DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

November 13, 2020

Tracy Johnson
Medicaid Director
Colorado Department of Health Care Policy and Financing
1570 Grant Street
Denver, CO 80203

Dear Ms. Johnson:

Under section 1115 of the Social Security Act (the Act), the Secretary of Health and Human Services (HHS) may approve any experimental, pilot, or demonstration project that, in the judgment of the Secretary, is likely to assist in promoting the objectives of certain Act programs, including Medicaid. Congress enacted section 1115 of the Act to ensure that federal requirements did not "stand in the way of experimental projects designed to test out new ideas and ways of dealing with the problems of public welfare recipients." S. Rep. No. 87-1589, at 19 (1962), *as reprinted in* 1962 U.S.C.C.A.N. 1943, 1961. As relevant here, section 1115(a)(2) of the Act allows the Secretary to provide federal financial participation (FFP) for demonstration costs that would not otherwise be considered as federally matchable expenditures under section 1903 of the Act, to the extent and for the period prescribed by the Secretary.

For the reasons discussed below, the Centers for Medicare & Medicaid Services (CMS) is approving Colorado's application for a section 1115(a) demonstration titled "Expanding the Substance Use Disorder Continuum of Care" (Project Number 11-W-00336/8) effective January 1, 2021 through December 31, 2025. Approval of this demonstration will enable the state to receive FFP, once CMS approves the required implementation plan, as specified in the accompanying Special Terms and Conditions (STCs), for inpatient, residential and other services provided to otherwise-eligible Medicaid beneficiaries while residing in institutions for mental diseases (IMD) for primary diagnoses of substance use disorder (SUD). CMS's approval of this section 1115(a) demonstration is subject to the limitations specified in the attached expenditure authority, STCs, and any supplemental attachments defining the nature, character, and extent of federal involvement in this demonstration project. As detailed in the demonstration's STCs, all state plan requirements apply, regardless of whether the services themselves are authorized under the state plan, unless a requirement is specifically identified as waived or not applicable. The state may deviate from Medicaid state plan requirements only to the extent those requirements have been specifically listed as not applicable under the demonstration.

CMS and Colorado are continuing to develop the state's SUD Implementation Plan, which like all SUD demonstrations, must be approved by CMS prior to the state receiving federal matching dollars under this demonstration. Once approved, CMS will include it as Attachment C of the STCs.

Extent and Scope of the Demonstration

This demonstration will provide authority for the state to receive FFP to provide high-quality, clinically appropriate treatment for otherwise-eligible Medicaid beneficiaries who are short-term residents in residential and inpatient treatment settings that qualify as IMDs. It will also support state efforts to enhance provider capacity, improve the availability of Medication-Assisted Treatment and improve access to a continuum of evidence-based SUD services at varied levels of intensity, including withdrawal management services.

Determination that the demonstration project is likely to assist in promoting Medicaid's objectives

Under section 1901 of the Act, the Medicaid program provides federal funding to participating states "[f]or the purpose of enabling each state, as far as practicable under the conditions in such state, to furnish (l) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care." While this statutory text is not necessarily an exhaustive source of Medicaid objectives, it makes clear that at least one objective of Medicaid is to enable states to "furnish… medical assistance" to certain vulnerable populations (i.e., payment for certain healthcare services defined at section 1905 of the Act, the services themselves, or both). This demonstration promotes that Medicaid objective by expanding on coverage to provide coverage of health care costs that would otherwise not be available. In addition to providing expanded coverage, the provision of this additional coverage may lower program costs through improved beneficiary health, making it possible for the state to expand other coverage with the dollars saved. This further promotes the coverage objective of the Medicaid statute.

CMS also has determined that approval of the Expanding the Substance Use Disorder Continuum of Care demonstration is likely to promote the objectives of the Medicaid program for the following reasons:

- This demonstration will assist Colorado in increasing identification, initiation, and engagement of Medicaid beneficiaries diagnosed with SUD;
- This demonstration will increase access to necessary levels of care for beneficiaries by adding Medicaid coverage for inpatient and residential SUD treatment programs; and
- This demonstration will assist Colorado in reducing inappropriate or preventable utilization of emergency departments and inpatient hospital settings through improved access to a continuum of care services.

Consideration of Public Comments

To increase the transparency of demonstration projects, sections 1115(d)(1) and (2) of the Act direct the Secretary to issue regulations providing for two periods of public comment on a state's application for a section 1115 demonstration that would result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing. The first comment period occurs at the state level before submission of the section 1115 application, and the second comment period occurs at the federal level after the application is received by the Secretary.

As enacted by the Affordable Care Act, and incorporated under sections 1115(d)(2)(A) and (C) of the Act, comment periods should be "sufficient to ensure a meaningful level of public input" but the statute imposed no additional requirement on the states or the Secretary to provide an individualized response to address those comments, as might otherwise be required under a general rulemaking. Accordingly, the implementing regulations issued in 2012 provide that CMS will review and consider all comments received by the deadline, but will not provide individualized written responses to public comments. See 42 CFR 431.416(d)(2).

CMS received one comment during the federal comment period on the Colorado's Expanding the Substance Use Disorder Continuum of Care demonstration. The sole comment was supportive of this demonstration and Colorado's efforts to increase coverage for SUD treatment and services. However, the commentator did stress to CMS and the state to assure that Indian Health Care Providers be a component of the Colorado Medicaid SUD delivery system and be included as an integral partner in all implementation efforts. The state was put in touch with the commenter and concluded that this demonstration provides that assurance.

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

Other Information

CMS's approval of this demonstration project is conditioned upon compliance with the enclosed list of waiver and expenditure authorities and the STCs defining the nature, character, and extent of anticipated federal involvement in the demonstration. The award is subject to our receiving your written acknowledgement of the award and acceptance of these STCs within 30 days of the date of this letter.

Your project officer for this demonstration is Mr. Jack Nocito. He is available to answer any questions concerning your section 1115 demonstration. Mr. Nocito's contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-25-26
7500 Security Boulevard
Baltimore, MD 21244-1850
Email: Jack.Nocito@cms.hhs.gov

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

Sincerely,

[redacted]

Seema Verma

Enclosure

cc: Curtis Volesky, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: 11-W-00336/8

TITLE: Expanding the Substance Use Disorder Continuum of Care

AWARDEE: Colorado Department of Health Care Policy and Financing

Under the authority of section 1115(a)(2) of the Social Security Act ("the Act"), expenditures made by Colorado for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from January 1, 2021 through December 31, 2025, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

As discussed in the Centers for Medicare & Medicaid Services' (CMS) approval letter, the Secretary of Health and Human Services has determined that the Colorado Expanding the Substance Use Disorder Continuum of Care demonstration, including the granting of the expenditure authority described below, is likely to assist in promoting the objectives of title XIX of the Act.

The following expenditure authority may only be implemented consistent with the approved Special Terms and Conditions (STCs) and shall enable Colorado to operate the above-identified section 1115(a) demonstration.

1. **Residential and Inpatient Treatment for Individuals with Substance Use Disorder (SUD).** Expenditures for otherwise covered Medicaid services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD).

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00336/8

TITLE: Expanding the Substance Use Disorder Continuum of Care

AWARDEE: Colorado Department of Health Care Policy and Financing

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the "Colorado Expanding the Substance Use Disorder Continuum of Care" section 1115(a) Medicaid demonstration (hereinafter "demonstration"), to enable the Colorado Department of Health Care Policy and Financing (hereinafter "state") to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted authority waivers of requirements under section 1902(a) of the Social Security Act (Act), and expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on those waivers and expenditure authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS related to the demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted.

The demonstration will be statewide and is approved for a five-year period, from January 1, 2021 through December 31, 2025.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Eligibility and Enrollment
V. Demonstration Programs and Benefits
VI. Cost Sharing
VII. Delivery System
VIII. General Reporting Requirements
IX. Monitoring
X. Evaluation of the Demonstration
XI. General Financial Requirements Under Title XIX
XII. Monitoring Budget Neutrality for the Demonstration
XIII. Schedule of Deliverables for the Demonstration Period

Additional attachments have been included to provide supplementary information and guidance for specific STCs.

Attachment A: Developing the Evaluation Design

Attachment B: Preparing the Interim and Summative Evaluation Reports
Attachment C: Reserved for SUD Implementation Plan and Health IT Plan
Attachment D: Reserved for SUD Monitoring Protocol
Attachment E: Reserved for SUD Evaluation Design

II. PROGRAM DESCRIPTION AND OBJECTIVES

This demonstration will provide the state with authority to provide high-quality, clinically appropriate treatment to beneficiaries with a substance use disorder (SUD) while they are short-term residents in residential and inpatient treatment settings that qualify as Institutions for Mental Diseases (IMD). It will also support state efforts to enhance provider capacity, improve the availability of Medication Assisted Treatment (MAT) and improve access to a continuum of SUD evidence-based services at varied levels of intensity, including withdrawal management services.

During the demonstration period, the state seeks to achieve the following goals:

1. Increased rates of identification, initiation, and engagement in treatment;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services;
5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; and
6. Improved access to care for physical health conditions among beneficiaries.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).

2. **Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly

waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
    a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
    b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

5. **State Plan Amendments**. The state will not be required to submit title XIX or XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP state plans govern.

6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit

required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

a. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;
b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
c. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
d. An up-to-date CHIP allotment worksheet, if necessary;
e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

8. **Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer of the state in accordance with the requirements of 442 Code of Federal Regulations (CFR) 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit phase-out plan consistent with the requirements of STC 9.

9. **Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.

a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.
b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid or CHIP

eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.

c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.

d. Transition and Phase-out Procedures. The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210 and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR §431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

e. Exemption from Public Notice Procedures 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).

f. Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.

g. Federal Financial Participation (FFP). If the project is terminated or any relevant waivers are suspended by the state, FFP must be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

10. Withdrawal of Waiver or Expenditure Authority. CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX and title XXI. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services,

continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

11. **Adequacy of Infrastructure.** The state will ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.

12. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR section 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

    The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 7 or extension, are proposed by the state.

13. **Federal Financial Participation (FFP).** No federal matching funds for expenditures for this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.

14. **Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, MCOs, and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

15. **Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(b)(5).

IV. ELIGIBILITY AND ENROLLMENT

16. **Eligibility Groups Affected by the Demonstration.** Under the demonstration, there is no change to Medicaid eligibility and the standards and methodologies for eligibility remain set forth under the state plan.

V. DEMONSTRATION PROGRAMS AND BENEFITS

17. **SUD Program Benefits.** Effective upon CMS' approval of the SUD Implementation Plan, the demonstration benefit package for Medicaid beneficiaries will include SUD treatment services, including services provided in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD), which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Medicaid beneficiaries who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance and SUD benefits that would otherwise be matchable if the beneficiary were not residing in an IMD once CMS approves the state's Implementation Plan. The state will aim for a statewide average length of stay of 30 days or less in residential treatment settings, to be monitored pursuant to the SUD Monitoring Protocol as outlined in STC 19, to ensure short-term residential stays. Under this demonstration beneficiaries will have access to high quality, evidence-based OUD/SUD treatment services across a comprehensive continuum of care, ranging from residential and inpatient treatment to ongoing chronic care for these conditions in cost-effective community-based settings.

18. **SUD Implementation Plan and Health IT Plan**.
    a. The state must submit the SUD Implementation Plan within 90 calendar days after approval of this demonstration. The state must submit the revised SUD Implementation Plan within sixty (60) days after receipt of CMS's comments. The state may not claim FFP for services provided in IMDs to beneficiaries who are primarily receiving SUD treatment and withdrawal management services until CMS has approved the SUD Implementation Plan. Once approved, the SUD Implementation Plan will be incorporated into the STCs as Attachment C and, once incorporated, may be altered only with CMS approval. After approval of the applicable implementation plans required by these STCs, FFP will be available prospectively, not retrospectively.
    b. Failure to submit a SUD Implementation Plan will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SUD program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral as described in STC 25.
    c. At a minimum, the SUD Implementation Plan must describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives for the program:

i. Access to Critical Levels of Care for OUD and other SUDs. Coverage of OUD/SUD treatment services across a comprehensive continuum of care including: outpatient; intensive outpatient; medication assisted treatment (medication as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state); intensive levels of care in residential and inpatient settings; and medically supervised withdrawal management, within 12-24 months of demonstration approval.

ii. Use of Evidence-based SUD-specific Patient Placement Criteria. Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of demonstration approval;

iii. Patient Placement. Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of demonstration approval;

iv. Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities. The state must establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;

v. Standards of Care. Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;

vi. Standards of Care. Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of demonstration approval;

vii. Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for SUD/OUD. An assessment of the availability of providers in the critical levels of care throughout the state, or in the regions of the state participating under this demonstration, including those that offer MAT within 12 months of demonstration approval;

viii. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and SUD/OUD. Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well

as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;

ix. Improved Care Coordination and Transitions between levels of care. Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of demonstration approval.

x. SUD Health IT Plan. Implementation of the milestones and metrics as detailed in STC 18(d) [or Attachment C].

d. SUD Health Information Technology Plan ("Health IT Plan"). The SUD Health IT plan applies to all states where the Health IT functionalities are expected to impact beneficiaries within the demonstration. As outlined in SMDL #17-003, respectively, states must submit to CMS the applicable Health IT Plan(s), to be included as a section(s) of the associated Implementation Plan(s) (see STC 18(a) and 18(c)), to develop infrastructure and capabilities consistent with the requirements outlined in each demonstration-type.

The Health IT Plan must detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The plan(s) will also be used to identify areas of health IT ecosystem improvement. The Plan must include implementation milestones and projected dates for achieving them (see Attachment C), and must be aligned with the state's broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state's Behavioral Health (BH) IT Health Plan.

i. The state must include in its Monitoring Protocol (see STC 18(d)) an approach to monitoring its SUD Health IT Plan which will include performance metrics to be approved in advance by CMS.

ii. The state must monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in in an addendum to its Annual Report (see STC 28).

iii. As applicable, the state should advance the standards identified in the 'Interoperability Standards Advisory—Best Available Standards and Implementation Specifications' (ISA) in developing and implementing the state's SUD Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.

iv. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state should use the federally-recognized standards, barring another compelling state interest.

v. Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally-recognized ISA standards, barring no other compelling state interest.

vi. Components of the Health IT Plan include:

1) The Health IT Plan must describe the state's goals, each DY, to enhance the state's prescription drug monitoring program (PDMP).[1]
2) The Health IT Plan must address how the state's PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[2] This must also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan must describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients' history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.
3) The Health IT Plan will, as applicable, describe the state's capabilities to leverage a master patient index (or master data management service, etc.) in support of SUD care delivery. Additionally, the Health IT Plan must describe current and future capabilities regarding PDMP queries—and the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.
4) The Health IT Plan will describe how the activities described in (i), (ii) and (iii) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.[3]
5) The Health IT Plan will describe the state's current and future capabilities to support providers implementing or expanding Health IT functionality in the following areas: 1) Referrals, 2) Electronic care plans and medical records, 3) Consent, 4) Interoperability, 5) Telehealth, 6) Alerting/analytics, and 7) Identity management.
6) In developing the Health IT Plan, states should use the following resources:
    1. States may use federal resources available on Health IT.Gov (https://www.healthit.gov/topic/behavioral-health) including but not limited to "Behavioral Health and Physical Health Integration" and "Section 34: Opioid Epidemic and Health IT" (https://www.healthit.gov/playbook/health-information-exchange/).
    2. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at

[1] Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance prescriptions in states. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the "opioid" epidemic and facilitate a nimble and targeted response.
[2] *Ibid.*
[3] Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015.* MMWR Morb Mortal Wkly Rep 2017;66.

https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.

3. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP interoperability, electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.

19. **SUD Monitoring Protocol.** The state must submit a Monitoring Protocol for the SUD programs authorized by this demonstration within 150 calendar days after approval of the demonstration. The Monitoring Protocol Template must be developed in cooperation with CMS and is subject to CMS approval. The state must submit a revised Monitoring Protocol within sixty (60) calendar days after receipt of CMS's comments. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs, as Attachment D. Progress on the performance measures identified in the Monitoring Protocol must be reported via the quarterly and annual monitoring reports. Components of the Monitoring Protocol include:
    a. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 18(a) and (c) and reporting relevant information to the state's Health IT plan described in STC 18(d);
    b. A description of the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Section VIII of the demonstration; and
    c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.

20. **Evaluation.** The SUD Evaluation will be subject to the same requirements as the overall demonstration evaluation, as described in Sections VIII (General Reporting Requirements) and X (Evaluation of the Demonstration) of these STCs.

21. **Unallowable Expenditures Under the SUD Expenditure Authority.** In addition to the other unallowable costs and caveats already outlined in these STCs, the state may not receive FFP under any expenditure authority approved under this demonstration for any of the following:
    a. Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

VI. COST SHARING

22. **Cost Sharing.** Cost sharing imposed upon individuals enrolled in the demonstration is consistent with the provisions of the approved state plan.

VII. DELIVERY SYSTEM

23. Delivery System. The state's Medicaid SUD delivery system will continue to be operated under a capitated managed care structure and administered by Regional Accountable Entities (RAE). The inpatient and residential SUD treatment services, withdrawal management, and MAT services will be covered under the same delivery system, with capitation payments made from the state to the RAEs which, in turn, manage the delivery of services. The new services, including care coordination, will be considered as the state develops the new capitation rate methodology.

VIII. GENERAL REPORTING REQUIREMENTS

24. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement. The following process will be used: 1) Thirty (30) days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) Thirty days (30) after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state's written extension request.
c. If CMS agrees to an interim corrective plan in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.
d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement with respect to required deliverable(s), and the state submits

the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified in these STCs, the deferral(s) will be released.

e. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

25. **Deferral of Federal Financial Participation (FFP) from IMD Claiming for Insufficient Progress Toward Milestones.** Up to $5,000,000 in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones and goals as evidenced by reporting on the milestones in the Implementation Plan and the required performance measures in the Monitoring Plan agreed upon by the state and CMS. Once CMS determines the state has not made adequate progress, up to $5,000,000 will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made.

26. **Submission of Post-approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.

27. **Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state will work with CMS to:
    a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
    b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
    c. Submit deliverables to the appropriate system as directed by CMS.

IX. MONITORING

28. **Monitoring Reports.** The state must submit three (3) Quarterly Monitoring Reports and one (1) Annual Monitoring Report each DY. The fourth quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual Report. The Quarterly Monitoring Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The Annual Monitoring Report is due no later than ninety (90) calendar days following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.
    a. Operational Updates. The operational updates will focus on progress toward meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key

challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

b. Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately.

d. Evaluation Activities and Interim Findings. Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

e. SUD Health IT. The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 18(d).

29. SUD Mid-Point Assessment. The state must conduct an independent mid-point assessment by July 1, 2023. In the design, planning and conduction of the mid-point assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of MCOs, RAEs, SUD treatment providers, beneficiaries, and other key partners.

The state must require that the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than 60 days after July 1, 2023. This timeline will allow for the assessment report to capture approximately the first two-and-a-half years of demonstration program data, accounting for data run-out and data completeness. The state must brief CMS on the report.

For milestones and measure targets at medium to high risk of not being achieved, the state must submit to CMS modifications to the SUD Implementation Plan and SUD Monitoring Plan for ameliorating these risks. Modifications to the applicable Implementation and Monitoring Protocol are subject to CMS approval. Elements of the mid-point assessment include:

a. An examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plans and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol;
b. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date;
c. A determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets;
d. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state's SUD Implementation Plans or to pertinent factors that the state can influence that will support improvement; and
e. An assessment of whether the state is on track to meet the budget neutrality requirements.

30. **Corrective Action.** If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10.

31. **Close-Out Report**. Within 120 calendar days after the expiration of the demonstration, the state must submit a Draft Close-Out Report to CMS for comments.
    a. The draft close-out report must comply with the most current guidance from CMS.
    b. The state will present to and participate in a discussion with CMS on the close-out report.
    c. The state must take into consideration CMS' comments for incorporation into the final close-out report.
    d. The final close-out report is due to CMS no later than thirty (30) calendar days after receipt of CMS' comments.
    e. A delay in submitting the draft or final version of the close-out report may subject the state to penalties described in STC 24.

32. **Monitoring Calls**. CMS will convene periodic conference calls with the state.
    a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to) any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, enrollment and access, budget neutrality, and progress on evaluation activities.
    b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.
    c. The state and CMS will jointly develop the agenda for the calls.

33. **Post Award Forum.** Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least thirty (30) days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state must also post the most recent annual report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Report.

X. EVALUATION OF THE DEMONSTRATION

34. **Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 25.

35. **Independent Evaluator.** Upon approval of the demonstration, the state must begin to arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party to sign an agreement that the independent party will conduct the demonstration evaluation in an independent manner in accordance with the CMS-approved draft Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

36. **Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after the approval of the demonstration. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The draft Evaluation Design must be developed in accordance with the following CMS guidance (including but not limited to):
    a. All applicable Evaluation Design guidance, including guidance about SUD. Hypotheses applicable to the demonstration as a whole, and to all key policies