DATE

Deputy Administrator Daniel Tsai
U.S. Department of Health and Human Services
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Deputy Administrator Tsai,

On behalf of the citizens of North Carolina, I am pleased to submit to the U.S. Department of Health and Human Services (DHHS) a request to temporarily extend the North Carolina Section 1115 Demonstration Project (11-W00313/4) for Residential and Inpatient Treatment for Individuals with a substance use disorder (SUD). The State is requesting no changes to the currently approved demonstration. As discussed with CMS, the State is requesting a temporary extension of only the SUD component of the demonstration at this time. The State will submit a full waiver renewal application later in 2023.

North Carolina's current demonstration approval authorizes significant transformations of North Carolina's Medicaid delivery system, which includes a waiver of the institution for mental diseases (IMD) exclusion for substance use disorder treatment.

Prior to submitting this amendment, North Carolina sought feedback from the public and the Eastern Band of Cherokee Indians, North Carolina's only federally recognized tribe. Through that engagement process, PLACEHOLDER FOR INPUT FROM PUBLIC NOTICE

Thank you for considering these requests. We greatly appreciate DHHS's continued partnership on North Carolina's 1115 waiver demonstration as we work toward our shared goals of advancing high-value care, improving population health, engaging and supporting providers, and promoting the sustainability of the Medicaid program.

Best regards,

Kody Kinsley
Secretary, North Carolina Department of Health and Human Services

I. Historical Narrative Summary of the Demonstration Project

The North Carolina Medicaid Reform demonstration was approved by the Centers for Medicare & Medicaid Services (CMS) on Oct. 19, 2018, and includes a waiver of the institution for mental disease (IMD) exclusion for substance use disorder (SUD) treatment to expand access to the full continuum of SUD care. The current waiver is effective Jan. 1, 2019, through Oct. 31, 2023. The State requests to extend the SUD waiver for an additional five years.

The current demonstration benefit package for North Carolina Medicaid recipients includes Opioid Use Disorder (OUD)/SUD treatment services, including short-term residential services provided in residential and inpatient treatment settings that qualify as an IMD, which are not otherwise matchable expenditures under section 1903 of the Act. The State is eligible to receive federal financial participation (FFP) for North Carolina Medicaid recipients who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance, including OUD/SUD benefits that would otherwise be matchable if the beneficiary were not residing in an IMD. The State is required to aim for a statewide average length of stay of 30 days in residential treatment settings, to be monitored pursuant to the SUD Monitoring Protocol as outlined in STC 19(b) and to ensure short-term residential treatment stays. Under the demonstration, beneficiaries have access to high-quality, evidence-based OUD and other SUD treatment services ranging from medically supervised withdrawal management to ongoing chronic care for these conditions in cost-effective settings while also improving care coordination and care for comorbid physical and mental health conditions.

North Carolina's goal in the current waiver and requested extension is to reduce SUD; the State will test and evaluate the following hypotheses in pursuit of this goal:

- Expanding coverage of SUD services to include residential services furnished in institutions for mental disease (IMDs) as part of a comprehensive strategy will decrease the long-term use of opioids and increase the use of medication-assisted treatment (MAT) and other opioid treatment services.
- Expanding coverage of SUD services to include residential services furnished to short-term residents in IMDs with a SUD diagnosis as part of a comprehensive strategy will result in improved care quality and outcomes for patients with SUD.

As required by CMS, the components of the SUD waiver are organized around six milestones: (1) Access, (2) Placement Criteria, (3) Provider Qualifications, (4)Capacity, (5) Prescribing and Overdose, and (6) Care Coordination. North Carolina's Mid-point Assessment determined the State is at the following risk levels:

- High risk of not achieving demonstration Milestone 1
- Medium risk of not achieving Milestones 3 and 6
- Medium/low risk of not achieving Milestone 4
- Low risk of not achieving Milestones 2 and 5

Recommendations for progress are provided in the Mid-point Assessment and include:

- Provide greater web content for providers and beneficiaries on the SUD components of the waiver
- Determine barriers for metrics not meeting targets and identify incentives that could address these barriers
- Continue COVID-19 flexibilities
- Use monitoring metrics to mount an adaptive response to immediate needs
- Triangulate code lists and service definitions going forward
- Prioritize minimum MAT access requirements for residential treatment facilities
- Streamline the licensure process for facility-based treatment

- Support inpatient service capacity through direct financial support and/or improved allocation of beds
- Consider expanding Medicaid in North Carolina to cover those who do not have access to SUD services
- Identify and reward higher levels of beneficiary engagement in care.

II. Changes Requested

No changes requested.

III. Requested Waivers and Expenditure Authorities

Request same waiver and expenditure authorities as those approved in the current demonstration for Residential and Inpatient Treatment for Individuals with a Substance Use Disorder, expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for SUD who are short-term residents in facilities that meet the definition of an IMD.

IV. Quality Reports and Monitoring

As identified in the North Carolina 2020-2021 EQR Technical Report, Health Services Advisory Group, Inc. (HSAG) is the State's external quality review organization (EQRO). For state fiscal year (SFY) 2021 (July 1, 2020 through June 30, 2021), HSAG conducted preparatory activities with the State for the mandatory EQR activities displayed in Table 1 below and optional activities that include encounter data validation, consumer surveys, calculation of additional performance measures, focus studies on quality, quality rating of health plans, annual performance reports, annual care management performance evaluation and collaborative quality improvement forums. In the SFY 2022 report, HSAG highlights substantive findings and actionable State-specific recommendations, when applicable, to further promote its Quality Strategy goals and objectives.

Table 1. EQR Activities

Activity	Description	CMS EQR Protocol
Mandatory Activities*		
Validation of Performance Improvement Projects (PIPs)	This activity verifies whether a PIP conducted by a health plan used sound methodology in its design, implementation, analysis, and reporting.	**Protocol 1.** Validation of Performance Improvement Projects
Performance Measure Validation (PMV)	This activity assesses whether the performance measures (PMs) calculated by a health plan are accurate based on the measure specifications and State reporting requirements.	**Protocol 2.** Validation of Performance Measures
Compliance With Standards	This activity determines the extent to which a Medicaid and CHIP plan is in compliance with federal standards and associated State-specific requirements, when applicable.	**Protocol 3.** Review of Compliance with Medicaid and CHIP Managed Care Regulations

* Until the CMS network adequacy validation protocol is issued, health plans will only be subject to three mandatory EQR-related activities.

Table 2 from the North Carolina Medicaid Annual Quality Report (December 2020) is a summary of performance for 2019 by Quality Strategy Aims and Goals.

Table 2. Summary of NC Medicaid Quality Performance 2019

AIMS	GOALS	OVERALL PERFORMANCE
AIM 1: Better Care Delivery. Make health care more person-centered, coordinated and accessible.	**GOAL 1:** Ensure appropriate access to care	★★
	GOAL 2: Drive patient-centered, whole-person care	★★
AIM 2: Healthier People, Healthier Communities. In collaboration with community partners improve the health of North Carolinians through prevention, better treatment of chronic conditions and better behavioral health care.	**GOAL 3:** Promote wellness and prevention	★★
	GOAL 4: Improve chronic condition management	★
	GOAL 5: Work with communities to improve population health	★★
AIM 3: Smarter Spending. Pay for value rather than volume, incentivize innovation and ensure appropriate care.	**GOAL 6:** Pay for value	★★

★★★ Performance across all measures in the group was **ABOVE** the national median.

★★ Performance across all measures in the group was **AROUND** the national median.

★ Performance across all measures in the group was **BELOW** the national median.

Table 3 is the North Carolina Fiscal Year 2020 Annual Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Form CMS-416.which collects information on the State's Medicaid program and CHIP to assess the effectiveness of EPSDT services.

Table 3. North Carolina Fiscal Year 2020 Annual EPSDT Form CMS-416

CMS Generated Reporting of State Form CMS-416 Data Using T-MSIS									
Description	**Cat**	**Total**	**< 1**	**1-2**	**3-5**	**6-9**	**10-14**	**15-18**	**19-20**
1a.Total Individuals Eligible for EPSDT	CN	1,284,952	70,132	145,946	215,359	252,876	310,120	212,485	78,034
	MN	2,014	46	82	129	291	492	489	485
	Total	1,286,966	70,178	146,028	215,488	253,167	310,612	212,974	78,519
1b.Total Individuals Eligible for EPSDT for 90 Continuous Days	CN	1,224,019	56,840	141,370	209,308	241,796	297,876	203,568	73,261
	MN	1,472	18	65	103	224	360	326	376
	Total	1,225,491	56,858	141,435	209,411	242,020	298,236	203,894	73,637
1c. Total Individuals Eligible Under a CHIP Medicaid Expansion	CN	173,159	187	18,024	36,239	39,915	45,201	30,799	2,794
	MN	0	0	0	0	0	0	0	0
	Total	173,159	187	18,024	36,239	39,915	45,201	30,799	2,794
2a. State Periodicity Schedule			5	4	3	4	5	4	2
2b. Number of Years in Age Group			1	2	3	4	5	4	2
2c. Annualized State Periodicity Schedule			5	2	1	1	1	1	1
3a. Total Months of Eligibility	CN	13,668,019	423,872	1,613,984	2,397,672	2,733,861	3,385,846	2,307,920	804,864
	MN	15,313	149	700	1,098	2,294	3,675	3,369	4,028
	Total	13,683,332	424,021	1,614,684	2,398,770	2,736,155	3,389,521	2,311,289	808,892
3b. Average Period of Eligibility	CN	0.93	0.62	0.95	0.95	0.94	0.95	0.94	0.92
	MN	0.87	0.69	0.90	0.89	0.85	0.85	0.86	0.89
	Total	0.93	0.62	0.95	0.95	0.94	0.95	0.94	0.92
4. Expected Number of Screenings per Eligible	CN		3.10	1.90	0.95	0.94	0.95	0.94	0.92
	MN		3.45	1.80	0.89	0.85	0.85	0.86	0.89
	Total		3.10	1.90	0.95	0.94	0.95	0.94	0.92
5. Expected Number of Screenings	CN	1,412,674	176,204	268,603	198,843	227,288	282,982	191,354	67,400
	MN	1,382	62	117	92	190	306	280	335
	Total	1,414,056	176,266	268,720	198,935	227,478	283,288	191,634	67,735
6. Total Screens Received	CN	1,026,251	261,515	291,251	143,919	105,079	133,031	78,417	13,039
	MN	542	29	83	41	78	138	103	70
	Total	1,026,793	261,544	291,334	143,960	105,157	133,169	78,520	13,109
7. SCREENING RATIO	CN	0.73	1.00	1.00	0.72	0.46	0.47	0.41	0.19
	MN	0.39	0.47	0.71	0.45	0.41	0.45	0.37	0.21
	Total	0.73	1.00	1.00	0.72	0.46	0.47	0.41	0.19
8.Total Eligibles Who Should Receive at Least One Initial or Periodic Screen	CN	1,166,077	56,840	141,370	198,843	227,288	282,982	191,354	67,400
	MN	1,286	18	65	92	190	306	280	335
	Total	1,167,363	56,858	141,435	198,935	227,478	283,288	191,634	67,735
9.Total Eligibles Receiving at Least One Initial or Periodic Screen	CN	DS	DS	DS	DS	DS	DS	DS	DS
	MN	DS	DS	DS	DS	DS	DS	DS	DS
	Total	617,594	54,718	117,816	131,076	100,674	127,194	73,901	12,215

CMS Generated Reporting of State Form CMS-416 Data Using T-MSIS									
Description	**Cat**	**Total**	**< 1**	**1-2**	**3-5**	**6-9**	**10-14**	**15-18**	**19-20**
10. PARTICIPANT RATIO	CN	DS	DS	DS	DS	DS	DS	DS	DS
	MN	DS	DS	DS	DS	DS	DS	DS	DS
	Total	0.53	0.96	0.83	0.66	0.44	0.45	0.39	0.18
11. Total Eligibles Referred for Corrective Treatment	CN	DS	DS	DS	DS	DS	DS	DS	DS
	MN	DS	DS	DS	DS	DS	DS	DS	DS
	Total	317,220	51,518	84,314	51,009	40,925	49,870	33,318	6,266
12a. Total Eligibles Receiving Any Dental Services	CN	DS	DS	DS	DS	DS	DS	DS	DS
	MN	DS	DS	DS	DS	DS	DS	DS	DS
	Total	566,868	685	28,613	102,565	141,795	169,330	101,903	21,977
12b. Total Eligibles Receiving Preventive Dental Services	CN	DS	DS	DS	DS	DS	DS	DS	DS
	MN	DS	DS	DS	DS	DS	DS	DS	DS
	Total	520,225	252	27,352	98,339	134,571	156,792	86,462	16,457
12c. Total Eligibles Receiving Dental Treatment Services	CN	DS	DS	DS	DS	DS	DS	DS	DS
	MN	DS	DS	DS	DS	DS	DS	DS	DS
	Total	243,189	286	1,941	29,237	63,846	77,622	57,441	12,816
12d. Total Eligibles Receiving a Sealant on a Permanent Molar Tooth	CN	57,279				30,417	26,862		
	MN	53				20	33		
	Total	57,332				30,437	26,895		
12e. Total Eligibles Receiving Dental Diagnostic Services	CN	DS	DS	DS	DS	DS	DS	DS	DS
	MN	DS	DS	DS	DS	DS	DS	DS	DS
	Total	544,130	664	28,496	101,178	137,682	162,252	93,729	20,129
12f. Total Eligibles Receiving Oral Health Services Provided by a Non-Dentist Provider	CN	DS	DS	DS	DS	DS	DS	DS	DS
	MN	DS	DS	DS	DS	DS	DS	DS	DS
	Total	88,055	5,238	67,525	15,195	49	33	DS	DS
12g. Total Eligibles Receiving Any Preventive Dental or Oral Health Service	CN	DS	DS	DS	DS	DS	DS	DS	DS
	MN	DS	DS	DS	DS	DS	DS	DS	DS
	Total	588,861	5,418	81,680	107,450	134,588	156,801	86,465	16,459
13.Total Eligibles Enrolled in Managed Care	CN	1,201,631	52,304	139,711	207,046	239,201	294,553	200,347	68,469
	MN	1,353	15	64	99	214	336	298	327
	Total	1,202,984	52,319	139,775	207,145	239,415	294,889	200,645	68,796
14a.Total Number of Screening Blood Lead Tests	CN	DS	DS	DS	DS				
	MN	DS	DS	DS	DS				
	Total	97,329	225	84,688	12,416				
14b. Methodology Used to Calculate the Total Number of Screening Blood Lead Tests			Enter X for Method I		Enter X for Method II		Enter X for Method III		
		CPT Code 83655 within certain diagnoses codes (Method I)	X	HEDIS (Method II)		Combin-ation Method-ology (Method III)			

CN = Categorically Needy
MN = Medically Needy
DS = Data suppressed because data cannot be displayed per the Centers for Medicare & Medicaid Services' cell-size suppression policy, which prohibits the direct reporting of data for beneficiary and record counts of 1 to 10 and values from which users can derive values of 1 to 10.
* States are not required to provide the EPSDT benefits to children enrolled in Medicaid through the medically needy benefit. CMS recommends that FFY 2020 data are not trended with data from other fiscal years due to both the significant change in delivery of services because of the COVID-19 public health emergency and the initial use of T-MSIS as a data source in 19 states.

n/a = Not Applicable

V. Financial Data

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VI. Evaluation Report

Table 4 from the Mid-point Assessment summarizes the percent of action items complete and the proportion of monitoring targets met for each milestone. In summary, North Carolina is at Low risk of not meeting two of the six milestones: Placement Criteria (Milestone 2) and Prescribing and Overdose (Milestone 5). The State is at Low/Medium risk of not meeting Milestone 4 (Capacity). The assessment depends on the relative importance of changes in the metrics (number of providers providing SUD and Medication for Opioid Use Disorders (MOUD) services to Medicaid beneficiaries from claims data) to completion of the process activities specified in the Implementation Plan and STCs. These documents require network adequacy assessments and provider outreach, which have not yet been completed. The Milestone 4 metrics are advancing in the intended direction (implying Low risk of not meeting the milestone), while the process activities have not been completed (implying Medium risk).

The State is at Medium risk for not completing Milestone 3 on the use of nationally recognized standards to set provider qualifications based solely on implementation activities and Milestone 6 on Coordination of Care. Finally, the State is at High risk for not completing Milestone 1 on Access to Critical Levels of Care for SUD based on a lack of progress in achieving targets for a number of metrics reflecting service use.

Table 4. Assessed risk of not achieving milestones.

Milestone	Proportion of monitoring metric goals met (# metrics / total)	Percentage of fully completed action items (# completed / total)	Key themes from stakeholder feedback	Risk level
1. Access	**43% (3/7)**	2% (1/61)	♦ Milestone 1 has been a main focus of DHHS agencies. ♦ Several factors contributed to delays, including COVID-19, Standard Plan launch, exit of one LME/MCO and preparing for Tailored Plans. ♦ Providers and LME/MCOs report waiting for finalized policies for new services before beginning to establish networks and care standards.	High

Milestone	Proportion of monitoring metric goals met (# metrics / total)	Percentage of fully completed action items (# completed / total)	Key themes from stakeholder feedback	Risk level
			♦ Multiple stakeholders express concerns about preparedness for Tailored Plans. ♦ Beneficiaries report good access to SUD care overall and improved access to care as a result of COVID-19 flexibilities.	
2. Placement Criteria	**50% (1/2)**	60% (6/10)	DHHS agencies have made significant efforts around training providers in ASAM criteria, with over 600 trained. Turnout has not been as high as hoped, which may be partially attributable to the small fee for training.	Low
3. Qualifications	--	0% (0/4)	The State's presentations have clarified licensure requirements. LME/MCOs have concerns about the licensure process for residential facilities, which is long and costly. Some programs in NC still do not offer medication to treat opioid or alcohol use disorder.	Medium
4. Capacity	**100% (2/2)**	0% (0/4)	Staffing inpatient facilities and ensuring sufficient outpatient provider supply is a persistent concern for both State agencies and LMEs. Providers perceived shortages of inpatient beds, outpatient care and office-based opioid treatment (OBOT). LMEs report that developing capacity for facility-based treatment is overall more challenging, especially with lack of startup funds. Funding services is an issue, given that most people with SUD in NC are uninsured. State funds are critical for this, and the ongoing lack of Medicaid expansion threatens funding streams for new services.	Low/ Medium

Milestone	Proportion of monitoring metric goals met (# metrics / total)	Percentage of fully completed action items (# completed / total)	Key themes from stakeholder feedback	Risk level
5. Prescribing and Overdose	**50% (2/4)**	100% (1/1)	There is a broad consensus that improvements to the PDMP have been very successful.	Low
6. Coordination	**71% (5/7)**	66% (2/3)	Both providers and State agencies report co- locating services has improved care coordination. Several providers report needing to make hard decisions about care management going forward, especially with the coming launch of Tailored Plans.	Medium

VII. Public Notice Process Compliance Documentation

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