANF) Recipients. Expenditures for health care related costs for low- income adults enrolled in TANF. These individuals are exempt from receiving a MAGI determination in accordance with §1902(e)(14)(D)(i)(I) of the Act. b. Demonstration Population 9 (HCBS Expansion). Individuals who are not otherwise eligible, are receiving HCBS, and who are determined to be medically needy based on New York's medically needy income level, after application of community spouse and spousal impoverishment eligibility and posteligibility rules consistent with section 1924 of the Act. c. Demonstration Population 10 (Institution to Community). Expenditures for health care related costs for individuals moved from institutional nursing facility settings to community settings for long term services and supports who would not otherwise be eligible based on income, but whose income does not exceed the income standard described in STC 4(c) of section IV, and who receive services through the managed long term care program under the demonstration. d. Included in Demonstration Population 12 (Fo1 Children)-Medically needy children Fo1 Demonstration children under age 21 with a waiver of 1902(a)(10)(C)(i)(III) who meet the targeting criteria, risk factors, and clinical eligibility standard for #NY.4125 waiver including ICF, NF, or Hospital Level of
		Care (LOC) who are not otherwise enrolled in the Children's 1915(c).
2.	Twelve-Month Continuous Eligibility Period.	a. Expenditures for health care related costs for individuals who have been determined eligible under groups specified in Table 1 of STC 3 in Section IV for continued benefits during any periods within a twelve-month eligibility period when these individuals would be found ineligible if subject to redetermination. This authority includes providing continuous coverage for the Adult Group determined financially eligible using Modified Adjusted Gross Income (MAGI) based eligibility methods. For expenditures related to the Adult Group, specifically, the State shall make a downward adjustment of 2.6 percent in claimed expenditures for federal matching at the enhanced federal matching rate and will instead claim those expenditures at the regular matching rate.

	Expenditure Authority		Reason and Use of Expenditure Authority
3.	Facilitated Enrollment Services.	a.	Expenditures for enrollment assistance services provided by managed care organizations (MCO), the costs for which are included in the claimed MCO capitation rates.
4.	Demonstration Services for Behavioral Health Provided under Mainstream Medicaid Managed Care (MMMC).	a.	Expenditures for provision of residential addiction services, crisis intervention and licensed behavioral health practitioner services to MMMC members only and are not provided under the State Plan [Demonstration Services 9].
5.	Targeted Behavioral Health (BH) HCBS Services.	a.	Expenditures for the provision of BH HCBS services under Health and Recovery Plans (HARP) and HIV Special Needs Plans (SNP) that are not otherwise available under the approved State Plan [Demonstration Services 8].
6.	Self-Direction Pilot.	a.	Expenditures to allow the State to make self-direction services available to HARP and HIV/SNP members receiving BH HCBS or children meeting targeting criteria for the Children's 1915(c) Waiver and in MMMC receiving HCBS under the Children's Waiver. The program will be in effect from January 1, 2017 through March 31, 2021 [Demonstration Services 8].

Budget Neutrality

The State is seeking CMS approval to extend the vital programs authorized under its existing 1115 waiver authority for a period of three years to allow the State and its stakeholders to develop a renewal proposal that addresses existing and emerging needs identified through the State's MRT II process and from the collective experiences gained from addressing COVID-19. In addition, this proposal includes two carveouts: 1) moving the NEMT benefit for MLTC plan members from Managed Care into FFS, and 2) moving the pharmacy benefit from Managed Care to FFS.

As required for all 1115 waiver amendment applications, the State has prepared the necessary Budget Neutrality documentation in this section. We also identified in the above sections, the fiscal and programmatic implications of the two proposed amendments as well as the overall underlying extension proposal. Through this exercise, the State has identified several considerations for discussion with CMS as part of the review process.

Considerations Impacting Caseloads & Costs

The purpose of this extension request was to maintain existing programs with minor modifications. Accordingly, we do not expect caseloads and costs to significantly change due to this extension proposal. However, the State anticipates caseloads and costs may be impacted by the following factors outside of the State's control;

COVID-19: The pandemic has been challenging for many New Yorkers and New York businesses. According to a September 2020 report from the New York State Comptroller, 1.9 million jobs were lost in March-April 2020, with only 28% of those jobs regained statewide. 14

¹⁴ Office of New York State Comptroller. "New York's Economy and Finances in the COVID-19 Era", September 2, 2020. Available online at: https://www.osc.state.ny.us/reports/covid-19-september-2-2020#prior

Small businesses were hit especially hard, and New York currently ranks second nationally in jobs lost behind California. 15 While not everyone will lose employer-sponsored coverage and choose to seek Medicaid coverage, even a small percentage of 1.9 million would increase projected caseloads substantially. While we do not anticipate caseloads to change significantly due to this proposal, due to COVID-19, a September 2020 report reported that the State has seen total caseloads increase by approximately 600,000 beneficiaries since the declaration of the Public Health Emergency in March.¹⁶

Minimum Wage Increase: The State passed legislation in 2016 seeking to increase the State's minimum wage to \$15 per hour by December 31, 2021, using a phased regional approach. 17 This increase impacts a number of health care providers, resulting in increases in Home Care MLTC and MMMC cost, as well as MLTC Reconciliation. The projected total computable dollars for DY23 do not currently include an adjustment for future minimum wage increases that are not in the historical base experience.

In addition to these considerations to the budget neutrality calculations of the State's extension proposal, the anticipated caseloads and projected impacts for both amendments can be seen below.

Anticipated Waiver Cost & Caseloads

This extension proposal is budget neutral and does not request any additional federal funding. It instead seeks to extend existing waiver authorities and programs and does not include a funding request. This 1115 extension proposal is expected to have no or nominal impact on annual Medicaid enrollment.

Based on an analysis of available Budget Neutrality quarterly reporting data that is currently available and previously submitted to CMS, the NYS 1115 MRT Waiver has met requirements for Budget Neutrality as detailed in the STCs Section IX. General Financial Requirements.

Projected waiver expenditures for the renewal period were calculated in adherence with CMS Budget Neutrality and Rebasing guidance as detailed in SMD # 18-009 issued August 22, 2018. Estimated Without Waiver baseline PMPMs were calculated based on claims data from the fiveyear period 4/1/15 - 3/31/20. The programmatic aspects of the demonstration as detailed in this extension application remain unchanged apart from the proposed Pharmacy and MLTC Transportation benefits carveouts. Therefore, as neither carveout has an impact on eligibility criteria, the State projects no change to enrollment in this renewal.

The State anticipates a total caseload across the extension proposal to be 4.9M members for DY23, inclusive of the recent increases due to COVID-19. The anticipated total computable cost for this caseload is \$53.9B. The historical caseloads and costs for the current demonstration period are detailed below in Exhibit 1, and the projected caseloads and costs are provided below in Exhibit 2. The full budget neutrality workbooks can be found in Attachment E.

https://www.health.ny.gov/health_care/medicaid/enrollment/docs/by_resident_co/2020/sept-2020.pdf https://labor.ny.gov/workerprotection/laborstandards/workprot/minwage.shtm

¹⁵ Office of New York State Comptroller, "New York's Economy and Finances in the COVID-19 Era", October 14, 2020, Available online at: https://www.osc.state.ny.us/reports/covid-19-october-14-2020

¹⁶ New York State Department of Health Enrollment by County, September 2020

Exhibit 1: Historical Caseloads and Costs (in total computable dollars) *

Demonstration Year	DY18	DY19	DY20	DY21*	DY22*
Historical Caseload	5,883,962	5,860,033	6,202,557	5,051,990	5,296,895
Historical Cost	\$47,739,999,038	\$44,488,018,228	\$50,916,108,128	\$52,379,623,963	\$47,970,320,886

^{*}Includes projected data.

Exhibit 2: Projected Caseloads and Costs (in total computable dollars) *

Demonstration Year	DY23	DY24	DY25
Projected Caseload of the Demonstration	4.7 million	4.7 million	4.7 million
MLTC Transportation Carveout Only	0	n/a	n/a
Pharmacy Carveout Only	0	n/a	n/a
Projected Cost	\$53.9 billion	\$56.2 billion	\$ 58.5 billion
MLTC Transportation Carveout Only	\$0.292 billion	n/a	n/a
Pharmacy Carveout Only**	\$6.282 billion	n/a	n/a

^{*}The numbers above represent projected caseload and costs for the entire waiver proposal, as well as specific details related to the two proposed amendments.

Demonstration Evaluations To-Date

Below is a summary of waiver evaluation efforts to date. While the pandemic has severely impacted evaluation timelines, the State has worked with its evaluators across the various programs to develop preliminary evaluation reports, as well as summarized reports from external quality review organizations.

Summaries of External Quality Review Organization Reports (EQROs)

In compliance with federal regulations, the State contracts with IPRO to conduct the annual External Quality Review ("EQR") of the MCOs certified to provide Medicaid coverage in the State. The State is dedicated to providing and maintaining the highest quality of care for enrollees in managed care organizations, The NYSDOH's OHIP and Office of Quality and Patient Safety ("OQPS") collaboratively employ an ongoing strategy to improve the quality of care provided to plan enrollees, to ensure the accountability of these plans, and to maintain the continuity of care to the public.

This report serves as an aggregate of the detailed information included in the MCO-specific technical reports. In accordance with federal regulations, these reports summarize the results of the 2017 EQR to evaluate access to, timeliness of, and quality of care provided to NYS Medicaid beneficiaries. Mandatory EQR-related activities (as per Federal Regulation 42 CFR § 438.358) reported include validation of performance improvement projects ("PIPs"), validation of MCO-reported and NYSDOH-calculated performance measures, and review for MCO compliance with NYSDOH structure and operation standards. Optional EQR-related activities (as per Federal Regulation 42 CFR § 438.358) reported include administration of a consumer survey of quality of care ("CAHPS®") by an NCQA-certified survey vendor and technical

^{**}Caseload is based on total Member Months reported (CY2020 Q4 submission of the Budget Neutrality Reporting Tool, MemMon Total Tab).

^{**}Total historical cost figures as reported in the CY2020 Q4 submission of the Budget Neutrality Reporting Tool, WW Spending Total

^{**}MLTC Transportation and Pharmacy Carveouts will not impact membership as neither carveout affects member eligibility.

assistance by the NYS EQRO to MCOs regarding PIPs and reporting performance measures. Other data incorporated to provide additional background on the MCOs include the following: MCO corporate profiles, enrollment data, provider network information, encounter data summaries, PQI/compliance/satisfaction/quality points and incentive, and deficiencies and citations summaries.¹⁸

The report is organized into the following domains: MCO Corporate Profiles, Enrollment and Provider Network, Utilization, Performance Indicators, and Structure and Operation Standards. Although the technical reports focus primarily on Medicaid data, selected sections of the individual, MCO-specific reports also include data from the MCOs' Child Health Plus ("CHP") and Commercial product lines. The CHP product line is the NYS version of the federal Child Health Insurance Program ("CHIP"), which provides health coverage to eligible children in families with incomes too high to qualify for Medicaid, but who cannot afford private coverage. CHP data are part of the Medicaid managed care data sets used in this report. For some measures, including QARR 2018 (MY 2017), aggregate rates are used, which represent the combined population of the Medicaid and CHP product lines. These measures are noted as such. Additionally, when available and appropriate, the MCOs' data are compared with statewide benchmarks. Unless otherwise noted, when benchmarks are utilized for rates other than HEDIS®/QARR or CAHPS®, comparative statements are based on differences determined by standard deviations: a difference of one standard deviation is used to determine rates that are higher or lower than the statewide average.

Section VII of the individual, MCO-specific technical reports provides an assessment of the MCOs' strengths and opportunities for improvement in the areas of accessibility, timeliness, and quality of services. For areas in which the MCOs have opportunities for improvement, recommendations for improving the quality of the MCOs' health care services are provided. To achieve full compliance with federal regulations, this section also includes an assessment of the degree to which the MCOs effectively addressed the recommendations for quality improvement made by the NYS EQRO in the previous year's EQR report. The MCOs were given the opportunity to describe current or proposed interventions that address areas of concern, as well as an opportunity to explain areas that the MCOs did not feel were within their ability to improve. The responses by the MCOs are appended to this section of the individual, MCO-specific reports.

In an effort to provide the most consistent presentation of this varied information, the technical reports are prepared based on data for the most current calendar year available. This report includes data from Reporting Year 2017. The entirety of the report can be found on the New York MRT website by accessing this link:

https://www.health.ny.gov/statistics/health_care/managed_care/plans/reports/docs/all_plan_summary.pdf.

Preliminary Interim Evaluation Reports

As required under the terms and conditions of the current MRT waiver, New York engaged independent research organizations to evaluate the performance of the Children's Design, the Self-Directed Care Pilot, HARP program, and evaluation of components of the MRT waiver. The State contracted the RAND Corporation to conduct independent evaluations for the aforementioned components of the demonstration which can be found as attachments A-D.

¹⁸ External Appeals data are reported in the Full EQR Technical Report prepared every third year.

Where preliminary results are available in the 1115 evaluation, results show encouraging signs of progress towards achieving the State's goals. Because of significant delays borne out of the State's need to pivot towards COVID-19 emergency response, subsequent findings and data will provide a fuller picture of the demonstration's progress towards achieving success for its goals. Per written guidance from CMS provided to the State on July 23, 2020 concerning the interference of COVID-19 with delivering full interim reports, the State has provided an explanation of the resultant gaps and the evaluation efforts the State has made thus far, as well as a timeline to complete the full interim evaluation for each of the reports attached. The preliminary interim evaluation reports can be found as Attachments A-D.

Children's Design Preliminary Interim Evaluation

As part of the ongoing redesign efforts, the State has developed amendments to the 1115 MRT waiver and the 1915(c) Children's Waiver (collectively known as the "Children's Redesign" that aims to consolidate and streamline care for children and youth under the age of 21 who have needs of Behavioral Health (BH) and Home and Community Based Services ("HCBS"). This preliminary report provides an overview of the approved and planned evaluation, that was significantly impacted by COVID-19, which required not only the State DOH personnel to shift attention, resources and priorities, but also the entire health care system in New York. This shift caused contract execution and data access delays which prevented adequate time for analysis and development of findings. As a result of these delays, the Children's independent evaluation timeline was significantly impacted and therefore no preliminary interim findings are available at this time. New York State contracted with the RAND Corporation in 2020 to conduct the Children's independent evaluation. The preliminary Children's independent evaluation report, which can be found in Attachment A, contains an explanation of progress towards findings to date, as well as a timeline for analysis and presentation of these findings, with an anticipated date of Spring 2021.

Health and Recovery Plan Preliminary Interim Evaluation

With the goal of improving access to and quality of health care for the Medicaid population through a managed care delivery system, this Demonstration included reforms specifically targeted to beneficiaries with behavioral health ("BH") needs (hereafter, BH Demonstration); one of them is the Health and Recovery Plans ("HARP") program. New York State contracted with the RAND Corporation in 2019 to conduct an independent evaluation of the BH Demonstration programs, including a HARP program evaluation (New York State Department of Health, 2019). Similarly, to the Children's evaluation, this HARP preliminary report provides an overview of the approved and planned evaluation that was significantly impacted by COVID-19, requiring DOH to shift personnel, resources and priorities to respond the pandemic therefore delaying the timeline for completion of this evaluation. As a result of this shift, the independent evaluation timeline was significantly impacted and therefore no preliminary interim findings are available at this time. The preliminary independent evaluation report can be found in Attachment B with an explanation of progress towards findings to date, as well as a timeline for analysis and presentation of these findings, with an anticipated date of Spring 2021 for completion.

<u>Self-Directed Care Preliminary Interim Evaluation</u>
The Self-Directed Care ("SDC") pilot program was implemented as part of the behavioral health (BH) reforms included in the larger Section 1115 Demonstration. In 2019 NYS contracted with the RAND Corporation to conduct an independent evaluation of the SDC pilot program. As with all evaluations, this preliminary report provides an overview of the approved and planned evaluation that was significantly impacted by COVID-19, requiring DOH to shift personnel, resources and priorities to respond the pandemic therefore delaying the timeline for completion

of this evaluation. As a result of this shift, the independent evaluation timeline was significantly impacted and therefore no preliminary interim findings are available at this time. The SDC preliminary independent evaluation report can be found in Attachment C with an explanation of progress towards findings to date, as well as a timeline for analysis and presentation of these findings, with an anticipated date of Spring 2021 for completion.

1115 Preliminary Interim Evaluation

To meet the special terms and conditions specified by the Centers for Medicare and Medicaid Services for the waiver renewal, RAND Corporation was competitively selected as the independent evaluator to assess two components under this 1115 Demonstration Waiver: The Managed Long-Term Care (MLTC) program and the 12-month continuous eligibility and enrollment. This interim evaluation aims to examine if these two programs have achieved the following two goals:

- MLTC: expanding access to long-term services and supports and improving patient safety, quality of care, and consumer satisfaction
- Twelve-month continuous eligibility: reducing enrollment gaps and increasing Medicaid enrollment duration

As with all evaluations, this preliminary report provides an overview of the approved and planned evaluation that was significantly impacted by COVID-19, requiring DOH to shift personnel, resources and priorities to respond the pandemic therefore delaying the timeline for completion of this evaluation. As a result of this shift, 11 out of the 23 research questions in this preliminary report were able to be evaluated or responded to. The 1115 Demonstration preliminary independent evaluation report can be found in Attachment D with an explanation of progress towards findings to date, as well as a timeline for analysis and presentation of these findings, with an anticipated date of Spring 2021 for completion.

Public Notice Compliance and Documentation

In compliance with 42 CFR § 431.408(a), the final rule regarding Review and Approval Process for Section 1115 Demonstrations; Application, Review, and Reporting Process for Waivers for State Innovation, as well as the current STCs regarding the Public Forum requirement, the State certifies that the abbreviated and full public notices for the formal waiver extension were published in the New York State Register on December 16, 2020 with written comments to be received by electronic or written mail by January 15, 2021. A copy of the State Register with the highlighted abbreviated and full public notices can be found in Appendix A.

Due to in-person limitations that social distancing requires, the State did not hold in-person hearings and instead scheduled two virtual public hearings to be held on two separate occasions, on January 21, 2021, and January 27, 2021. The public hearings were broadcast live via WEBEX (accessible via the New York MRT website) and were scheduled to gather feedback and public input on the waiver extension request, as well as afford the public opportunity to comment on the waiver writ large in compliance with Public Forum requirements. All interested speakers were given an opportunity to express their views which were documented and incorporated into the final waiver extension application. All commenters were advised of a five-minute limit per comment to ensure that all public comments were able to be heard. Public comment transcripts, slides, and a recording of the hearings, as well as supporting materials are publicly available on the New York MRT website, which can be accessed using the following link: https://www.health.ny.gov/health_care/medicaid/redesign/mrt2/ext_request/index.htm

Both comment sessions included a current overview of current MRT waiver initiatives as well as a brief summary of New York's Medicaid Redesign Team (MRT) extension application request. After the presentation by NYS DOH staff, commenters, both registered and unregistered were afforded the opportunity to present oral comments, questions, or recommendations to the panel of NYS DOH staff. All comments that were presented during these sessions were made available in a taped recording and transcripts that were posted on the NY MRT website.

The State confirms that it used an electronic mailing list to notify the public of the State's intent to seek a waiver extension on December 16, 2020. The State created a Medicaid Redesign Team Listserv (MRT Listserv) in order to notify interested parties that new information was posted on the MRT website. The notices alerted subscribers to new information available on the MRT website which included: meeting announcements, access to webcasts, meeting materials, updated timelines, press releases and any other information of interest. This listserv was available to the public for email sign-up. Individuals who wished to submit written comments during the aforementioned periods were able to do so by writing an email to 1115waivers@health.ny.gov by including "1115 waiver extension comment" in the subject line.

Public Comment Overview

The State received 721 written comments regarding the extension application, as well as an additional 41 comments received verbally from the virtual hearings from individuals, advocacy groups, community providers, and other stakeholders. Of the 721 written comments received, 702 focused solely on the Pharmacy Carveout, 8 comments addressed the general waiver extension, 6 comments addressed the MLTC Transportation Carveout, and 5 comments were received that addressed multiple subject areas (e.g., a combination of comments related to the Carveouts and the general waiver extension). The majority of comments received regarding the extension application were concerning Pharmacy Carveout amendment, with specific regard to the impact on the 340B program and the impact to 340B "Covered Entities." The State appreciates all of the comments and feedback shared by its stakeholders regarding this waiver extension application. These comments informed the content and approach of the waiver extension and will continue to help shape the State's pursuit of future programmatic initiatives that go beyond this extension and carveout amendments and will be taken under advisement as the State works with CMS to design a larger extension. The current application reflects the importance of stakeholder public comment and the responsiveness of the State to these suggestions. In response to stakeholder comments and questions, the State developed FAQs regarding the overall extension and both the Pharmacy and MLTC Transportation Carveouts. The FAQs can be accessed through the following link:

https://www.health.ny.gov/health_care/medicaid/redesign/mrt2/ext_request/index.htm

Public Comment Themes and State Responses

General Waiver Extension Comments

Regarding the waiver extension proposal (exclusive of the two amendments, whose comments are summarized below), the State received several comments regarding future programmatic initiatives as well as comments supporting the continuation of DSRIP. The State appreciates these comments and recognition of the need to continue systems transformation particularly in light of the COVID-19 pandemic, improving health equity and increasing Community-Based Organization ("CBO") support. Furthermore, the State looks forward to pursuing larger

programmatic initiatives in the future upon approval of this waiver extension application and designing a renewal package that is inclusive of broader transformation needs of the state and its stakeholders. Comments that were not germane and outside of the scope of this waiver extension and the related carveout amendments were not included in this summary.

Pharmacy Carveout Amendment Comments

Over 98% of all comments received during the public comment period on the extension application were regarding the Pharmacy Carveout amendment. While many of these comments supported the overarching goals of the extension application, the majority of comments regarding the Pharmacy Carveout amendment expressed concern regarding the potential for a negative impact on safety-net providers such as Federally Qualified Health Centers ("FQHCs"), Ryan White and Disproportionate Share Hospitals ("DSH") to use savings from the 340B program to fund gaps in services or care. The State 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 and subsequent years thereafter (subject to federal approval), to directly support covered entities and preserve critical services that are currently funded with 340B revenue. After the Carveout, 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.

Additional comments regarding the Pharmacy Carveout amendment received were concerned with the State's ability to accurately capture real-time pharmacy data, which could have a negative impact on care management. The State 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 more 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 MCO's and providers continue post transition.

The State also received a comment regarding the Pharmacy Carveout amendment's impact on budget neutrality calculations and that the cost projections may not have captured accurately the savings that would be generated from the Carveout. In developing the fiscal implications and savings assumptions for the Carveout, the State took the following factors into account to ensure accurate capture of Carveout savings:

- Additional federal and State supplemental drug rebates resulting from a shift of drug
 utilization from the managed care delivery system to the FFS delivery system under a
 uniform preferred drug list, which will increase leverage when negotiating with drug
 manufacturers.
- Reduction of administrative costs and non-claim components of spending, including the
 costs associated to administrative functions of multiple pharmacy benefits managers
 used by MCOs as well as taxes and surplus funded in managed care premiums; and
- Savings on 340B drugs from reimbursement of actual acquisition cost, which is the
 federally required reimbursement for 340B drugs in FFS. The \$87.3M in State share
 savings assumes that approximately 60% of the 340B savings will be realized in the SFY
 2021-22.

• In addition, the State share savings projection is based on current FFS reimbursement methodology, which includes a \$10.08 professional dispensing fee.

In response to stakeholder feedback, the State has largely retained the Pharmacy Carveout amendment as written and has clarified that the amendment is pursuing technical corrections to the STCs to reflect the shift in authority from the 1115 waiver to the State Plan in how the benefit is administered and how federal match is claimed.

MLTC Transportation Carveout Amendment Comments

Comments provided regarding the MLTC Transportation Carveout amendment were primarily focused on the State's transition to a broker model as well as concerns regarding this shift to a single broker and away from health plans. The State developed this amendment based on MRT II recommendations through its stakeholder process, and appreciates the concern raised regarding the shift to a broker model. Through this amendment, the management of the trips (e.g., scheduling, assignment of the most appropriate mode, prior authorization) will be performed by a professional transportation management broker—either statewide or in certain regions of the State. Such broker(s) will be procured by the State in a risk-based arrangement(s). This change in transportation management streamlines and centralizes the benefit for Medicaid members, and adheres to the principles of value-based care - payment to improve outcomes.

Some commenters further expressed concern about potential benefit disruption and confusion among members as a result of this carveout. This carveout is intended to shift the delivery system of the benefit from MLTC to FFS with minimal to no disruptive effects on the provision of NEMT transportation services to members.

Tribal Notification

New York State is home to nine federally recognized Tribal Nations: Tonawanda, Tuscarora, Seneca, Onondaga, St. Regis Mohawk, Oneida, Cayuga, Shinnecock, Unkechaug (Poospatuck).¹⁹

In accordance with 42 CFR § 431.408(b), on December 16, 2020 Tribal letters were sent out. Tribes were provided at least 30 days to comment. The Department of Health advised the above-mentioned tribes and associated tribal health centers by letter of the intent to request a three-year extension request (refer to Appendix B, Tribal Letter). During this notice period, no comments were received from any of the aforementioned tribes.

-

¹⁹ https://www.health.ny.gov/community/american_indian_nation/

Appendix A- Compliance with Public Comment Circulation Requirements

MISCELLANEOUS NOTICES/HEARINGS

Notice of Abandoned Property Received by the State Comptroller

Pursuant to provisions of the Abandoned Property Law and related laws, the Office of the State Comptroller receives unclaimed monies and other property deemed abandoned. A list of the names and last known addresses of the entitled owners of this abandoned property is maintained by the office in accordance with Section 1401 of the Abandoned Property Law. Interested parties may inquire if they appear on the Abandoned Property Listing by contacting the Office of Unclaimed Funds, Monday through Friday from 8:00 a.m. to 4:30 p.m. at:

1-800-221-9311 or visit our web site at: www.osc.state.ny.us

Claims for abandoned property must be filed with the New York State Comptroller's Office of Unclaimed Funds as provided in Section 1406 of the Abandoned Property Law. For further information contact: Office of the State Comptroller, Office of Unclaimed Funds, 110 State St., Albany, NY 12236.

PUBLIC NOTICE

GreenNY Interagency Committee on Sustainability and Green Procurement

Pursuant to Executive Order No. 4: Establishing a State Green Procurement and Agency Sustainability Program, April 24, 2008 ("EO 4"), the Interagency Committee on Sustainability and Green Procurement hereby gives public notice of the following:

Four green specifications were tentatively approved by the Interagency Committee on Sustainability and Green Procurement and have been posted for public comment.

These include new or amended specifications on the following topics:

Apparel and Textile Materials, Coating Removal Products, Garment Cleaning, and Laundry Detergent.

All of the above specifications are available for viewing at: https://ogs.ny.gov/greenny/executive-order-4-tentatively-approved-specifications

Information regarding the green specification approval process is also available at the above link.

Comments may be submitted electronically to: GreenEO4@ogs.ny.gov

Comments from the public regarding the tentatively approved specifications will be accepted until Friday, March 19, 2021.

PUBLIC NOTICE

Department of Health MRT 1115 Waiver Extension Request

In compliance with 42 CFR 431.408(a)(2)(ii) as well as the current MRT Waiver Special Terms and Conditions regarding the annual Public Forum requirement, the Department of Health is pleased to announce that it will conduct two virtual public hearings/public forums, to provide an overview of the State's 1115 waiver extension request and allow members of the public to provide comments. This notice

further serves to open the 30-day public comment period which will close on Friday, January 15, 2021. In addition to this 30-day comment period where the public will be afforded the opportunity to provide written comments, the Department of Health will be hosting two virtual public hearings during which the public may provide oral comments. Any updates related to the public hearings and forum will be sent via the MRT ListServ.

The New York State Department of Health ("NYSDOH") is requesting a three-year extension of the existing Section 1115 Medicaid Redesign Team ("MRT") waiver demonstration, which is set to expire on March 31, 2021. This extension proposal seeks an extension of all current programs and authorities in the State's current waiver demonstration, with the following two programmatic amendments:

• Carveout of the Non-Emergency Medical Transportation (NEMT) Benefit for Managed Long-Term Care Members to Fee-For-Service: The goals of this amendment request are as follows:

 o Improve administrative simplification by creating a consistently managed transportation benefit and removing the benefit from the MRT Waiver;

o Reduce cost-risk by shifting the broker arrangement to a risk-based arrangement; and

o Create a larger pool of members by combining all members, except PACE for which the transportation benefit must be managed by the PACE Organization under federal rules, for brokers to provide NEMT service to.

 Carveout of Pharmacy Benefits from Medicaid Managed Care to Fee-For-Service. The goals of this amendment request are as follows:

o Provide the State with full visibility into prescription drug costs; o Centralize and leverage negotiation power;

o Provide a single drug formulary with standardized utilization management protocols; and

o Address the growth of the 340B program and associated reductions in State rebate revenue.

These amendments were developed by the State's Medicaid Redesign Team II (MRT II), and are part of a larger, more comprehensive set of reforms that the State is planning to innovate and improve the Medicaid program. MRT II brought together a comprehensive set of stakeholders to collectively find solutions that improve the delivery of care and outcomes for Medicaid members and contain spending growth in the Medicaid program.

The two virtual public hearing/public forum meetings will be held as follows:

1. First Public Hearing/Public Forum

a. Thursday, January 21, 2021 from 1-4pm.

b. Pre-registration is required for anyone wishing to provide oral comment using this link: https://meetny.webex.com/meetny/onstage/g.php?MTID=eafaac7a7545ec85e7a621bdc99cdb98d.

c. Individuals who wish to provide comment will need to register with an "SP" in front of their name (ex: SP Jane Doe) and must email 1115 waivers @health.ny.gov no later than Wednesday, January 20, 2021 at 4pm to confirm registration.

d. Individuals will speak in their order of registration. We kindly request that all comments be limited to five minutes per presenter to ensure that all public comments may be heard.

- 2. Second Public Hearing/Public Forum
 - Wednesday, January 27, 2021 from 1-4pm.
- b. Pre-registration is required for anyone wishing to provide oral comment using this link: https://meetny.webex.com/meetny/onstage/g.php?MTID=eb77f943a1d8bfdd61a0caba29cf338bf
- c. Individuals who wish to provide comment will need to register with an "SP" in front of their name (ex: SP Jane Doe) and must email 1115waivers@health.ny.gov no later than Tuesday, January 26, 2021 at 4pm to confirm registration.
- d. Individuals will speak in their order of registration. We kindly request that all comments be limited to five minutes per presenter to ensure that all public comments may be heard.
- A draft of the proposed MRT Waiver extension request available for review at: https://www.health.ny.gov/health_care/medicaid/redesign/mrt2/ext_request/index.htm.

Due to COVID-19 pandemic, the Department of Health offices are operating at a reduced in-person capacity. For individuals with limited online access and require special accommodation to access paper copies, please call (518) 473-0919. While the State will be accepting physical written comments due to COVID-19, comments submitted electronically by email is preferred.

Prior to finalizing the proposed MRT Waiver extension application, the Department of Health will consider all written and verbal com-ments received. These comments will be summarized and addressed in the final version that is submitted to CMS. The Department will post a transcript of the public hearings, as well as any submitted written public comments, on the following website: https:// www.health.ny.gov/health_care/medicaid/redesign/mrt2/ext_request/ index.htm.

Please direct all questions to 1115waivers@health.ny.gov.

Written comments will be accepted by email at 1115waivers@health.ny.gov or by mail at Department of Health, Office of Health Insurance Programs, Waiver Management Unit, 99 Washington Ave., 7th Fl., Suite 720, Albany, NY 12210.

All comments must be postmarked or emailed by 30 days of the date of this notice.

PUBLIC NOTICE

Department of Health

MRT 1115 Waiver Extension Request

In compliance with 42 CFR 431.408(a)(1) as well as the current MRT Waiver Special Terms and Conditions regarding the annual Public Forum requirement, the New York State Department of Health is pleased to announce that it will conduct two virtual public hearings/public forums, to provide an overview of the State's 1115 waiver extension request and allow members of the public to provide comments. This notice further serves to open the 30-day public comment period which will close on Friday, January 15, 2021. In addition to this 30-day comment period where the public will be afforded the opportunity to provide written comments, the Department of Health will be hosting two virtual public hearings during which the public may provide oral comments. Any updates related to the public hearings and forum will be sent via the MRT ListServ.

The two virtual public hearing/public forum meetings will be held

- 1. First Public Hearing/Public Forum
 - a. Thursday, January 21, 2021 from 1-4pm.
- b. Pre-registration is required for anyone wishing to provide oral comment using this link: https://meetny.webex.com/meetny/onstage/g.php?MTID=eafaac7a7545ec85e7a621bdc99cdb98d.
- c. Individuals who wish to provide comment will need to register with an "SP" in front of their name (ex: SP Jane Doe) and must email 1115waivers@health.ny.gov no later than Wednesday, January 20, 2021 at 4pm to confirm registration.
- d. Individuals will speak in their order of registration. We kindly request that all comments be limited to five minutes per presenter to ensure that all public comments may be heard.

- 2. Second Public Hearing/Public Forum
 - a. Wednesday, January 27, 2021 from 1-4pm.
- b. Pre-registration is required for anyone wishing to provide oral comment using this link: https://meetny.webex.com/meetny/onstage/g.php?MTID=eb77f943a1d8bfdd61a0caba29cf338bf
- c. Individuals who wish to provide comment will need to register with an "SP" in front of their name (ex: SP Jane Doe) and must email 1115waivers@health.ny.gov no later than Tuesday, January 26, 2021 at 4pm to confirm registration.
- d. Individuals will speak in their order of registration. We kindly request that all comments be limited to five minutes per presenter to ensure that all public comments may be heard.

Prior to finalizing the proposed MRT Waiver extension application, the Department of Health will consider all written and verbal com-ments received. These comments will be summarized and addressed in the final version that is submitted to CMS

Extension Proposal Summary and Objectives

The New York State Department of Health ("NYSDOH") is requesting a three-year extension of the existing Section 1115 Medicaid Redesign Team ("MRT") waiver demonstration, which is set to expire on March 31, 2021. This extension proposal seeks an extension of all current programs and authorities in the State's current waiver demonstration, with the following two programmatic amendments:

- Carveout of the Non-Emergency Medical Transportation (NEMT)
 Benefit for Managed Long-Term Care Members to Fee-For-Service: The goals of this amendment request are as follows:
- o Improve administrative simplification by creating a consistently managed transportation benefit and removing the benefit from the MRT Waiver:
- o Reduce cost-risk by shifting the broker arrangement to a riskbased arrangement; and
- o Create a larger pool of members by combining all members, except PACE for which the transportation benefit must be managed by the PACE Organization under federal rules, for brokers to provide NEMT service to.
- · Carveout of Pharmacy Benefits from Medicaid Managed Care to Fee-For-Service. The goals of this amendment request are as follows:
 - o Provide the State with full visibility into prescription drug costs;
 - o Centralize and leverage negotiation power;
- o Provide a single drug formulary with standardized utilization management protocols; and
- o Address the growth of the 340B program and associated reductions in State rebate revenue
- These amendments were developed by the State's Medicaid Redesign Team II (MRT II), and are part of a larger, more comprehensive set of reforms that the State is planning to innovate and improve the Medicaid program. MRT II brought together a comprehensive set of stakeholders to collectively find solutions that improve the delivery of care and outcomes for Medicaid members and contain spending growth in the Medicaid program.

Eligibility, Benefits, and Cost-Sharing Changes

This extension proposal, inclusive of the two proposed amendments, contains no changes to eligibility, scope of benefits, or costsharing requirements. The two proposed amendments simply shift the administration and delivery of the two identified benefits by carving out these two benefits from the Medicaid Managed Care delivery systems to Fee-For-Service in the State Plan.

Enrollment and Fiscal Projections

Please see the Appendix at the end of this Issue for the Enrollment and Fiscal Projections

Hypotheses and Evaluation

- In July 1997, New York State (the "State") received approval from the Centers for Medicare and Medicaid Services ("CMS") for its "Partnership Plan" Medicaid Section 1115 Demonstration (the "1115 Demonstration"). In implementing the 1115 Demonstration, the State sought to achieve the following goals
 - · Improve access to health care for the Medicaid population;

- · Improve the quality of health services delivered;
- · Expand access to family planning services; and
- Expand coverage to additional low-income New Yorkers with resources generated through managed care efficiencies.

The primary purpose of the Demonstration was to enroll a majority of the State's Medicaid population into managed care; to use a managed care delivery system to deliver benefits to Medicaid recipients; to create efficiencies in the Medicaid program, and enable the extension of coverage to certain individuals who would otherwise be without health insurance. The MRT Waiver continues to meet the goals and objectives that were established at the initial approval of the demonstration.

The current hypotheses for the aforementioned goals are:

- The MRT Waiver will improve access to health care for the Medicaid population;
- The MRT Waiver will improve the quality of health services delivered;
- The MRT Waiver will expand access to family planning services;
 and
- The MRT Waiver will expand coverage to additional low-income New Yorkers with resources generated through managed care efficiencies.

Waiver and Expenditure Authorities

As specified in the MRT Waiver extension application, the State requests a continuation of the following waiver and expenditure authorities to operate the demonstration:

Waiver Authority

 Extension of Existing Demonstration Section 1115(a)

2. Statewideness Section 1902(a)(1)

3. Comparability Section 1902(a)(10), section 1902(a)(17)

Reason and Use of Waiver Authority a. To the extent necessary to enable the

a. To the extent necessary to enable the State to extend the existing waiver for an additional three years.

a. To permit New York to geographically phase in the Managed Long-Term Care (MLTC) program and the Health and Recovery Plans (HARP) and to phase in Behavioral Health (BH) Home and Community Based Services (HCBS) into HIV Special Needs Plans (HIV SNP).

a. To enable New York to apply a more liberal income standard for individuals who are deinstitutionalized and receive HCBS through the managed long-term care program than for other individuals receiving community-based long-term

b. To the extent necessary to permit New York to waive cost sharing for non-drug benefit cost sharing imposed under the Medicaid State Plan for members enrolled in the Mainstream Medicaid Managed Care Plan (MMMC) – including Health and Recovery Plans (HARP) and HIV SNPs – and who are not otherwise exempt from cost sharing in § 447.56(a)(1).

Waiver Authority

Reason and Use of Waiver Authority

c. Family of One Non-1915 Children, or "Fo1 Children" — To allow the State to target eligibility to, and impose a participation capacity limit on, medically needy children under age 21 who are otherwise described in 42 CFR § 435-308 of the regulations who: 1) receive Health Home Comprehensive Care Management under the State Plan in replacement of the case management services such individuals formerly received through participation in New York's NY #4125 1915(c) waiver and who no longer participate in such waiver due to the elimination of the case management services, but who continue to meet the targeting criteria, risk factors, and clinical eligibility standard for such waiver, and 2) receive HCBS 1915(c) services who meet the risk factors, targeting criteria, and clinical eligibility standard for the above-identified 1915(c) waiver. Individuals who meet either targeting classification will have excluded from their financial eligibility determination the income and resources could otherwise be deemed available under 42 CFR § 435.602(a)(2)(i). Such individuals will also have their income and resources compared to the medically needy income level (MNIL) and resource standard for a single individual, as described in New York's State Medicaid Plan.

4. Amount, Duration & Scope Section 1902(a)(10)(B)

a. To enable New York to provide behavioral health (BH) HCBS services, whether furnished as a State Plan benefit or as a demonstration benefit to targeted populations that may not be consistent with the targeting authorized under the approved State Plan, in amount, duration and scope that exceeds those available to eligible individuals not in those targeted populations.

5. Freedom of Choice Section 1902(a)(23)(A)

a. To the extent necessary to enable New York to require members to enroll in Managed Care Organizations, including the Mainstream Medicaid Managed Care (MMMC), and MLTC (excluding individuals designated as "Long-Term Nursing Home Stays") and HARPs programs in order to obtain benefits offered by those plans. Members shall retain freedom of choice of family planning providers.

6. Reasonable Promptness Section 1902(a)(8) a. To enable the State to limit the number of medically needy Fo1 Children not otherwise enrolled in the Children's 1915(c) waiver

Title XIX Requirements Not Applicable to Self-Direction Pilot Program (see Expenditure Authority 6, "Self-Direction Pilot")

7. Direct Payment to Providers Section 1902(a)(32)

a. To the extent necessary to permit the State to make payments to members enrolled in the Self Direction Pilot Program to the extent that such funds are used to obtain self-directed HCBS LTC services and supports.

The State is requesting the use of the same expenditure authorities as approved in the existing 1115 demonstration, except for expenditure authority to provide incentive payments and planning grants for the previously numbered Expenditure Authority 7, Delivery System Incentive Reform Payment (DSRIP) program, which are expiring in March of 2020, or previously numbered Expenditure Authority 6, Designated State Health Program Funding, which expired in 2020.



The following Appendix was filed with a Public Notice for the Department of Health published in this issue of the State Register.

Enrollment and Fiscal Projections

This 1115 extension proposal is expected to have no or nominal impact on annual Medicaid enrollment, and is further expected to be budget neutral. The tables below illustrate historical caseloads and costs of the current waiver (Exhibit 1), as well as projected caseloads and costs of the demonstration as proposed (Exhibit 2).

Exhibit 1: Historical Caseloads and Costs (in total computable dollars) *

Demonstration Year	DY18	DY19	DY20	DY21*	DY22*
Historical Caseload**	4,903,302	4,883,361	5,170,656	5,472,989	5,738,303
Historical Cost	\$47,739,999,038	\$47,739,999,038	\$47,739,999,038	\$47,739,999,038	\$47,739,999,038

^{*}Includes projected data.

Exhibit 2: Projected Caseloads and Costs (in total computable dollars) *

Demonstration Year	DY23	DY24	DY25 4.9 million	
Projected Caseload of the Demonstration	4.9 million	4.9 million		
MLTC Transportation Carveout Only	0	n/a	n/a	
Pharmacy Carveout Only	0	n/a	n/a	
Projected Cost	\$51.2 billion	\$53.5 billion	\$ 56.0 billion	
MLTC Transportation Carveout Only	\$16.6 million	n/a	n/a	
Pharmacy Carveout Only**	\$698.1 million	n/a	n/a	

^{*}The numbers above represent projected caseload and costs for the entire waiver proposal, as well as specific details related to the two proposed amendments.

^{**}Total historical cost figures as reported in the CY2020 Q3 submission of the Budget Neutrality Reporting Tool, WW Spending Total

Tab.

**Caseload is based on total Member Months reported /12 (CY2020 Q3 submission of the Budget Neutrality Reporting Tool,

^{**}MLTC Transportation and Pharmacy Carveouts will not impact membership as neither carveout affects member eligibility.

^{***}The costs below do not include a projection for MEG 9 (HCBS Expansion) and MEG 10 (Institute to Community).

Appendix B- Tribal Letter



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

LISA J. PINO, M.A., J.D. Executive Deputy Commissioner

December 16, 2020

Re: MRT 1115 Waiver Extension Request

Dear Colleague:

Governor

The New York State Department of Health ("NYSDOH") is requesting a three-year extension of the existing Section 1115 Medicaid Redesign Team ("MRT") waiver demonstration, which is set to expire on March 31, 2021. *This extension proposal seeks an extension of all current programs and authorities in the State's current waiver demonstration, with the following two programmatic amendments*:

- Carveout of the Non-Emergency Medical Transportation (NEMT) Benefit for Managed Long-Term Care Members to Fee-For-Service: The goals of this amendment request are as follows:
 - Improve administrative simplification by creating a consistently managed transportation benefit and removing the benefit from the MRT Waiver;
 - Reduce cost-risk by shifting the broker arrangement to a risk-based arrangement;
 and
 - Create a larger pool of members by combining all members, except PACE for which
 the transportation benefit must be managed by the PACE Organization under federal
 rules, for brokers to provide NEMT service to.
- Carveout of Pharmacy Benefits from Medicaid Managed Care to Fee-For-Service. The goals of this amendment request are as follows:
 - Provide the State with full visibility into prescription drug costs;
 - Centralize and leverage negotiation power;
 - Provide a single drug formulary with standardized utilization management protocols; and
 - Address the growth of the 340B program and associated reductions in State rebate revenue.

These amendments were developed by the State's Medicaid Redesign Team II (MRT II), and are part of a larger, more comprehensive set of reforms that the State is planning to innovate and improve the Medicaid program. MRT II brought together a comprehensive set of stakeholders to collectively find solutions that improve the delivery of care and outcomes for Medicaid members and contain spending growth in the Medicaid program.

Eligibility, Benefits, and Cost-Sharing Changes

This extension proposal, inclusive of the two proposed amendments, contains **no changes to eligibility**, **scope of benefits**, **or cost-sharing requirements**. The two proposed amendments simply shift the administration and delivery of the two identified benefits by <u>carving out</u> these two benefits from the Medicaid Managed Care delivery systems to Fee-For-Service in the State Plan. The State does not anticipate any additional or unique impact on Tribes.

Enrollment and Fiscal Projections

This 1115 extension proposal is expected to have no or nominal impact on annual Medicaid enrollment, and is further expected to be budget neutral. The tables below illustrate historical caseloads and costs of the current waiver (Exhibit 1), as well as projected caseloads and costs of the demonstration as proposed (Exhibit 2).

Exhibit 1: Historical Caseloads and Costs (in total computable dollars) *

Demonstrati on Year	DY18	DY19	DY20	DY21*	DY22*
Historical Caseload**	4,903,302	4,883,361	5,170,656	5,472,989	5,738,303
Historical Cost	\$47,739,999, 038	\$47,739,999, 038	\$47,739,999, 038	\$47,739,999, 038	\$47,739,999, 038

^{*}Includes projected data.

Exhibit 2: Projected Caseloads and Costs (in total computable dollars) *

Demonstration Year	DY23	DY24	DY25
Projected Caseload of the Demonstration	4.9 million	4.9 million	4.9 million
MLTC Transportation Carveout Only	0	n/a	n/a
Pharmacy Carveout Only	0	n/a	n/a
Projected Cost	\$51.2 billion	\$53.5 billion	\$ 56.0 billion
MLTC Transportation Carveout Only	\$16.6 million	n/a	n/a
Pharmacy Carveout Only**	\$698.1 million	n/a	n/a

^{*}The numbers above represent projected caseload and costs for the entire waiver proposal, as well as specific details related to the two proposed amendments.

Hypotheses and Evaluation

In July 1997, New York State (the "State") received approval from the Centers for Medicare and Medicaid Services ("CMS") for its "Partnership Plan" Medicaid Section 1115 Demonstration (the "1115 Demonstration"). In implementing the 1115 Demonstration, the State sought to achieve the following goals:

- · Improve access to health care for the Medicaid population;
- · Improve the quality of health services delivered;
- · Expand access to family planning services; and
- Expand coverage to additional low-income New Yorkers with resources generated through managed care efficiencies.

^{**}Total historical cost figures as reported in the CY2020 Q3 submission of the Budget Neutrality Reporting Tool, WW Spending Total Tab.

^{**}Caseload is based on total Member Months reported /12 (CY2020 Q3 submission of the Budget Neutrality Reporting Tool, MemMon Total Tab).

^{**}MLTC Transportation and Pharmacy Carveouts will not impact membership as neither carveout affects member eligibility.

^{***}The costs below do not include a projection for MEG 9 (HCBS Expansion) and MEG 10 (Institute to Community).

The primary purpose of the Demonstration was to enroll a majority of the State's Medicaid population into managed care; to use a managed care delivery system to deliver benefits to Medicaid recipients; to create efficiencies in the Medicaid program, and enable the extension of coverage to certain individuals who would otherwise be without health insurance. The MRT Waiver continues to meet the goals and objectives that were established at the initial approval of the demonstration.

The current hypotheses for the aforementioned goals are:

- . The MRT Waiver will improve access to health care for the Medicaid population;
- The MRT Waiver will improve the quality of health services delivered;
- · The MRT Waiver will expand access to family planning services; and
- The MRT Waiver will expand coverage to additional low-income New Yorkers with resources generated through managed care efficiencies.

Waiver and Expenditure Authorities

As specified in the MRT Waiver extension application, the State requests a continuation of the following waiver and expenditure authorities to operate the demonstration:

Waiver Authority	Reason and Use for Authority
1. Extension of Existing Demonstration Section 1115(a)	To the extent necessary to enable the State to extend the existing waiver for an additional three years.
2. Statewideness Section 1902(a)(1)	a. To permit New York to geographically phase in the Managed Long-Term Care (MLTC) program and the Health and Recovery Plans (HARP) and to phase in Behavioral Health (BH) Home and Community Based Services (HCBS) into HIV Special Needs Plans (HIV SNP).
3. Comparability Section 1902(a)(10), section 1902(a)(17)	 a. To enable New York to apply a more liberal income standard for individuals who are deinstitutionalized and receive HCBS through the managed long-term care program than for other individuals receiving community-based long-term care. b. To the extent necessary to permit New York to waive cost sharing for non-drug benefit cost sharing imposed under the Medicaid State Plan for members enrolled in the Mainstream Medicaid Managed Care Plan (MMMC) – including Health and Recovery Plans (HARP) and HIV SNPs – and who are not otherwise exempt from cost sharing in §447.56(a)(1). c. Family of One Non-1915 Children, or "Fo1 Children" – To allow the State to target eligibility to, and impose a participation capacity limit on, medically needy children under age 21 who are otherwise described in 42 CFR §435.308 of the regulations who: 1) receive Health Home Comprehensive Care Management under the State Plan in replacement of the case management services such individuals formerly received through participation in New York's NY #.4125 1915(c) waiver and who no longer participate in such waiver due to the elimination of the case management services, but who continue to meet the targeting criteria, risk factors, and clinical eligibility standard for such waiver; and 2) receive HCBS 1915(c) services who meet the risk factors, targeting criteria, and clinical eligibility

	Waiver Authority	Reason and Use for Authority
4.	Amount, Duration & Scope Section 1902(a)(10)(B)	standard for the above-identified 1915(c) waiver. Individuals who meet either targeting classification will have excluded from their financial eligibility determination the income and resources of third parties whose income and resources could otherwise be deemed available under 42 CFR § 435.602(a)(2)(i). Such individuals will also have their income and resources compared to the medically needy income level (MNIL) and resource standard for a single individual, as described in New York's State Medicaid Plan. a. To enable New York to provide behavioral health (BH) HCBS services, whether furnished as a State Plan benefit or as a demonstration benefit to targeted populations that may not be consistent with the targeting authorized under the approved State Plan, in amount, duration and scope that exceeds those available to eligible individuals not in those
5.	Freedom of Choice Section 1902(a)(23)(A)	targeted populations. a. To the extent necessary to enable New York to require members to enroll in Managed Care Organizations, including the Mainstream Medicaid Managed Care (MMMC), and MLTC (excluding individuals designated as "Long-Term Nursing Home Stays") and HARPs programs in order to obtain benefits offered by those plans. Members shall retain freedom of choice of family planning providers.
6.	Reasonable Promptness Section 1902(a)(8)	To enable the State to limit the number of medically needy Fo1 Children not otherwise enrolled in the Children's 1915(c) waiver.
		ements Not Applicable to Self-Direction Pilot Program (see spenditure Authority 6, "Self-Direction Pilot")
7.		To the extent necessary to permit the State to make payments to members enrolled in the Self Direction Pilot Program to the extent that such funds are used to obtain self-directed HCBS LTC services and supports.

The State is requesting the use of the same expenditure authorities as approved in the existing 1115 demonstration, except for expenditure authority to provide incentive payments and planning grants for the previously numbered Expenditure Authority 7, Delivery System Incentive Reform Payment (DSRIP) program, which are expiring in March of 2020, or previously numbered Expenditure Authority 6, Designated State Health Program Funding, which expired in 2020. While the State is not requesting the use of the DSRIP Expenditure Authority, CMS provided additional authority to provide DSRIP administration and a schedule of PPS payments until 2021, this additional authority is not part of this extension request. The State requests the continuation of the remaining expenditure authorities and are as follows:

Expenditure Authority	Reason and Use of Expenditure Authority
Demonstration- Eligible Populations.	Expenditures for healthcare related costs for the following populations that are not otherwise eligible under the Medicaid State Plan: a. Demonstration Population 2 (TANF Adult). Temporary Assistance for Needy Families (TANF) Recipients. Expenditures for health care related costs for low- income adults enrolled in TANF. These individuals are exempt from receiving a MAGI determination in accordance with §1902(e)(14)(D)(i)(l) of the Act.

	Expenditure	Reason and Use of Expenditure Authority
	Authority	
		 b. Demonstration Population 9 (HCBS Expansion). Individuals who are not otherwise eligible, are receiving HCBS, and who are determined to be medically needy based on New York's medically needy income level, after application of community spouse and spousal impoverishment eligibility and post-eligibility rules consistent with section 1924 of the Act. c. Demonstration Population 10 (Institution to Community). Expenditures for health care related costs for individuals moved from institutional nursing facility settings to community settings for long term services and supports who would not otherwise be eligible based on income, but whose income does not exceed the income standard described in STC 4(c) of section IV, and who receive services through the managed long term care program under the demonstration.
		d. Included in Demonstration Population 12 (Fo1 Children)- Medically needy children Fo1 Demonstration children under age 21 with a waiver of 1902(a)(10)(C)(i)(III) who meet the targeting criteria, risk factors, and clinical eligibility standard for #NY.4125 waiver including ICF, NF, or Hospital Level of Care (LOC) who are not otherwise enrolled in the Children's 1915(c).
2.	Twelve-Month Continuous Eligibility Period.	a. Expenditures for health care related costs for individuals who have been determined eligible under groups specified in Table 1 of STC 3 in Section IV for continued benefits during any periods within a twelve-month eligibility period when these individuals would be found ineligible if subject to redetermination. This authority includes providing continuous coverage for the Adult Group determined financially eligible using Modified Adjusted Gross Income (MAGI) based eligibility methods. For expenditures related to the Adult Group, specifically, the State shall make a downward adjustment of 2.6 percent in claimed expenditures for federal matching at the enhanced federal matching rate and will instead claim those expenditures at the regular matching rate.
3.	Facilitated Enrollment Services.	Expenditures for enrollment assistance services provided by managed care organizations (MCO), the costs for which are included in the claimed MCO capitation rates.
	Demonstration Services for Behavioral Health Provided under Mainstream Medicaid Managed Care (MMMC).	Expenditures for provision of residential addiction services, crisis intervention and licensed behavioral health practitioner services to MMMC members only and are not provided under the State Plan [Demonstration Services 9].
5.	Targeted Behavioral Health (BH) HCBS Services.	 Expenditures for the provision of BH HCBS services under Health and Recovery Plans (HARP) and HIV Special Needs Plans (SNP) that are not otherwise available under the approved State Plan [Demonstration Services 8].
6.	Self-Direction Pilot.	a. Expenditures to allow the State to make self-direction services available to HARP and HIV/SNP members receiving BH HCBS or children meeting targeting criteria for the Children's 1915(c) Waiver and in MMMC receiving HCBS under the Children's

Expenditure Authority	Reason and Use of Expenditure Authority	
280	Waiver. The program will be in effect from January 1, 2017	
	through March 31, 2021 [Demonstration Services 8].	

Submission and Review of Public Comments

A draft of the proposed MRT Waiver extension request available for review at: https://www.health.nv..gov/health-care/medicaid/redesign/mrt2/ext-request/index.htm. Due to COVID-19 pandemic, the Department of Health offices are operating at a reduced in-person capacity. For individuals with limited online access and require special accommodation to access paper copies, please call (518) 473-0919. While the State will be accepting physical written comments due to COVID-19, comments submitted electronically by email is preferred.

Written comments will be accepted by email at 1115waivers@health.nv.gov or by mail at:

Department of Health
Office of Health Insurance Programs
Waiver Management Unit
99 Washington Ave.
Suite 720, 7th floor
Albany, NY 12210

All comments must be postmarked or emailed by January 22, 2021. We look forward to our continued collaboration.

Sincerely,

Gregory S. Allen, Director

Division of Program Development & Management

Office of Health Insurance Programs

cc: Brett Friedman, NYSDOH Phil Alotta, NYSDOH Michele Hamel, NYSDOH Sean Hightower, HHS Nancy Grano, CMS

Attachments

Attachment A-Children's Design Preliminary Interim Evaluation

Attachment B-HARP Preliminary Interim Evaluation

Attachment C-SDC Preliminary Interim Evaluation

Attachment D-1115 Demonstration Preliminary Interim Evaluation

Attachment E- Budget Neutrality Workbooks