

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-25-26
Baltimore, Maryland 21244-1850



State Demonstrations Group

AUG 03 2018

Henry Lipman
Director
Office of Medicaid Business and Policy
New Hampshire Department of Health and Human Services
129 Pleasant Street
Concord, NH 03301-6521

Dear Mr. Lipman:

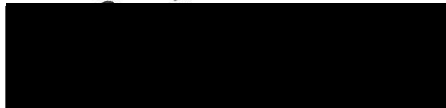
The Centers for Medicare & Medicaid Services (CMS) is issuing technical corrections to the New Hampshire section 1115(a) Medicaid demonstration, titled "Substance Use Disorder Treatment and Recovery Access" (Project No. 11-W-00321/1), which was approved on July 10, 2018 under the authority of section 1115(a) of the Social Security Act ("the Act"). The technical corrections ensure that the Special Terms and Conditions (STC) reflect how the state is currently operating its demonstration.

Changes made include correcting the numbering throughout the STCs, updating cross references and various other non-substantial edits intended to correct and clarify.

If you have any questions, please do not hesitate to contact your project officer, Mr. Michael Trieger. Mr. Trieger can be reached at (410) 786-0745, or at Michael.Trieger1@cms.hhs.gov.

We look forward to continuing work with your staff on the administration of New Hampshire's Substance Use Disorder Treatment and Recovery Access section 1115(a) demonstration.

Sincerely,



Angela D. Garner
Director
Division of System Reform Demonstrations

cc: Richard McGreal, Associate Regional Administrator, CMS Boston Regional Office
Joyce Butterworth, State Lead, CMS Boston Regional Office

**CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY**

NUMBER: 11-W-00321/1

TITLE: Substance Use Disorder Treatment and Recovery Access

AWARDEE: New Hampshire Department of Health and Human Services

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by New Hampshire for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from July 10, 2018 through June 30, 2023, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

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

1. Residential Treatment for Individuals with Substance Use Disorder (SUD).

Expenditures for otherwise covered 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 disease (IMD).

**CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS**

NUMBER: 11-W-00321/1

TITLE: Substance Use Disorder Treatment and Recovery Access

AWARDEE: New Hampshire Department of Health and Human Services

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the “Substance Use Disorder Treatment and Recovery Access” (SUD – TRA) section 1115(a) Medicaid demonstration (hereinafter “demonstration”), to enable the New Hampshire Department of Health and Human Services (hereinafter “state”), to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on those expenditure authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state’s obligations to CMS during the life of the demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted. The STCs are effective as of the date of the approval letter, unless otherwise specified.

The STCs related to the programs for those state plan populations affected by the demonstration are effective from July 10, 2018 through June 30, 2023.

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 Extension 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 Evaluation Design
- Attachment D: Substance Use Disorder (SUD) Implementation Plan Protocol
- Attachment E: Reserved for SUD Monitoring Protocol

II. PROGRAM DESCRIPTION AND OBJECTIVES

The goal of this demonstration is for the state to maintain critical access to opioid use disorder (OUD) and other substance use disorder (SUD) services and continue delivery system improvements for these services to provide more coordinated and comprehensive OUD/SUD treatment for Medicaid beneficiaries. This demonstration will provide the state with authority to provide high-quality, clinically appropriate SUD treatment services for short-term residents in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD). It will also build on the state's existing efforts to improve models of care focused on supporting individuals in the community and home, outside of institutions and strengthen a continuum of SUD services based on the American Society of Addiction Medicine (ASAM) criteria or other nationally recognized assessment and placement tools that reflect evidence-based clinical treatment guidelines.

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

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, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.
2. **Compliance with Medicaid and Child Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid program, or the Children's Health Insurance Program (CHIP) for the separate CHIP population, expressed in 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 law, regulation, or policy statement, come into compliance with any changes in federal 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 demonstration as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph.
 - b. If mandated changes in the federal law require state legislation, 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.
- 5. State Plan Amendments.** The state will not be required to submit title XIX or XXI state plan amendments 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 state plan governs.
- 6. Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, 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. Amendments to the demonstration are not retroactive and FFP will not be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below.

- 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 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 15. 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 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;
 - c. An up-to-date CHIP allotment worksheet, if necessary.
 - d. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation; and
 - 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 demonstration extensions under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in statute. Otherwise, if the state intends to request a demonstration extension under section 1115(a) of the Act, the state must submit the extension application no later than 12 months prior to the expiration date of the demonstration. The Governor or Chief Executive Officer of the state must submit to CMS either a demonstration extension request that meets federal requirements at CFR section 431.412(c) or a phase-out plan consistent with the requirements of STC 10.
- 9. Compliance with Transparency Requirements 42 CFR Section 431.412.** As part of the demonstration extension requests the state must provide documentation of compliance with the transparency requirements 42 CFR Section 431.412 and the public notice and tribal consultation requirements outlined in STC 15, as well as include the following supporting documentation:
- a. Demonstration Summary and Objectives: The state must provide a narrative summary of the demonstration project, reiterate the objectives set forth at the time the demonstration was proposed and provide evidence of how these objectives have been met as well as future goals of the program. If changes are requested, a

narrative of the changes being requested along with the objective of the change and desired outcomes must be included.

- b. Special Terms and Conditions: The state must provide documentation of its compliance with each of the STCs. Where appropriate, a brief explanation may be accompanied by an attachment containing more detailed information. Where the STCs address any of the following areas, they need not be documented a second time.
- c. Waiver and Expenditure Authorities: The state must provide a list along with a programmatic description of the waivers and expenditure authorities that are being requested in the extension.
- d. Quality: The state must provide summaries of: External Quality Review Organization (EQRO) reports; managed care organization (MCO) reports; state quality assurance monitoring; and any other documentation that validates the quality of care provided or corrective action taken under the demonstration.
- e. Compliance with Budget Neutrality Cap: The state must provide financial data (as set forth in the current STCs) demonstrating the state's detailed and aggregate, historical and projected budget neutrality status for the requested period of the extension as well as cumulatively over the lifetime of the demonstration. CMS will work with the state to ensure that federal expenditures under the extension of this project do not exceed the federal expenditures that would otherwise have been made. In doing so, CMS will take into account the best estimate of current trend rates at the time of the extension. In addition, the state must provide up to date responses to the CMS Financial Management standard questions. If title XXI funding is used in the demonstration, a CHIP Allotment Neutrality worksheet must be included.
- f. Evaluation Report: The state must provide an evaluation report reflecting the hypotheses being tested and any results available. For the proposed extension period, the state must provide a narrative summary of the evaluation design, status (including evaluation activities and findings to date), and plans for evaluation activities during the extension period.
- g. Documentation of Public Notice 42 CFR section 431.408: The state must provide documentation of the state's compliance with public notice process as specified in 42 CFR section 431.408 including the post-award public input process described in 431.420(c) with a report of the issues raised by the public during the comment period and how the state considered the comments when developing the demonstration extension application.

10. 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 phase-out plan. The state must submit its notification letter and a draft phase-out plan to CMS no less than 6 months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft phase-out plan to CMS, the state must publish on its website the draft phase-out plan for a 30-

day public comment period. In addition, the state must conduct tribal consultation in accordance with its approved tribal consultation State Plan Amendment. Once the 30-day public comment period has ended, the state must provide a summary of each public comment received the state's response to the comment and how the state incorporated the received comment into a revised phase-out plan.

The state must obtain CMS approval of the phase-out plan prior to the implementation of the phase-out activities. Implementation of phase-out activities must be no sooner than 14 calendar days after CMS approval of the phase-out plan.

- b. 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 eligibility for the affected beneficiaries, and ensure ongoing coverage for eligible individuals, as well as any community outreach activities.
- c. Phase-out Procedures: The state must comply with all notice requirements found in 42 CFR §431.206, 431.210 and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration participants as outlined in 42 CFR §431.220 and 431.221. If a demonstration participant 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 eligibility under a different eligibility category as discussed in October 1, 2010, State Health Official Letter #10-008.
- d. Federal Financial Participation (FFP): If the project is terminated or any relevant waivers suspended by the state, FFP must be limited to normal closeout costs associated with terminating the demonstration including services and administrative costs of disenrolling participants.

11. CMS Right to Terminate or Suspend. CMS may suspend or terminate the demonstration in whole or in part at any time before the date of expiration, whenever it determines, following a hearing that the state has materially failed to comply with the terms of the project. CMS will promptly notify the state in writing of the determination and the reasons for the suspension or termination, together with the effective date.

12. Finding of Non-Compliance. The state does not relinquish its rights to challenge CMS' finding that the state materially failed to comply.

13. Withdrawal of 1115(a) Authority. CMS reserves the right to withdraw waiver 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. 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 and administrative costs of dis-enrolling participants.

14. 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.

15. 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 section 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 section 431.408(b), State Medicaid Director Letter #01-024, and contained in the state's approved Medicaid State plan, when any program changes to the demonstration, either through amendment as set out in STC 6 or extension, are proposed by the state.

16. Federal Financial Participation (FFP). No federal matching funds for expenditures for this demonstration will take effect until the effective date identified in the demonstration approval letter, or later date if so identified elsewhere in these STCs or in the list of waiver or expenditure authorities.

17. 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.

18. Common Rule Exemption. The state must ensure that the only involvement of human subjects in research activities which may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and which are designed to study, evaluate, or otherwise examine the Medicaid program – including public benefit or service programs; procedures for obtaining Medicaid benefits or services; possible changes in or alternatives to those programs or procedures; or possible changes in methods or level of payment for benefits or services under those programs. 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 46.101(b)(5).

IV. ELIGIBILITY AND ENROLLMENT

19. Eligibility Groups Affected by the Demonstration. Under the demonstration, there is no change to Medicaid eligibility. Standards for eligibility remain set forth under the state plan. The demonstration will allow Medicaid recipients under age 65 to receive OUD/SUD treatment services 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. Demonstration services are delivered through a managed care or fee for service (FFS) delivery system. FFS recipients are primarily those in their managed care plan selection period, except for a small number of recipient who are exempt from managed care. All affected groups derive their eligibility through the Medicaid state plan, and are subject to all applicable Medicaid laws and regulations in accordance with the Medicaid state plan. All Medicaid eligibility standards and methodologies for these eligibility groups remain applicable.

V. DEMONSTRATION PROGRAMS AND BENEFITS

20. Opioid Use Disorder/Substance Use Disorder Program. Effective upon CMS' approval of the OUD/SUD Implementation Protocol, the demonstration benefit package for Medicaid recipients will include OUD/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 recipients residing 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. New Hampshire will 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 Section VIII below, to ensure short-term residential treatment stays. Under this demonstration, beneficiaries will have access to high quality, evidence-based OUD and other SUD treatment services ranging from medically supervised withdrawal management to on-going chronic care for these conditions in cost-effective settings while also improving care coordination and care for comorbid physical and mental health conditions.

The extension of coverage to services for all recipients while they are in short-term residential treatment for OUD/SUD will expand the available settings and allow the state to offer a full continuum of care for recipients with OUD/SUD (see Table 1). Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

Table 1: New Hampshire OUD/SUD Benefits Coverage with Expenditure Authority

SUD Benefit	Medicaid Authority	Expenditure Authority
Outpatient Services	State plan (Individual services covered)	Services provided to individuals in an IMD
Intensive Outpatient Services	State plan (Individual services covered)	Services provided to individuals in an IMD
Residential Treatment	State plan (Individual services covered)	Services provided to individuals in an IMD
Medically Supervised Withdrawal Management	State plan	Services provided to individuals in an IMD
Screening, Brief Intervention, and Referral to Treatment (SBIRT)	State plan	Services provided to individuals in an IMD
Medication Assisted Treatment	State Plan	Services provided to individuals in an IMD
Partial Hospitalization	State plan	Services provided to individuals in an IMD
Recovery Support Services	State plan	Services provided to individuals in an IMD.

21. SUD Implementation Protocol. The state must submit an OUD/SUD Implementation Protocol within 90 calendar days after approval of this demonstration. The state may not claim FFP for services provided in IMDs until CMS has approved the Implementation Protocol. Once approved, the Implementation Protocol will be incorporated into the STCs, as Attachment D, and once incorporated, may be altered only with CMS approval. After approval of the Implementation Protocol, FFP will be available prospectively, not retrospectively. Failure to submit an Implementation Protocol 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 OUD/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. At a minimum, the OUD/SUD Implementation Protocol 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 of the SUD component of this demonstration program:

- a. **Access to Critical Levels of Care for OUD and other SUDs:** Service delivery for new benefits, including residential treatment and withdrawal management, within 12-24 months of OUD/SUD program demonstration approval;
- b. **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 comparable assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of OUD/SUD program demonstration approval;
- c. **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 SUD program demonstration approval;
- d. **Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities:** Currently, residential treatment service providers must be a licensed organization, pursuant to the residential service provider qualifications described in the New Hampshire Code of Administrative Rules at He-W 513. The state will 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 comparable, 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 OUD/SUD program demonstration approval;
- e. **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 SUD program demonstration approval;
- f. **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 SUD program demonstration approval;
- g. **Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for OUD:** An assessment of the availability of providers in the key 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 SUD program demonstration approval;
- h. **Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and 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;

i. **SUD Health IT Plan:** Implementation of the milestones and metrics as detailed in STC 24 ; and

j. **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 SUD program demonstration approval.

22. SUD Monitoring Protocol. The state must submit a SUD Monitoring Protocol within 150 calendar days after approval of SUD program under this demonstration. The SUD Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs, as Attachment E. At a minimum, the SUD Monitoring Plan Protocol will include reporting relevant to each of the program implementation areas listed in STC 21. The protocol will also describe the data collection, reporting and analytic methodologies for performance measures identified by the state and CMS for inclusion. The SUD Monitoring Protocol will specify 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 STC 29 of the demonstration. In addition, for each performance measure, the SUD Monitoring Protocol will identify a baseline, a target to be achieved by the end of the demonstration and an annual goal for closing the gap between baseline and target expressed as percentage points.

Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings. CMS will closely monitor demonstration spending on services in IMDs to ensure adherence to budget neutrality requirements. Progress on the performance measures identified in the Monitoring Protocol will be reported via the quarterly and annual monitoring reports.

23. Mid-Point Assessment. The state must conduct an independent mid-point assessment of the demonstration by March 30, 2021. The assessor must collaborate with key stakeholders, including representatives of MCOs, SUD treatment providers, beneficiaries, and other key partners in the design, planning and conducting of the mid-point assessment. The assessment will include an examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Protocol, and toward closing the gap between baseline and target each year in performance measures as approved in the SUD Monitoring Protocol. The assessment will also include a determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date, and a determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and about the risk of possibly missing those milestones and performance targets. The mid-point assessment will also provide a status update of budget neutrality requirements. For each milestone or measure target at medium to high risk of not being met, the assessor will provide, for consideration by the state, recommendations for adjustments in the state's implementation plan or to pertinent factors

that the state can influence that will support improvement. The assessor will 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. A copy of the report will be provided to CMS. CMS will be briefed on the report.

For milestones and measure targets at medium to high risk of not being achieved, the state will submit to CMS modifications to the SUD Implementation Protocol and SUD Monitoring Plan Protocols for ameliorating these risks subject to CMS approval.

- 24. SUD Health Information Technology (Health IT).** The state will provide CMS with an assurance that it has a sufficient health IT infrastructure/”ecosystem” at every appropriate level (i.e. state, delivery system, health plan/MCO and individual provider) to achieve the goals of the demonstration—or it will submit to CMS a plan to develop the infrastructure/capabilities. This “SUD Health IT Plan,” or assurance will be included as a section of the state’s “Implementation Plan” (see STC 21) to be approved by CMS. The SUD Health IT Plan will detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The plan will also be used to identify areas of SUD health IT ecosystem improvement.
- a. The SUD Health IT section of the Implementation plan will include implementation milestones and dates for achieving them.
 - b. The SUD Health IT Plan must be aligned with the state’s broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state’s Behavioral Health (BH) “Health IT” Plan.
 - c. The SUD Health IT Plan will describe the state’s goals, each DY, to enhance the state’s prescription drug monitoring program’s (PDMP).¹
 - d. The SUD Health IT Plan will address how the state’s PDMP will enhance ease of use for prescribers and other state and federal stakeholders.² This will also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan will 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.
 - e. The SUD 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 SUD 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

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.*

will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.

- f. The SUD Health IT Plan will describe how the activities described in (a) through (e) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.³
- g. In developing the Health IT Plan, states should use the following resources:
 - i. States may use resources at Health IT.Gov (<https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/>) in “Section 4: Opioid Epidemic and Health IT.”
 - ii. 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 <https://www.medicare.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.
 - iii. 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 plans and, more generally, to meet the goals of the demonstration
- h. The state will include in its monitoring Plan (see STC 22) an approach to monitoring its SUD Health IT Plan which will include performance metrics provided by CMS or State defined metrics to be approved in advance by CMS.
- i. The state will 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 Reports (see STC 29).
- j. 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.
 - i. 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.
 - ii. 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.

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.

VI. COST SHARING

Cost sharing imposed upon individuals under the demonstration is consistent with the provisions of the approved state plan.

VII. DELIVERY SYSTEM

The state's SUD/OD Medicaid delivery system is based on an integrated managed care model for physical and behavioral health. It utilizes Managed Care Organizations (MCO) to deliver integrated physical and behavioral health services, including SUD with a small number of members receiving services through FFS. Under the demonstration, Substance Use Disorder Treatment and Recovery Access will continue to operate as approved in Section 1932(a) state plan authority for managed care and concurrent 1915(b) and 1115 demonstrations. .

VIII. GENERAL REPORTING REQUIREMENTS

- 25. Submission of Post-approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.
- 26. Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in the amount of \$5,000,000 (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 found to not be consistent with the requirements approved by CMS. Specifically:
- a. Thirty (30) calendar days after the deliverable was due, CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverables.
 - b. For each deliverable, the state may submit a written request for an extension to submit the required deliverable. Extension requests that extend beyond the current fiscal quarter must include a Corrective Action Plan (CAP).
 - i. CMS may decline the extension request.
 - ii. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided.
 - iii. If the state's request for an extension includes a CAP, CMS may agree to or further negotiate the CAP as an interim step before applying the deferral.
 - c. The deferral would be issued against the next quarterly expenditure report following the written deferral notification.
 - d. When the state submits the overdue deliverable(s) that are accepted by CMS, the deferral(s) will be released.
 - e. As the purpose of a section 1115 demonstration is to test new methods of operation or services, a state's failure to submit all required deliverables may preclude a state from renewing a demonstration or obtaining a new demonstration.
 - f. CMS will consider with the state an alternative set of operational steps for implementing the intended deferral to align the process with the state's existing deferral process, for example, what quarter the deferral applies to and how the

deferral is released.

27. 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 Protocol and the required performance measures in the Monitoring protocol 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.

28. 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

29. Monitoring Reports. The state must submit three (3) Quarterly Reports and one (1) compiled Annual Report each DY. The information for the fourth quarter should be reported as distinct information within the Annual Report. The Quarterly Reports are due no later than sixty (60 calendar days) following the end of each demonstration quarter. The compiled Annual 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 - 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 – 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 24.

30. 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 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 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 26.

31. Monitoring Calls. CMS will convene periodic conference calls with the state.

- a. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, enrollment and access, budget neutrality, and progress on evaluation activities.
- b. CMS will provide updates on any amendments or concept papers under review, 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.

32. 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 30 calendar 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

33. 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 independent party must sign an agreement to conduct the demonstration evaluation in an independent manner in accord 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.

34. Evaluation Budget. A budget for the evaluation must be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluation such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.

35. 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 effective date of these STCs. 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 state must use an independent evaluator to develop the draft Evaluation Design.

36. Evaluation Design Approval and Updates. The state must submit a revised draft Evaluation Design within sixty (60) days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design to the state's website within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in these STCs. Once CMS approves the evaluation

design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

- 37. Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS’s Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
- 38. Interim Evaluation Report.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Report should be posted to the state’s website with the application for public comment.
- a. The interim evaluation report will discuss evaluation progress and present findings to date as per the approved evaluation design.
 - b. For demonstration authority that expires prior to the overall demonstration’s expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
 - c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses, and how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
 - d. The state must submit the final Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state’s website.
 - e. The Interim Evaluation Report must comply with Attachment B of these STCs.
- 39. Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with Attachment B of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration’s current approval period, July 10, 2018 – June 30, 2023, within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

- a. Unless otherwise agreed upon in writing by CMS, the state must submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.
- b. The final Summative Evaluation Report must be posted to the state's Medicaid website within 30 calendar days of approval by CMS.

40. State Presentations for CMS. CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the interim evaluation, and/or the summative evaluation.

41. Public Access. The state shall post the final documents (e.g., Monitoring Reports, Close Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 days of approval by CMS.

42. Additional Publications and Presentations. For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

43. Cooperation with Federal Evaluators. As required under 42 CFR 431.420(f), the state shall 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 shall include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they shall 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 27.

XI. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

44. Reporting Expenditures under the Demonstration. The following describes the reporting of expenditures subject to the Budget Neutrality agreement:

- a. Tracking Expenditures. In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in section 2500 of the State Medicaid Manual. All demonstration expenditures

claimed under the authority of title XIX of the Act and subject to the BN expenditure limit must be reported each quarter on separate Forms CMS-64.9 Waiver and/or 64.9P Waiver, identified by the demonstration project number (11-W-00321/1) assigned by CMS, including the project number extension which indicates the Demonstration Year (DY) in which services were rendered.

- b. Cost Settlements. For monitoring purposes, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (Form CMS-64.9P Waiver) for the Summary Sheet Line 10B, in lieu of Lines 9 or 10C. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual.
- c. Pharmacy Rebates. When claiming these expenditures the state may refer to the July 24, 2014 CMCS Informational Bulletin which contains clarifying information for quarterly reporting of Medicaid Drug Rebates in the Medicaid Budget and Expenditures (MBES) (<http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-24-2014.pdf>). The state must adhere to the requirement at section 2500.1 of the State Medicaid Manual that all state collections, including drug rebates, must be reported on the CMS-64 at the applicable Federal Medical Assistance Percentage (FMAP) or other matching rate at which related expenditures were originally claimed.
- d. Use of Waiver Forms. For each demonstration year, separate Forms CMS-64.9 Waiver and/or 64.9P Waiver must be completed, using the waiver names listed below. Expenditures should be allocated to these forms based on the guidance which follows.
 - i. **Medicaid Adults (Non-Group VIII Adults):** All expenditures for costs of medical assistance that could be covered for Medicaid Adults, were it not for the IMD prohibition, under the state plan, provided to otherwise eligible individuals during a month in an IMD.
 - ii. **Expansion Adults (Group VIII Adults):** All expenditures for costs of medical assistance that could be covered for Expansion Adults, were it not for the IMD prohibition, under the state plan, provided to otherwise eligible individuals during a month in an IMD.
 - iii. **Adolescents:** All expenditures for costs of medical assistance that could be covered for Adolescents, were it not for the IMD prohibition, under the state plan, provided to otherwise eligible individuals during a month in an IMD.

e. Demonstration Years. The demonstration years are as follows:

<i>Demonstration Year 1</i>	<i>July 10, 2018 – June 30, 2019</i>
<i>Demonstration Year 2</i>	<i>July 12019 – June 30, 2020</i>
<i>Demonstration Year 3</i>	<i>July 1, 2020 – June 30, 2021</i>
<i>Demonstration Year 4</i>	<i>July 1, 2021 – June 30, 2022</i>
<i>Demonstration Year 5</i>	<i>July 1, 2022 – June 30, 2023</i>

45. Budget Neutrality Monitoring Tool. The state and CMS will jointly develop a BN monitoring tool (using a mutually agreeable spreadsheet program) for the state to use for quarterly BN status updates including established baseline and member months data and other in situations when an analysis of BN is required. The tool will incorporate the “C Report” for monitoring actual expenditures subject to BN. A working version of the monitoring tool will be available for the state’s first Annual Report.

46. Quarterly Expenditure Reports: The state must provide quarterly expenditure reports using the Form CMS-64 to report total expenditures for services provided through this under the Medicaid program, including those provided through the demonstration under section 1115 authority that are subject to budget neutrality. This project is approved for expenditures applicable to services rendered during the demonstration period. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.

FFP will be provided for expenditures net of collections in the form of pharmacy rebates, cost sharing, or third party liability.

47. Expenditures Subject to the Budget Neutrality Agreement. For the purpose of this section, the term “expenditures subject to the budget neutrality agreement” means expenditures for the EGs outlined in Section XII, Monitoring Budget Neutrality for the Demonstration, except where specifically exempted. All expenditures that are subject to the budget neutrality agreement are considered demonstration expenditures and must be reported on Forms CMS-64.9 Waiver and/or 64.9P Waiver.

48. Administrative Costs. Administrative costs will not be included in the budget neutrality limit, but the state must separately track and report additional administrative costs that are directly attributable to the demonstration, using separate CMS-64.10 waiver and 64.10 waiver forms, with waiver name “ADM”.

49. Claiming Period. All claims for expenditures subject to the budget neutrality limit (including any cost settlements) must be made within two (2) years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including any cost settlements) must be made within two (2) years after the conclusion or termination of the demonstration. During the latter 2-year period, the state must continue to identify separately net expenditures related to dates of service during the operation of the section 1115 demonstration on the Form CMS-64 in order to properly account for these expenditures in determining budget neutrality.

50. Reporting Member Months. The following describes the reporting of member months for demonstration populations.

- a. For the purpose of calculating the BN expenditure limit and for other purposes, the state must provide to CMS, as part of the BN Monitoring Tool required under STC 45, the actual number of eligible member months for the each MEG defined in subparagraph D below. The state must submit a statement accompanying the BN Monitoring Tool, which certifies the accuracy of this information. To permit full recognition of “in-process” eligibility, reported counts of member months may be subject to revision.

- b. The term "eligible member/months" refers to the number of months in which persons are eligible to receive services. For example, a person who is eligible for 3 months contributes 3 eligible member months to the total. Two individuals who are eligible for 2 months each contribute 2 eligible member months to the total, for a total of 4 eligible member/months.
- c. The state must report separate member month totals for individuals enrolled in the Substance Use Disorder Treatment and Recovery Access demonstration, and the member months must be subtotaled according to the MEGs defined in STC 44(d)(i).
- d. The required member month reporting MEG is:
 - i. **Medicaid Adults (Non-Group VIII Adults)**: Medicaid Adults Member Months are months of Medicaid eligibility during which the individual is an inpatient in an IMD under terms of the demonstration for any day during the month and must be reported separately for each Medicaid Adult MEG, as applicable.
 - ii. **Expansion Adults (Group VIII Adults)**: Expansion Adults Member Months are months of Medicaid eligibility during which the individual is an inpatient in an IMD under terms of the demonstration for any day during the month and must be reported separately for each Expansion Adult MEG, as applicable.
 - iii. **Adolescents**: Adolescents Member Months are months of Medicaid eligibility during which the individual is an inpatient in an IMD under terms of the demonstration for any day during the month and must be reported separately for each Adolescent MEG, as applicable.

51. Standard Medicaid Funding Process. The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable Medicaid expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report those expenditures by quarter for each FFY on the Form CMS-37 (narrative section) for both Medical Assistance Payments (MAP) and state and Local Administrative Costs (ADM). As a supplement to the Form CMS-37, the state will provide updated estimates of expenditures subject to the budget neutrality limit. CMS will make federal funds available based upon the state's estimate, as approved by CMS. Within 30 calendar days after the end of each quarter, the state must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter just ended. CMS will reconcile expenditures reported on the Form CMS-64 quarterly with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

52. Extent of Federal Financial Participation for the Demonstration. Subject to CMS approval of the source(s) of the non-federal share of funding. CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole for the following, subject to the limits described in Section XII:

- a. Administrative costs, including those associated with the administration of the demonstration;
- b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
- c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.

53. Sources of Non-Federal Share. The state certifies that the matching non-federal share of funds for the demonstration is state/local monies. The state further certifies that such funds must not be used as the match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

- a. CMS may review at any time the sources of the non-federal share of funding for the demonstration. The state agrees that all funding sources deemed unacceptable by CMS must be addressed within the time frames set by CMS.
- b. Any amendments that impact the financial status of the program must require the state to provide information to CMS regarding all sources of the non-federal share of funding.
- c. The state assures that all health care-related taxes comport with section 1903(w) of the Act and all other applicable federal statutory and regulatory provision, as well as the approved Medicaid state plan.

54. State Certification of Funding Conditions. The state must certify that the following conditions for non-federal share of demonstration expenditures are met:

- a. Units of government, including governmentally operated health care providers, may certify that state or local monies have been expended as the non-federal share of funds under the demonstration.
- b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
- c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR §433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to

receive other federal matching funds under 42 CFR §433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match;

- d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state.
- e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR §447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the State any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

55. Program Integrity. The state must have a process in place to ensure that there is no duplication of federal funding for any aspect of the demonstration.

XIII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

56. Limit on Title XIX Funding. The state will be subject to a limit on the amount of federal title XIX funding that the state may receive on selected Medicaid expenditures during the period of approval of the demonstration. The limit is determined by using the per capita cost method described in STCs 57 and 58, and budget neutrality expenditure limits are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. Actual expenditures subject to the budget neutrality expenditure limit must be reported by the state using the procedures described in Section XI. The data supplied by the state to CMS to set the annual caps is subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit. CMS' assessment of the state's compliance with these annual limits will be done using the Schedule C report from the CMS-64.

57. Risk. The state will be at risk for the per capita cost (as determined by the method described below) for state plan and hypothetical populations, but not at risk for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration populations, CMS will not place the state at risk for changing economic conditions. However, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration.

58. Calculation of the Budget Neutrality Limit and How It Is Applied. For the purpose of calculating the overall budget neutrality limit for the demonstration, annual budget limits will be calculated for each DY on a total computable basis, by multiplying the predetermined PMPM cost for each EG (shown on the table in STC 60) by the

corresponding actual member months total, and summing the results of those calculations. The annual limits will then be added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality limit by Composite Federal Share, which is defined in STC 62 below. The demonstration expenditures subject to the budget neutrality limit are those reported under the following Waiver Names; SUD IMD.

59. Impermissible DSH, Taxes, or Donations. CMS reserves the right to adjust the budget neutrality ceiling to be consistent with enforcement of laws and policy statements, including regulations and letters regarding impermissible provider payments, health care related taxes, or other payments (if necessary adjustments must be made). CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Social Security Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

60. Main Budget Neutrality Test. The trend rates and per capita cost estimates for each EG for each year of the demonstration are listed in the table below.

MEG	TREND	DY 1 - PMPM	DY 2 PMPM	DY 3 PMPM	DY 4 PMPM	DY 5 PMPM
Medicaid Adults (Non-Group VIII Adults)	4.4%	\$961	\$1,004	\$1,048	\$1,094	\$1,142
Expansion Adults (Group VIII Adults)	4.7%	\$608	\$636	\$666	\$698	\$730
Adolescents	3.7%	\$573	\$595	\$617	\$639	\$663

61. Hypothetical Model. As part of the SUD initiative, the state may receive FFP for the continuum of services to treat OUD and other SUDs, provided to Medicaid enrollees in an IMD. These are state plan services that would be eligible for reimbursement if not for the IMD exclusion. Therefore, they are being treated as hypothetical for the purposes of budget neutrality. Hypothetical services can be treated in budget neutrality in a way that is similar to how Medicaid state plan services are treated, by including them as a “pass through” in both the without-waiver and with-waiver calculations. However, the state will not be allowed to obtain budget neutrality “savings” from these services.

62. Composite Federal Share Ratios. The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP

received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration’s approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method.

63. Exceeding Budget Neutrality. The budget neutrality limits calculated in STC 60 will apply to actual expenditures for demonstration services as reported by the state under section XI of these STCs. If at the end of the demonstration period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

64. Enforcement of Budget Neutrality. CMS will enforce the budget neutrality agreement over the life of the demonstration, rather than on an annual basis. However, if the state exceeds the calculated cumulative target limit by the percentage identified below for any of the DYs, the state must submit a corrective action plan to CMS for approval.

Demonstration Year	Cumulative Target Definition	Percentage
DY 1	Cumulative budget neutrality limit	2.0 percent
DY 1 through DY 2	Cumulative budget neutrality limit	1.5 percent
DY 1 through DY 3	Cumulative budget neutrality limit	1.0 percent
DY 1 through DY 4	Cumulative budget neutrality limit	0.5 percent
DY 1 through DY 5	Cumulative budget neutrality limit	0.0 percent

XIII. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

Date	Deliverable	STC
30 days after approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
90 days after SUD program approval date	SUD Implementation Protocol	STC 21
150 days after SUD program approval date	SUD Monitoring Protocol	STC 22
180 days after approval date	Draft Evaluation Design	STCs 35 and 36
60 days after receipt of CMS comments	Revised Draft Evaluation Design	STCs 36
30 days after CMS Approval	Approved Evaluation Design published to state's website	STCs 36
March 30, 2021	Mid-Point Assessment	STC 23
One year prior to the end of the demonstration, or with renewal application	Draft Interim Evaluation Report	STC 38(c)
60 days after receipt of CMS comments	Final Interim Evaluation Report	STC 38(d)
18 months of the end of the demonstration	Draft Summative Evaluation Report	STC 39
60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	STC 39(a)
30 calendar days of CMS approval	Approved Final Summative Evaluation Report published to state's website	STC 39(b)
Monthly Deliverables	Monitoring Calls	STC 31
Quarterly Deliverables	Quarterly Monitoring Reports	STC 29
Due 60 days after end of each quarter, except 4 th quarter	Quarterly Expenditure Reports	STC 46

Annual Deliverables - Due 90 days after end of each 4 th quarter	Annual Reports	STC 29
Within 120 calendar days prior to the expiration of the demonstration	Draft Close-out Operational Report	STC 30
30 calendar days after receipt of CMS comments	Final Close-out Operational Report	STC 30(d)

ATTACHMENT A

Developing the Evaluation Design

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform both Congress and CMS about Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Designs

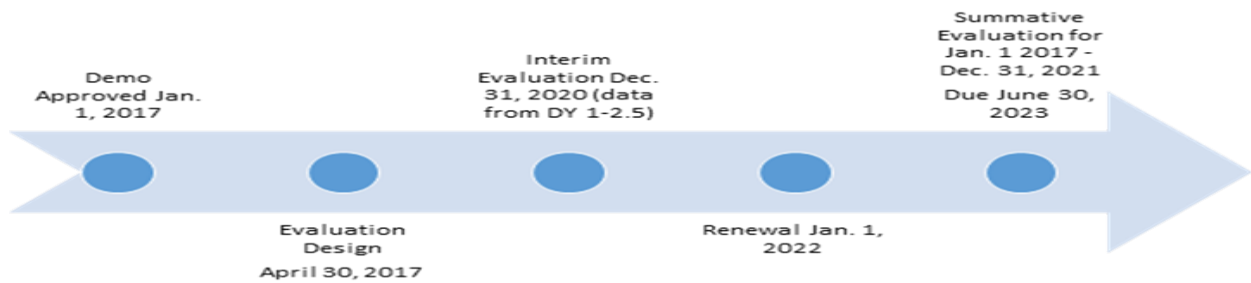
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals.

The format for the Evaluation Design is as follows:

General Background Information;
Evaluation Questions and Hypotheses;
Methodology;
Methodological Limitations;
Attachments.

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Design and Reports. (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within thirty (30) days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of All Evaluation Designs

The Evaluation Design sets the stage for the Interim and Summative Evaluation Reports. It is important that the Evaluation Design explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology (and limitations) for the evaluation. A copy of the state’s Driver Diagram (described in more detail in paragraph B2 below) should be included with an explanation of the depicted information.

A. General Background Information – In this section, the state should include basic information about the demonstration, such as:

- 1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).
- 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
- 3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;
- 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.
- 5) Describe the population groups impacted by the demonstration.

B. Evaluation Questions and Hypotheses – In this section, the state should:

1. Describe how the state’s demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.
 2. Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams:
<https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf>
 3. Identify the state’s hypotheses about the outcomes of the demonstration:
 4. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
 5. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.
- C. Methodology** – In this section, the state is to describe in detail the proposed research methodology.

The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

This section provides the evidence that the demonstration evaluation will use the best available data; reports on, controls for, and makes appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what will be measured and how. Specifically, this section establishes:

- 1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?
- 2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.
- 3) *Evaluation Period* – Describe the time periods for which data will be included.

- 4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by “owning”, defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:
- a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
 - b. Qualitative analysis methods may be used, and must be described in detail.
 - c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
 - d. Proposed health measures could include CMS’s Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
 - e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
 - f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.
- 5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

If primary data (data collected specifically for the evaluation) – The methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection. (Copies of any proposed surveys must be reviewed with CMS for approval before implementation).

- 6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:
- a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.
 - b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
 - c. A discussion of how propensity score matching and difference in differences

design may be used to adjust for differences in comparison populations over time (if applicable).

d. The application of sensitivity analyses, as appropriate, should be considered.

7) *Other Additions* – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

Table A. Example Design Table for the Evaluation of the Demonstration

Research Question	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
Hypothesis 1				
Research question 1a	-Measure 1 -Measure 2 -Measure 3	-Sample e.g. All attributed Medicaid beneficiaries -Beneficiaries with diabetes diagnosis	-Medicaid fee-for-service and encounter claims records	-Interrupted time series
Research question 1b	-Measure 1 -Measure 2 -Measure 3 -Measure 4	-sample, e.g., PPS patients who meet survey selection requirements (used services within the last 6 months)	-Patient survey	Descriptive statistics
Hypothesis 2				
Research question 2a	-Measure 1 -Measure 2	-Sample, e.g., PPS administrators	-Key informants	Qualitative analysis of interview material

D. Methodological Limitations – This section provides detailed information on the limitations of the evaluation. This could include the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize the limitations. Additionally, this section should include any information about features of the demonstration that effectively present methodological constraints that the state would like CMS to take into consideration in its review. For example:

- 1) When the state demonstration is:
 - a. Long-standing, non-complex, unchanged, or
 - b. Has previously been rigorously evaluated and found to be successful, or
 - c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)

- 2) When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:

- a. Operating smoothly without administrative changes; and
- b. No or minimal appeals and grievances; and
- c. No state issues with CMS-64 reporting or budget neutrality; and
- d. No Corrective Action Plans (CAP) for the demonstration.

E. Attachments

- 1) **Independent Evaluator.** This includes a discussion of the state’s process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include “No Conflict of Interest” signed by the independent evaluator.
- 2) **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.
- 3) **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

ATTACHMENT B

Preparing the Interim and Summative Evaluation Reports

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provide important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. As these valid analyses multiply (by a single state or by multiple states with similar demonstrations) and the data sources improve, the reliability of evaluation findings will be able to shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

Intent of this Guidance

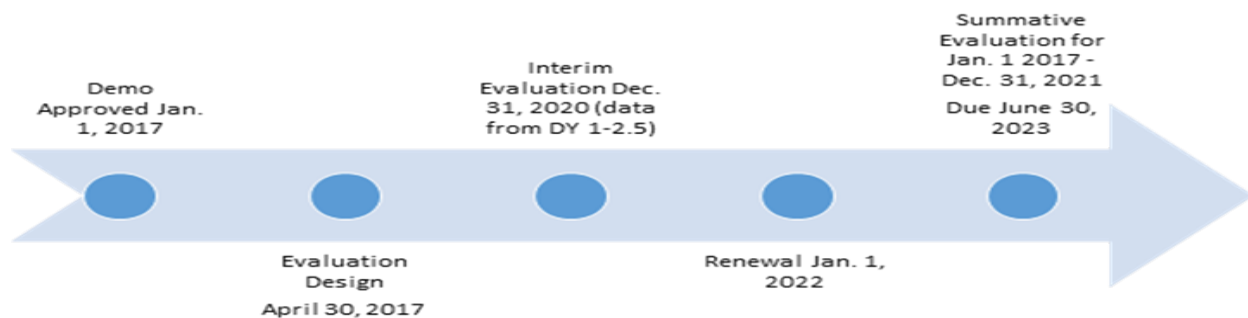
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Guidance is intended to assist states with organizing the required information in a standardized format and understanding the criteria that CMS will use in reviewing the submitted Interim and Summative Evaluation Reports.

The format for the Interim and Summative Evaluation reports is as follows:

- A. Executive Summary;
- B. General Background Information;
- C. Evaluation Questions and Hypotheses;
- D. Methodology;
- E. Methodological Limitations;
- F. Results;
- G. Conclusions;
- H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
- I. Lessons Learned and Recommendations; and
- J. Attachment(s).

Submission Timelines

There is a specified timeline for the state’s submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish to the state’s website the evaluation design within thirty (30) days of CMS approval, and publish reports within thirty (30) days of submission to CMS , pursuant to 42 CFR 431.424. CMS will also publish a copy to Medicaid.gov.



Required Core Components of Interim and Summative Evaluation Reports

The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. A copy of the state’s Driver Diagram (described in the Evaluation Design guidance) must be included with an explanation of the depicted information. The Evaluation Report should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the

implications on future Medicaid policy. Therefore, the state's submission must include:

- A. Executive Summary** – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.
- B. General Background Information about the Demonstration** – In this section, the state should include basic information about the demonstration, such as:
- 1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
 - 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
 - 3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
 - 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
 - 5) Describe the population groups impacted by the demonstration.
- C. Evaluation Questions and Hypotheses** – In this section, the state should:
- 1) Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
 - 2) Identify the state's hypotheses about the outcomes of the demonstration;
 - a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
 - b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
 - c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

D. Methodology – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design.

The evaluation design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An interim report should provide any available data to date, including both quantitative and qualitative assessments. The Evaluation Design should assure there is appropriate data development and collection in a timely manner to support developing an interim evaluation.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1. Evaluation Design – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?
2. Target and Comparison Populations – Describe the target and comparison populations; include inclusion and exclusion criteria.
3. Evaluation Period – Describe the time periods for which data will be collected
4. Evaluation Measures – What measures are used to evaluate the demonstration, and who are the measure stewards?
5. Data Sources – Explain where the data will be obtained, and efforts to validate and clean the data.
6. Analytic methods – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
7. Other Additions – The state may provide any other information pertinent to the evaluation of the demonstration.

A) Methodological Limitations - This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.

B) Results – In this section, the state presents and uses the quantitative and qualitative data to show to whether and to what degree the evaluation questions and hypotheses of the demonstration were achieved. The findings should visually depict the demonstration results (tables, charts, graphs). This section should include information on the statistical tests conducted.

C) Conclusions – In this section, the state will present the conclusions about the evaluation results.

- 1) In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
- 2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:
 - a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

D. Interpretations, Policy Implications and Interactions with Other State Initiatives –

In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long range planning. This should include interrelations of the demonstration with other aspects of the state’s Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretation of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

E. Lessons Learned and Recommendations – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the “opportunities” for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

1. What lessons were learned as a result of the demonstration?
2. What would you recommend to other states which may be interested in implementing a similar approach?

F. Attachment

Evaluation Design: Provide the CMS-approved Evaluation Design

ATTACHMENT C
Reserved for Evaluation Design

ATTACHMENT D
Substance Use Disorder (SUD) Implementation Plan Protocol

Section I – Milestone Completion

Milestones

1. Access to Critical Levels of Care for OUD and Other SUDs

To improve access to OUD and SUD treatment services for Medicaid beneficiaries, it is important to offer a range of services at varying levels of intensity across a continuum of care since the type of treatment or level of care needed may be more or less effective depending on the individual beneficiary. To meet this milestone, state Medicaid programs must provide coverage of the following services:

- Outpatient Services;
- Intensive Outpatient Services;
- Medication assisted treatment (medications 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

Current state:

New Hampshire provides coverage for a robust array of substance use disorder services, including all of those outlined above. Additional services covered by NH Medicaid include peer and non-peer recovery support services and continuous recovery monitoring. Where possible, all covered services are in alignment with the American Society for Addiction Medicine (ASAM) patient placement criteria. Medically supervised withdrawal management is in alignment ASAM criteria Levels 1WM-3.7WM. Coverage details for these services are in the state plan. Provider qualifications and eligible provider types are outlined in NH rule He-W 513 available at <https://www.dhhs.nh.gov/oos/aru/documents/hew513adopted.pdf>.

There are multiple ways SUD treatment services are paid for in NH. Typically, funding for services is blended between state General Funds, Medicaid, private insurance, and Federal funding. The state uses federal block grant funding through SAMHSA to enter into contracts with SUD providers. These contracts fund services that are either not covered by Medicaid/other insurance or the person's insurance leaves them underinsured for the needed level of care. These entities are considered state funded programs. Additionally, Medicaid is used to cover all levels of care as outlined above. There are some entities in the state that do not accept Medicaid or state funding. In those instances, standards for facilities licensing and program expectations are outlined in rules which align with NH's Medicaid requirements and those in state contracts.

Table 1. NH Medicaid Substance Use Disorder Benefit

SUD Service Type	Description
Screening, by Behavioral Health practitioner	Screening for a substance use disorder
SBIRT	Screening, Brief Intervention, Referral to Treatment
Crisis Intervention	Crisis services provided in an office or community setting
Evaluation	Evaluation to determine the level of care and/or other services needed.
Medically Managed Withdrawal Management	Withdrawal management in a hospital setting, with or without rehabilitation therapy
Medically Monitored Withdrawal Management	Withdrawal management provided in an outpatient or residential setting
Opioid Treatment Program	Methadone or Buprenorphine treatment in a clinic setting
Office based Medication Assisted Treatment	Medication Assisted Treatment in a physician's office provided in conjunction with other substance use disorder counseling services.
Outpatient Counseling	Individual, group, and/or family counseling for substance use disorders
Intensive Outpatient	Individual and group treatment and recovery support services provided at least 3 hours per day, 3 days per week.
Partial Hospitalization	Individual and group treatment and recovery support services for substance use disorder and co-occurring mental health disorders provided at least 20 hours per week.
Rehabilitative Services	Low, Medium, and High Intensity residential treatment.
Recovery Support Services	Community based peer and non-peer recovery support services provided in a group or individual setting.
Case Management	Continuous Recovery Monitoring

Future state:

NH will update the He-W 513 rule to align with the recently updated state plan. This will allow for Medicaid providers to understand what types of services are covered under each ASAM level of care. For example, for Level 2.1 intensive outpatient SUD services, the rule will be updated to include the following:

Support Systems

In Level 2.1 programs, necessary support systems include:

- Continued treatment planning individualized to the patients' needs
- Medical, psychological, psychiatric, laboratory, and toxicology services, which are available through consultation or referral. Psychiatric and other medical consultation is available within 24 hours by telephone and within 72 hours in person.
- Emergency services, which are available by telephone 24 hours a day, 7 days a week when the treatment program is not in session.
- Direct affiliation with (or close coordination through referral to) more and less intensive levels of care and supportive housing services.

Therapies

Therapies offered by Level 2.1 programs include:

- A minimum of 3 hours per day, 3 days per week for adults (age 21 and over) and 2 hours per day, 3 days per week for adolescents (under age 21) of skilled treatment services. Such services may include evaluation, individual and group counseling, medication management, family therapy with patient present, psychoeducational groups, skill restoration therapy, and other skilled therapies. Skill restoration therapy which is defined as services intended to reduce or remove barriers to clients who are achieving recovery and then maintaining recovery is also included. Services are provided in amounts, frequencies, and intensities appropriate to the objectives of the treatment plan.
- In cases in which the patient is not yet fully stable to safely transfer to a Level 1 program that is not associated with the treatment agency, the patient's treatment for Level 1 services may be continued within the current Level 2.1 program. Therapies must be delivered by, or recommended by, a physician or other licensed practitioner of the healing arts.
- Family therapy, which involves for the family members, guardians, or significant others and which is for the direct benefit of the patient in accordance with the patient's needs and treatment goals identified in the patient's treatment plan, and for the purpose of assisting in the patient's recovery in the assessment, treatment, and continuing care of the patient with the patient present.
- A planned format of therapies delivered on an individual and group basis and adapted to the patient's developmental stage and comprehension level.
- Motivational interviewing, enhancement, and engagement strategies, which are used in preference to confrontational approaches.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p>State Medicaid programs must provide coverage of the following services:</p> <ul style="list-style-type: none"> • Outpatient Services; • Intensive Outpatient Services; • Medication assisted treatment (medications 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 levels of care with codes covering hospital based, residential and ambulatory withdrawal management services 	<p>New Hampshire provides coverage for a robust array of substance use disorder services, including all of those outlined in the milestone requirement</p>	<p>NH will update the He-W 513 rule to align with the recently updated state plan. This update will include a list of therapies and supports that are offered under each ASAM level of care covered by NH. This will allow for Medicaid providers to understand what types of services are covered under each ASAM level of care, including understanding requirements around therapeutic milieu, hours of services, and types of staff required to deliver each.</p>	<p>Medicaid authority will update the He-w 513 rule in collaboration with Bureau of Drug and Alcohol Services by November 30, 2018.</p>

2. Use of Evidence-based, SUD-specific Patient Placement Criteria

Implementation of evidence-based, SUD-specific patient placement criteria is identified as a critical milestone that states are to address as part of the demonstration. To meet this milestone, states must ensure that the following criteria are met:

- Providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools, e.g., the ASAM Criteria, or other patient placement assessment tools that reflect evidence-based clinical treatment guidelines; and
- Utilization management approaches are implemented to ensure that (a) beneficiaries have access to SUD services at the appropriate level of care, (b) interventions are appropriate for the diagnosis and level of care, and (c) there is an independent process for reviewing placement in residential treatment settings.

Current state:

Patient Placement Criteria

All substance use disorder treatment programs and insurance carriers in NH are required to utilize the ASAM Criteria for placement per state law RSA 420-J:16, I, available at <http://www.gencourt.state.nh.us/rsa/html/XXXVII/420-J/420-J-16.htm>. In addition, all state funded treatment providers, are contractually obligated to use evidence based screening and assessment tools. To ensure that there is no entity in the state operating SUD services without the application of ASAM, all regulatory bodies require the same language regarding ASAM and evidence-based standards. This is critical due to the fact that while all state funded (state contracted) treatment providers are also Medicaid/MCO enrolled, not all Medicaid/MCO enrolled providers hold contracts with the state and receive additional state dollars. In instances when a provider is not Medicaid enrolled and also not funded through a contract with the state, the facilities licensing rules require ASAM. When ASAM is not applicable, both state funded providers and Medicaid providers are required to deliver services that are evidence based, as demonstrated by meeting one of the following criteria:

- a. The service shall be included as an evidence-based mental health and substance abuse intervention on the SAMHSA National Registry of Evidence-Based Programs and Practices (NREPP), available at <http://www.nrepp.samhsa.gov/AllPrograms.aspx>;
- b. The services shall be published in a peer-reviewed journal and found to have positive effects; or
- c. The SUD treatment and recovery support service provider shall be able to document the services' effectiveness based on the following:
 1. The service is based on a theoretical perspective that has validated research; or
 2. The service is supported by a documented body of knowledge generated from similar or related services that indicate effectiveness.

Future State

Effective January 11, 2018, SAMHSA has removed NREPP and the state rule must be updated to reflect that change.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Use of Evidence-based, SUD-specific Patient Placement Criteria	He-W 513 rule has NREPP as qualifying source for evidence based services	Update the evidence based language in rule to reflect changes made to NREPP. Explore additional criteria to offer to qualify an evidence based program	Medicaid authority will update the He-w 513 rule in collaboration with Bureau of Drug and Alcohol Services by November 30, 2018

Current state:

Utilization management

Utilization management (UM) takes place between MCOs and providers based on contractual agreements. The Department monitors utilization management through various channels. MCO utilization management policies are initially approved by DHHS and reviewed when changes are made. Timeliness of UM decisions as well as volume are monitored on a quarterly basis. The Department’s External Quality Review Organization conducts annual contract compliance reviews, which periodically includes MCO compliance with the UM standards in the Department’s contracts with the MCOs. Finally, the MCOs are required to be accredited by the National Committee for Quality Assurance of Health Plans (NCQA). The NCQA accreditation process includes the evaluation of 58 standards for the MCOs UM process and operations.

Additionally, NH DHHS conducts annual contract compliance audits for all state funded treatment facilities to ensure adherence to clinical standards when determining level of care placement. This is done through random chart audits that are conducted by licensed professionals familiar with ASAM criteria. Additionally, all state funded programs submit client placement data to the state sponsored Web Information Technology System when billing the Department for state-eligible clients and data is audited at the time of billing on a monthly basis to ensure that adequate information and documentation is presented for the level of care or services rendered. All state funded contractors are held to documentation standards in contracts explicitly noting that *“the Contractor shall maintain a data file on each recipient of services hereunder, which file shall include all information necessary to support an eligibility determination and such other information as the Department requests. The Contractor shall furnish the Department with all forms and documentation regarding eligibility determinations that the Department may request or require.”* Further, documentation standards are outlined in NH rule He-W 513 for all Medicaid SUD providers and the NH DHHS Program Integrity Unit reviews documentation as part of their pre and post enrollment site visits and re-validation processes for SUD providers. Specifically, documentation requirements state:

- (a) SUD treatment and recovery support services providers shall maintain supporting records, in accordance with He-W 520.

(b) Supporting documentation shall include:

(1) A complete record of all physical examinations, laboratory tests, and treatments including drug and counseling therapies, whether provided directly or by referral;

(2) Progress note for each treatment session, including:

- a. The treatment modality and duration;
- b. The signature of the primary therapist for each entry;
- c. The primary therapist's professional discipline; and
- d. The date of each treatment session; and

(3) A copy of the treatment plan that is:

- a. Updated at least every 4 sessions or 4 weeks, whichever is less frequent;
- b. Signed by the provider and the recipient prior to treatment being rendered; and
- c. Signed by the clinical supervisor, prior to treatment being rendered, if the service is an outpatient or comprehensive SUD program.

(c) The recipient's individual record shall include at a minimum:

- (1) The recipient's name, date of birth, address, and phone number; and
- (2) A copy of the evaluation described in He-W 513.05(p)(4).

NH DHHS also holds regular monthly meetings on behavioral health matters, including substance use disorder with each of the two managed care organizations. In these meetings, there is the opportunity to discuss trends in audit findings, provider needs related to technical assistance, opportunities for audit alignment, and information sharing. Information shared in these meetings may be used to inform state contract audits, reviews of provider practices, or offer training or technical assistance to specific contractors.

New Hampshire is confident that it has met this milestone based on the information presented above.

3. Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities

Through the new Section 1115 initiative, states will have an opportunity to receive federal financial participation (FFP) for a continuum of SUD services, including services provided to Medicaid enrollees residing in residential treatment facilities that qualify as institutions for mental diseases. To meet this milestone, states must ensure that the following criteria are met:

- Implementation of residential treatment provider qualifications (in licensure requirements, policy manuals, managed care contracts, or other guidance) that meet the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding the types of services, hours of clinical care and credentials of staff for residential treatment settings;
- Implementation of a state process for reviewing residential treatment providers to assure compliance with these standards; and

Residential treatment provider qualifications

Current state:

All residential treatment providers must be licensed by NH Bureau of Health Facilities Licensing. NH rule He-W 513 dictates specific provider qualifications for delivery of SUD services including required credentials. The rule defers to ASAM Criteria to reflect the types of covered services.

The Bureau of Drug and Alcohol Services has expired rules governing the Certification and Operation of Alcohol and other Drug Disorder Treatment Programs. These rules apply to all state funded SUD programs. Presently, requirements for these programs are outlined in contract. State contracts require specific staffing ratios for SUD programs, including the following:

The selected vendor must meet minimum staffing requirements that include:

- A minimum of one (1):
 - Masters Licensed Alcohol and Drug Counselor (MLADC); or
 - Licensed Alcohol and Drug Counselor (LADC) who also holds the Licensed Clinical Supervisor (LCS) credential.
- One (1) program director who assumes responsibility for the daily operation of each specific program.
- Minimum staff to resident ratios with documentation of the same on file for a minimum of 6-months, which includes:
 - One (1) staff person to 6 residents during awake hours.
 - One (1) staff person to 12 residents during sleeping hours.
- The selected vendor must ensure that all staff, including contracted staff;
 - Meet the educational, experiential and physical qualification of the position as listed in their job description;
 - Meet all criminal background standards; Are licensed, registered or certified as required by state statute and as applicable

- Receive an orientation within the first three (3) days of work, or prior, to direct contact with clients, which includes;
 - The vendor’s code of ethics, including ethical conduct and reporting of unprofessional conduct;
 - The vendor’s policies on client rights and responsibilities and complaint procedures;
 - Confidentiality requirements;
 - Grievance procedures for both clients and staff;
 - The duties and responsibilities and the policies, procedures and guidelines of the position they were hired for;
 - Topics covered by both the administrative and personnel manuals;
 - The vendor’s infection prevention program;
 - The vendor’s fire, evacuation and other emergency plans, which outline the responsibilities for personnel in an emergency; and
 - Mandatory reporting requirements for abuse or neglect, such as those found in RSA 161-F and RSA 169-C:29; and
 - Sign and date documentation that they have taken part in an orientation;
 - Complete a mandatory annual in-service education, which includes a review of all orientation elements.
- The selected vendor must ensure all unlicensed staff providing treatment, education and/or recovery support services shall be under the direct supervision of a licensed supervisor.
- The selected vendor must ensure no licensed supervisor supervises more than eight (8) unlicensed staff, unless the Department has approved an alternative supervision plan.
- The selected vendor must provide a minimum of one (1) Certified Recovery Support Worker (CRSW) for every 50 clients or portion thereof.
- The selected vendor must ensure unlicensed staff providing clinical or recovery support services obtain a CRSW certification within 6 months of hire or contract effective date, whichever is later.
- The selected vendor shall ensure a staff to resident ratio that is more stringent than the required staff to resident ratios stated above, when required by the resident’s treatment plan.
- The selected vendor must provide ongoing clinical supervision that occurs at regular intervals. The selected vendor must ensure clinical supervision includes, but is not limited to:
 - Receipt of, at least, one (1) hour of supervision for every twenty (20) hours of direct client contact;
 - Weekly discussion of cases with suggestions for resources or therapeutic approaches, co-therapy, and periodic assessment of progress;
 - Group supervision to help optimize the learning experience, when enough candidates are under supervision;
 - Training on:

- Knowledge, skills, values, and ethics with specific application to the practice issues faced by supervised staff;
- The 12 core functions as described in Addiction Counseling Competencies: The Knowledge, Skills, and Attitudes of Professional Practice, available at <http://store.samhsa.gov/product/TAP-21-Addiction-Counseling-Competencies/SMA15-4171> and
- The standards of practice and ethical conduct, as determined by licensing and review boards, with particular emphasis given to the counselor’s role and appropriate responsibilities, professional boundaries, and power dynamics.

Future state:

NH DHHS rule will be updated to reflect the types of services covered under each ASAM level of care. See example under *Milestone 1*.

Where possible, specific staffing ratio requirements as noted above will be included in He-A 300 rule and He-W 513 rules updates.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Implementation of residential treatment provider qualifications in licensure requirements, policy manuals, managed care contracts, or other guidance. Qualification should 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	<p>All residential treatment providers must be licensed by NH Bureau of Health Facilities Licensing. NH rule He-W 513 dictates specific provider qualifications for delivery of SUD services including required credentials, hours of clinical care. The rule defers to ASAM Criteria to reflect the types of covered services</p> <p>The Bureau of Drug and Alcohol Services has expired rules (He-A 300) governing the Certification and Operation of Alcohol and other Drug Disorder Treatment Programs</p>	<p>He-W 513 explicitly outlines the types of services and hours of clinically directed programming covered under each ASAM level of care.</p> <p>He-W 513 will outline required staffing ratios for residential programs.</p> <p>He-A 300 will be updated to outline required staffing ratios for residential programs.</p>	<p>Medicaid authority will update the He-W 513 rule in collaboration with Bureau of Drug and Alcohol Services by November 30, 2018</p> <p>Bureau of Drug and Alcohol Services will update the He-A 300 rule by Fall 2019.</p>

Reviewing compliance to standards

Current state:

NH DHHS is in the process of conducting contract audits for SUD providers and developing new health facilities rules to allow for better compliance oversight process. Additionally, the Bureau of Health Facilities conducts annual reviews of all licensed residential facilities. This entity will also follow up on any complaints or concerns shared about a facility. The NH DHHS Medicaid Program Integrity Unit also oversees compliance with He-W 513 as part of their pre and post enrollment site visits and re-validation processes. The Bureau of Drug and Alcohol Services has expired rules governing the Certification and Operation of Alcohol and other Drug Disorder Treatment Programs. These rules apply to all state funded SUD programs and compliance audits are done against contract requirements absent the He-A 300 rules.

Future state:

The NH DHHS will pursue several rule changes to ensure that there are clear and consistent standards for all SUD residential treatment providers. There will also be language specific to compliance requirements and frequencies of compliance audits across the various DHHS bureaus responsible for oversight. The rule changes proposed include:

- 1) The update of Bureau of Health Facilities rules specific to SUD residential treatment facilities to include requirements related to staffing, physical space expectations, programmatic design, and compliance requirements.
- 2) The update of He-A 300 through the Bureau of Drug and Alcohol Services rules to outline requirements related to staffing, physical space expectations, programmatic design, and compliance. These rules will govern the eligibility of all state-funded SUD treatment providers, including those enrolled in Medicaid to operate in the State of NH. Every effort will be made to align expectations in the He-A 300 rules with those in the He-W 513 rules to mitigate duplication of administrative requirements on providers and align expectations between program areas and Medicaid.
- 3) The update of He-W 513 rules through the Office of Medicaid to outline specific requirements around staffing, licensing, and service expectations for all SUD Medicaid services.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p>Implementation of a state process for reviewing residential treatment providers to ensure compliance with these standards</p>	<p>NH DHHS is in the process of conducting contract audits for SUD providers and developing new health facilities rules to allow for better compliance oversight process.</p> <p>Bureau of Health Facilities conducts annual reviews of all licensed residential facilities for compliance with He-P 807 rules governing facilities licensing. This entity will also follow up on any consumer or provider complaints or concerns reported about a facility.</p> <p>The DHHS Medicaid Program Integrity Unit oversees compliance with He-W 513 as part of their pre and post enrollment site visits and re-validation processes.</p> <p>The Bureau of Drug and Alcohol Service He-A 300 rules regarding Certification and Operation of Alcohol and other Drug Disorder Treatment Programs have expired.</p>	<p>Bureau of Health Facilities creates new rules specific to SUD residential treatment facilities; this includes requirements related to staffing, physical space expectations, programmatic design, and compliance requirements. The Bureau of Health Facilities will inspect facilities for compliance prior to issuing or renewing a license.</p> <p>Additional controls will be put in place through updates to He-W 513 and He-A 300 rules to ensure compliance checks from Medicaid Program Integrity and Bureau of Drug and Alcohol Service staff on an annual basis.</p>	<p>Health Facilities rule updated and effective by December 31, 2018</p> <p>He-W 513 rules will be updated to include language regarding annual compliance checks by Fall 2018</p> <p>He-A 300 rules will be updated to include language regarding specific standards and annual compliance by Fall 2019.</p>

Implementation of a requirement that residential treatment facilities offer MAT on-site or facilitate access off site.

Current state:

All state contracted treatment providers are required to recognize all paths to recovery and facilitate MAT access either on or off site. This is not a requirement for all Medicaid providers.

Future state:

NH DHHS will update the He-W 513 rule to require that all Medicaid providers follow the same standards for MAT that state funded providers adhere to.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Implementation of requirement that residential treatment facilities offer MAT on-site or facilitate access off site	All state contracted treatment providers are required to recognize all paths to recovery and facilitate MAT access either on or off site. This is outlined in a contract with the provider but is not a requirement for all Medicaid providers.	Update to He-W 513 rule requiring that all Medicaid providers follow same standards for MAT that state funded providers adhere to. Update to He-A 300 rule that requires on-site or facilitated access to MAT for all state funded SUD providers. This language will align with requirements updated in He-W 513.	Medicaid authority will update the He-w 513 rule in collaboration with Bureau of Drug and Alcohol Services by November 30, 2018 He-A 300 rules will be updated to include language around specific standards and requirements regarding offering MAT on-site or facilitating access off-site by Fall 2019.

4. Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment for OUD

To meet this milestone, states must complete an assessment of the availability of providers enrolled in Medicaid and accepting new patients in the critical levels of care listed in Milestone 1. This assessment must determine availability of treatment for Medicaid beneficiaries in each of these levels of care, as well as availability of MAT and medically supervised withdrawal management, throughout the state. This assessment should help to identify gaps in availability of services for beneficiaries in the critical levels of care.

Current state:

NH has no formal assessment process to determine availability of providers enrolled in Medicaid that are accepting new patients. NH has a state funded treatment locator which identifies providers by service type and payers accepted.

A treatment capacity report was created in early 2014 prior to expansion of Medicaid and is available at <https://www.dhhs.nh.gov/dcbcs/bdas/documents/nh-sud-treatment-capacity-report.pdf>

Future state:

NH will establish an assessment process to meet this milestone.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Completion of assessment of the availability of providers enrolled in Medicaid and accepting new patients in the following critical levels of care throughout the state (or at least in participating regions of the state) including those that offer MAT:	NH has no formal assessment process to determine availability of providers enrolled in Medicaid that are accepting new patients. NH has a state funded treatment locator which identifies providers by service type and payers accepted.	NH will establish an assessment process to identify Medicaid providers that are accepting new patients in critical levels of care, including those who offer MAT and those who offer adolescent-specific programming. This will be accomplished through secret shopper quality activities conducted by the NH DHHS EQRO	Secret shopper planning to begin Spring 2018, assessment to begin by Summer 2018, assessment to be completed by early 2019.
Outpatient Services;	A treatment capacity report was created in early 2014 prior to expansion of Medicaid.	NH will explore the possibility of updating the 2014 treatment capacity report.	Discuss opportunities of treatment capacity and treatment locator updates with current vendor by November 30, 2018
Intensive Outpatient Services;		NH will work with the vendor supporting the treatment locator to determine opportunities to enhance the program.	
Medication Assisted Treatment (medications as well as counseling and other services);			
Intensive Care in Residential and Inpatient Settings;			
Medically Supervised Withdrawal Management.			

5. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD

Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse:

Current state:

NH has created specific opioid prescribing guidelines via the Office of Professional Licensure through the Board of Medicine. Additionally, NH has implemented significant changes to the PDMP through statute.

NH Medicaid has several controls in place for opioid prescribing, specifically related to prevention of opioid abuse. Through requirements and reporting measures in the current managed care contracts, NH tracks several measures related to opioid prescribing (*Table 1*).

Measure ID	Measure Name	Data Collection Status	Results
CMS_A_OHD	Use of Opioids from Multiple Providers at High Dosage in Persons Without Cancer: Opioid High Dosage (CMS Adult Core Set)	Started with FFY 2016 Reporting (for measurement year 2015)	https://medicaidquality.nh.gov/reports/use-of-opioids-at-high-dosage-ohd-cms-adult-core-set-1
CMS_A_CUOB	Concurrent Use of Opioids and Benzodiazepines	Will start with FFY 2018 Reporting (for measurement year 2017)	N/A
PHA_RMQL09	Safety Monitoring - Opioid Prescriptions Meeting NH DHHS Morphine Equivalent Dosage Prior Authorization Compliance	Started with CY 2016 Quarter 2	https://medicaidquality.nh.gov/reports/safety-monitoring---opioid-prescriptions-meeting-nh-dhhs-morphine-equivalent-dosage-prior-authorization-compliance-1
SUD_1115.01	Continuity of Pharmacotherapy for Opioid Use Disorder	Will start with SFY 2019 Reporting	N/A

Table 1. Managed care opioid prescribing metrics

Future state:

New Hampshire DHHS intends to further enhance implementation of existing laws related to opioid prescribing in collaboration with key partners. NH will also explore language and reports

that can be added to future managed care contracts to ensure a comprehensive and robust approach to controlling and monitoring unnecessary opioid prescriptions.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p>Implementation of opioid prescribing guidelines along with other interventions to prevent opioid abuse</p>	<p>The Office of Professional Licensure and Certification (OPLC) developed prescribing guidelines that were placed in administrative rules for their licensees which include physicians, APRNs, Pas, dentists and veterinarians.</p> <p>The Opioid Prescribing Guidelines from the NH Board of Medicine went into effect on January 1, 2017 (https://www.oplc.nh.gov/medicine/documents/med502-adopted.pdf)</p> <p>Please see attached prior authorization criteria for Methadone, Long Acting Narcotics, Short Acting Fentanyl and Morphine Milligram Equivalence (MME).</p> <p>The pharmacy point of sale (POS) system has a cumulative morphine milligram equivalence (MME) calculator. NH DHHS has a system edit in place that will not allow claims to process once the cumulative MME is equal or greater than 100mg. Beneficiaries that require doses that are equal to or greater than 100mg MME are required to get prior authorization. Prior Authorization ensures that the high dose is medically necessary. Doses that exceed 100mg MME will not be authorized with concurrent use of benzodiazepines. The MCOs are also required to have a MME calculator in built into the pharmacy POS system and to require prior authorization for all prescriptions where the dose is equal to or greater than 100mg MME</p> <p>The MCOs are required to submit a quarterly report (PHARMQI.09) to the Medicaid Quality Unit. The report is distributed to the subject matter experts (SMEs) for review.</p>	<p>NH will explore additional opportunities for enhancing opioid prescribing guidelines through Managed Care re-procurement efforts</p> <p>NH will further enhance implementation of existing laws related to opioid prescribing in collaboration with the OPLC and Board of Medicine.</p>	<p>Meet with PDMP by August 2018</p> <p>Meet with Governor’s Commission on Opioid and Healthcare taskforces to discuss guidelines by August 2018</p> <p>Consult with vendor assisting with managed care re-procurement to develop language specific to opioid prescribing guidelines and associated reports.</p>

Expanded coverage of and access to naloxone for overdose reversal

Current state:

In 2015, NH DHHS began the Statewide Naloxone Distribution and Training Initiative in partnership with the Department of Safety (DOS) in an effort to combat the opioid crisis.

Funding from the SAMHSA block grant was used to purchase naloxone kits in order to supplement current state efforts to combat opioid abuse.

Each participating organization was required to meet the following criteria before receiving free kits:

1. The organization must have a current standing order, allowing them to dispense the medication without a prescription;

2. The organization must have been educated by State-approved staff and educate end users on how to administer the medication, and;

3. The organization must have written policies for their dispensing protocol. Organizations including social service agencies, treatment providers, and recovery organizations are screened by the DHHS Emergency Services Unit (ESU) before they receive a kit.

There are currently four ways for New Hampshire residents to get naloxone kits for themselves or someone they care about:

1. A physician or any licensed prescriber can write a prescription for naloxone that can be purchased at a pharmacy.

2. Naloxone can be purchased at a pharmacy through standing orders, which allow the purchase without a prescription.

3. Free kits are provided to clients of state-contracted health centers or treatment providers who are at risk for opioid overdose and don't have insurance that covers the cost or cannot afford to purchase naloxone.

4. Free kits are provided through events held by Regional Public Health Networks to those unable to access kits through another avenue.

The distribution of Naloxone following these guidelines continues and additional resources for Naloxone were recently made available to NH through the 21st Century Cures Act. As part of that funding, NH is providing naloxone kits to individuals re-entering the community from incarceration or who are on parole who are at risk of an overdose. Through these efforts, New Hampshire is confident that it has met this milestone.

Implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs.

Current state:

The New Hampshire Controlled Drug Prescription Health and Safety Program was authorized in June 2012 for the purpose of enhancing patient care, curtailing the misuse and abuse of controlled substances, combating illegal trade in and diversion of controlled substances, and enabling access to prescription information by practitioners, dispensers, and other authorized individuals and agencies.

The New Hampshire Board of Pharmacy administers and oversees the operation of the program and has selected Appriss Health to develop a database that will collect and store prescribing and dispensing data for Schedule II, III, and IV controlled substances. Appriss Health's prescription drug monitoring program (PDMP), PMP AWA_Rx_E, is a web-based program that facilitates the collection, analysis, and reporting of information on the prescribing, dispensing, and use of controlled substances.

New Hampshire law requires that each dispenser submit information regarding each prescription dispensed for a Schedule II, III, or IV controlled substance. Each time a controlled substance is dispensed, the dispenser shall submit the information required by New Hampshire law to the PDMP database within seven (7) days of the date the prescription was dispensed.

NH continues to work on strategies and policies associated with the PDMP.

Future state:

NH DHHS will work with NH PDMP staff and Board of Pharmacy to identify opportunities to increase utilization of PDMP.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs	NH PDMP is functional and there are laws in place regarding utilization of the program	NH DHHS will work with NH PDMP staff and Board of Pharmacy to identify opportunities to increase utilization of PDMP	NH DHHS to meet with PDMP contacts by November 30, 2018. Plan to improve utilization and functionality of the PDMP submitted to CMS by Spring 2019.

6. Improved Care Coordination and Transitions between Levels of Care

To meet this milestone, states must implement policies to ensure residential and inpatient facilities link beneficiaries, especially those with OUD, with community-based services and supports following stays in these facilities.

Improved Care Coordination and Transition between Levels of Care

Current state:

All state contracted treatment providers are required to begin discharge planning immediately upon entry into treatment based on contract terms. A review of compliance with this obligation is included in the annual chart audits conducted by program staff.

State managed care organizations also work with providers on discharge plans and care transition plans. Each managed care organization is required to evaluate patients with a substance use disorder for care coordination services and support the coordination of all their physical and

behavioral health needs and for referral to SUD treatment. The current MCO contract requires the following:

For those beneficiaries with a diagnosis for substance use disorder (SUD) and all infants with a diagnosis of neonatal abstinence syndrome (NAS), or that are otherwise known to have been exposed prenatally to opioids, alcohol or other drugs, the MCO shall evaluate these patients needs for care coordination services and support the coordination of all their physical and behavioral health needs and for referral to SUD treatment.

NH has also expanded peer recovery community services to link individuals to recovery supports and continuous recovery monitoring following a facility stay. This has been accomplished through state funding of a recovery community organization facilitating organization that subcontracts with nine recovery community organizations to provide both peer recovery support services and telephone recovery support. Medicaid covers the peer recovery support services provided by these entities, while state and federal funds cover the infrastructure and technical assistance costs associated with developing these services. Referrals to these services are a requirement of state contracted treatment providers.

Future state:

Expand discharge planning requirements to all Medicaid providers to align with state contracted provider requirements. The below language will be added as a new section to the He-W 513 rule outlining discharge and continuing care requirements:

1) Continuing Care and Discharge

All providers must adhere to continuing care and discharge guidelines, including but not limited to:

- Closed loop referrals to community providers.
- Providing active outreach to clients following discharge.
- Coordinating referrals, acceptance, and appointments for required services prior to discharge.

All services must have continuing care, transfer and discharge plans that address all ASAM (2013) domains as follows:

- Begin the process of discharge/transfer planning at the time of the client's intake into the program.
- Review the three (3) criteria for continuing services or the four (4) criteria for transfer/discharge, when addressing continuing care or discharge/transfer that include:
 - Continuing Service Criteria A: The patient is making progress, but has not yet achieved the goals articulated in the individualized treatment plan. Continued treatment at the present level of care is assessed as necessary to permit the patient to continue to work toward his or her treatment goals; or
 - Continuing Service Criteria B: The patient is not yet making progress, but has the capacity to resolve his or her problems. He/she is actively working toward the

goals articulated in the individualized treatment plan. Continued treatment at the present level of care is assessed as necessary to permit the patient to continue to work toward his/her treatment goals; and /or

- Continuing Service Criteria C: New problems have been identified that are appropriately treated at the present level of care. The new problem or priority requires services, the frequency and intensity of which can only safely be delivered by continued stay in the current level of care. The level of care which the patient is receiving treatment is therefore the least intensive level at which the patient's problems can be addressed effectively
- Transfer/Discharge Criteria A: The Patient has achieved the goals articulated in the individualized treatment plan, thus resolving the problem(s) that justified admission to the present level of care. Continuing the chronic disease management of the patient's condition at a less intensive level of care is indicated; or
- Transfer/Discharge Criteria B: The patient has been unable to resolve the problem(s) that justified the admission to the present level of care, despite amendments to the treatment plan. The patient is determined to have achieved the maximum possible benefit from engagement in services at the current level of care. Treatment at another level of care (more or less intensive) in the same type of services, or discharge from treatment, is therefore indicated; or
- Transfer/Discharge Criteria C: The patient has demonstrated a lack of capacity due to diagnostic or co-occurring conditions that limit his or her ability to resolve his or her problem(s). Treatment at a qualitatively different level of care or type of service, or discharge from treatment, is therefore indicated; or
- Transfer/Discharge Criteria D: The patient has experienced an intensification of his or her problem(s), or has developed a new problem(s), and can be treated effectively at a more intensive level of care.

Language regarding collaboration of care coordination for all entities offering it to clients with SUD will be added to state contracts, He-W 513 rules and updated managed care contracts. This will ensure continuity between various levels of care coordination provided to clients by multiple entities. The goal with this language change will be to reduce duplication and communication errors regarding care coordination responsibilities.

Specific requirements and standards for care coordination for co-occurring physical and mental health conditions will be added to the He-W 513 rule and He-A 300 rule. These rules will apply to all SUD Medicaid providers and state-funded SUD treatment providers. This language will come from a modified model of care coordination that is supported by NH's 1115(a) DSRIP Transformation Waiver, specifically requiring:

- Systematic strategies to identify and intervene with the client
- A care plan for each patient, updated on a regular basis
- Care coordination services that facilitate linkages and access to needed primary and specialty health care, prevention and health promotion services, mental health and

substance use disorder treatment, and long-term care services, as well as linkages to other community supports and resources

- Transitional care coordination across settings, including from the hospital to the community
- Robust patient engagement process around information sharing consent
- Coordination with other care coordination/management programs or resources that may be following the same patient so that to the extent possible, only one care coordinator/manager is playing a lead role in managing the patient’s care plan.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Additional policies to ensure coordination of care for co-occurring physical and mental health conditions	Discharge planning is required for all state contracted treatment facilities.	Expand discharge planning and continuing care requirements to all Medicaid providers Expand continuing care requirements for all Medicaid providers and state contracted SUD facilities.	Medicaid authority will update the He-W 513 rule in collaboration with Bureau of Drug and Alcohol Services by November 30, 2018 Bureau of Drug and Alcohol Services will update the He-A 300 rule regarding discharge planning and care coordination for all state funded SUD providers by Fall 2019

Section II – Implementation Administration

Please provide the contact information for the state’s point of contact for the Implementation plan.

Name and Title: Deborah Scheetz, New Hampshire Medicaid Deputy Director
 Telephone Number: 603-271-9459
 Email Address: Deborah.Scheetz@dhhs.nh.gov

Section III – Relevant Documents

Please provide any additional documentation or information that the state deems relevant to successful execution of the implementation plan.

Attachment A – Template for SUD Health Information Technology (IT) Plan

The New Hampshire Controlled Drug Prescription Health and Safety Program was authorized in June 2012 for the purpose of enhancing patient care, curtailing the misuse and abuse of

controlled substances, combating illegal trade in and diversion of controlled substances, and enabling access to prescription information by practitioners, dispensers, and other authorized individuals and agencies.

The New Hampshire Board of Pharmacy administers and oversees the operation of the program and has selected Appriss Health to develop a database that will collect and store prescribing and dispensing data for Schedule II, III, and IV controlled substances. Appriss Health's prescription drug monitoring program (PDMP), PMP AWARe, is a web-based program that facilitates the collection, analysis, and reporting of information on the prescribing, dispensing, and use of controlled substances.

New Hampshire law requires that each dispenser submit information regarding each prescription dispensed for a Schedule II, III, or IV controlled substance. Each time a controlled substance is dispensed, the dispenser shall submit the information required by New Hampshire law to the PDMP database within seven (7) days of the date the prescription was dispensed.

As noted above, the PDMP is administered and overseen by the Board of Pharmacy, which is housed at the Office of Professional Licensure. As such, the NH DHHS has no control over the rules promulgated or administration related to the PDMP and its use. NH DHHS intends to meet with the Board of Pharmacy, Office of Professional Licensure, and PDMP staff to identify opportunities to align the SUD Health IT Plan requirements with the capabilities of the NH Prescription Drug Monitoring Program and Board of Pharmacy policies to ensure practicability of requirements and identify the timelines associated with accomplishing demonstration goals following waiver approval. NH intends to utilize the offered technical assistance from CMS to aid in conducting an assessment and developing the plan to ensure NH has the specific health IT infrastructure necessary to meet the demonstration goals. The scope of the project NH is able to commit to for this plan is guided by the Centers for Disease Control report, *Integrating & Expanding Prescription Drug Monitoring Program Data*, issued in February 2017. It is expected that there may also be a need for alignment with HIT work being undertaken by the Integrated Delivery Networks to ensure that changes proposed under this plan for PDMP interoperability would align with the goals and activities outlined in the Statewide HIT Plan created by the IDNs.

Section I.

As a component of Milestone 5, Implementation of Strategies to Increase Utilization and Improve Functionality of Prescription Drug Monitoring Programs (PDMP), in the SMD #17-003, states with approved Section 1115 SUD demonstrations are generally required to submit an SUD Health IT Plan as described in the STCs for these demonstrations within 90 days of demonstration approval.

The SUD Health IT Plan will be a section within the state's SUD Implementation Plan Protocol and, as such, the state may not claim FFP for services provided in IMDs until this Plan has been approved by CMS.

In completing this plan, the following resources are available to the state:

- a. Health IT.Gov in “Section 4: Opioid Epidemic and Health IT.”⁴
- b. CMS 1115 Health IT resources available on “Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability” and, specifically, the “1115 Health IT Toolkit” for health IT considerations in conducting an assessment and developing their Health IT Plans.⁵

As the state develops its SUD Health IT Plan, it may also request technical assistance to conduct an assessment and develop its plan to ensure it has the specific health IT infrastructure with regards to the state’s PDMP plan and, more generally, to meet the goals of the demonstration. Contacts for technical assistance can be found in the guidance documents.

In the event that the state believes it has already made sufficient progress with regards to the health IT programmatic goals described in the STCs (i.e. PDMP functionalities, PDMP query capabilities, supporting prescribing clinicians with using and checking the PDMPs, and master patient index and identity management), it must provide an assurance to that effect via the assessment and plan below (see Table 1, “Current State”).

SUD Demonstration Milestone 5.0, Specification 3: Implementation of Strategies to Increase Utilization and Improve Functionality of PDMP

The specific milestones to be achieved by developing and implementing an SUD Health IT Plan include:

- Enhancing the health IT functionality to support PDMP interoperability; and
- Enhancing and/or supporting clinicians in their usage of the state’s PDMP.

The state should provide CMS with an analysis of the current status of its health IT infrastructure/”ecosystem” to assess its readiness to support PDMP interoperability. Once completed, the analysis will serve as the basis for the health IT functionalities to be addressed over the course of the demonstration—or the assurance described above.

The SUD Health IT Plan should detail the current and planned future state for each functionality/capability/support—and specific actions and a timeline to be completed over the course of the demonstration—to address needed enhancements. In addition to completing the summary table below, the state may provide additional information for each Health IT/PDMP milestone criteria to further describe its plan.

⁴ Available at <https://www.healthit.gov/playbook/opioid-epidemic-and-health-it>.

⁵ Available at <https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html>.

Table 1. State Health IT / PDMP Assessment & Plan

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p>5. Implementation of comprehensive treatment and prevention strategies to address Opioid Abuse and OUD, that is:</p> <p>--Enhance the state’s health IT functionality to support its PDMP; and</p> <p>--Enhance and/or support clinicians in their usage of the state’s PDMP.</p>	<p>Provide an overview of current PDMP capabilities, health IT functionalities to support the PDMP, and supports to enhance clinicians’ use of the state’s health IT functionality to achieve the goals of the PDMP.</p>	<p>Provide an overview of plans for enhancing the state’s PDMP, related enhancements to its health IT functionalities, and related enhancements to support clinicians’ use of the health IT functionality to achieve the goals of the PDMP.</p>	<p>Specify a list of action items needed to be completed to meet the HIT/PDMP milestones identified in the first column. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item</p>
Prescription Drug Monitoring Program (PDMP) Functionalities			
<p>Enhanced interstate data sharing in order to better track patient specific prescription data</p>	<p>NH does not have access or grant access to other state PDMPs</p>	<p>NH DHHS will develop a plan to identify the future state within 60 days of waiver submission on April 9, 2018</p>	<p>The plan submitted within 60 days of waiver submission will identify activities, action steps and timelines associated this milestone. The plan will also include 60-90 day check-in meetings with CMS to discuss progress towards future state goals.</p>
<p>Enhanced “ease of use” for prescribers and other state and federal stakeholders</p>	<p>The NH PDMP is web-based and has been assessed for ease of use, requiring approx. 3 clicks for providers to navigate through the program when conducting a query</p>	<p>NH DHHS will develop a plan to identify the future state within 60 days of waiver submission on April 9, 2018</p>	<p>The plan submitted within 60 days of waiver submission will identify activities, action steps and timelines associated this milestone. The plan will also include 60-90 day check-in meetings with CMS to discuss progress</p>

			towards future state goals.
Enhanced connectivity between the state’s PDMP and any statewide, regional or local health information exchange	There is no connectivity between the PDMP and other local HIE	NH DHHS will develop a plan to identify the future state within 60 days of waiver submission on April 9, 2018	The plan submitted within 60 days of waiver submission will identify activities, action steps and timelines associated this milestone. The plan will also include 60-90 day check-in meetings with CMS to discuss progress towards future state goals.
Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns ⁶ (see also “Use of PDMP” #2 below)	NH is continuing to invest in the capacity of the PDMP to identify data points that will enable the PDMP to aid in combating opioid and substance use. At this time, there are no formal processes for using the PDMP for this purpose given that NH is still working to build staffing and program capacity. Metrics being considered for identifying outliers that need intervention include:		The plan submitted within 60 days of waiver submission will identify activities, action steps and timelines associated this milestone. The plan will also include 60-90 day check-in meetings with CMS to discuss progress towards future state goals.

⁶ Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015. MMWR Morb Mortal Wkly Rep 2017;66:265–269. DOI: <http://dx.doi.org/10.15585/mmwr.mm6610a1>.

	<p>1) Individuals that have received prescriptions for a controlled drug from 3 prescribers who are filling those prescriptions at 3 separate pharmacies</p> <p>2) Combined total daily dosage of 100 MME</p> <p>3) Individuals prescribed opioids and benzodiazepines.</p>		
Current and Future PDMP Query Capabilities			
Facilitate the state’s ability to properly match patients receiving opioid prescriptions with patients in the PDMP (i.e. the state’s master patient index (MPI) strategy with regard to PDMP query)	The current state of this milestone is unknown at this time.	NH DHHS will submit the current state of this milestone to CMS within 30 days of waiver submission to CMS on April 9, 2018 and NH DHHS will develop a plan to identify the future state within 60 days of waiver submission on April 9, 2018	The plan submitted within 60 days of waiver submission will identify activities, action steps and timelines associated this milestone. The plan will also include 60-90 day check-in meetings with CMS to discuss progress towards future state goals.
Use of PDMP – Supporting Clinicians with Changing Office Workflows / Business Processes			
Develop enhanced provider workflow / business processes to better support clinicians in accessing the PDMP prior to prescribing an opioid or other controlled substance to address the issues which follow	The NH PDMP is web-based and has been assessed for ease of use for embedding the process into workflow, requiring approx. 3 clicks for providers to navigate through the program when conducting a query	NH DHHS will develop a plan to identify the future state within 60 days of waiver submission on April 9, 2018	The plan submitted within 60 days of waiver submission will identify activities, action steps and timelines associated this milestone. The plan will also include 60-90 day check-in meetings with CMS to discuss progress

			towards future state goals.
Develop enhanced supports for clinician review of the patients’ history of controlled substance prescriptions provided through the PDMP—prior to the issuance of an opioid prescription	The current state of this milestone is unknown at this time.	NH DHHS will submit the current state of this milestone to CMS within 30 days of waiver submission to CMS on April 9, 2018 and NH DHHS will develop a plan to identify the future state within 60 days of waiver submission on April 9, 2018	The plan submitted within 60 days of waiver submission will identify activities, action steps and timelines associated this milestone. The plan will also include 60-90 day check-in meetings with CMS to discuss progress towards future state goals.
Master Patient Index / Identity Management			
Enhance the master patient index (or master data management service, etc.) in support of SUD care delivery.	The current state of this milestone is unknown at this time.	NH DHHS will submit the current state of this milestone to CMS within 30 days of waiver submission to CMS on April 9, 2018 and will develop a plan to identify the future state within 60 days of waiver submission on April 9, 2018	The plan submitted within 60 days of waiver submission will identify activities, action steps and timelines associated this milestone. The plan will also include 60-90 day check-in meetings with CMS to discuss progress towards future state goals.
Overall Objective for Enhancing PDMP Functionality & Interoperability			

<p>Leverage the above functionalities / capabilities / supports (in concert with any other state health IT, TA or workflow effort) to implement effective controls to minimize the risk of inappropriate opioid overprescribing—and to ensure that Medicaid does not inappropriately pay for opioids</p>	<p>The current state of this milestone is unknown at this time.</p>	<p>NH DHHS will submit the current state of this milestone to CMS within 30 days of waiver submission to CMS on April 9, 2018 and NH DHHS will develop a plan to identify the future state within 60 days of waiver submission on April 9, 2018</p>	<p>The plan submitted within 60 days of waiver submission will identify activities, action steps and timelines associated this milestone. The plan will also include 60-90 day check-in meetings with CMS to discuss progress towards future state goals.</p>
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Attachment A, Section II – Implementation Administration

Please provide the contact information for the state’s point of contact for the SUD Health IT Plan.

Name and Title: Deborah Scheetz, New Hampshire Medicaid Deputy Director
 Telephone Number: 603-271-9459
 Email Address: Deborah.Scheetz@dhhs.nh.gov

Attachment A, Section III – Relevant Documents

Please provide any additional documentation or information that the state deems relevant to successful execution of the implementation plan.

ATTACHMENT E
Reserved for SUD Monitoring Protocol