



Administrator
Washington, DC 20201

NOV 21 2018

Margaret Brodie
Medicaid Director
Alaska Department of Health and Social Services
4501 Business Park Blvd, Bldg. L
Anchorage, AK 99503-7167

Dear Ms. Brodie:

This letter is to inform you that the Centers for Medicare & Medicaid Services (CMS) is approving Alaska's request for a new section 1115(a) demonstration titled, "Substance Use Disorder Treatment and Alaska Behavioral Health Program" (SUD – BHP) (Project Number 11-W-00318/0). This approval is effective from January 1, 2019, through December 31, 2023.

CMS's approval of this section 1115(a) demonstration is subject to the limitations specified in the approved waiver authorities and expenditure authorities, as well as the compliance with the enclosed special terms and conditions (STCs) and subsequent attachments defining the nature, character, and extent of federal involvement in this project. The state may deviate from the Medicaid state plan requirements only to the extent those requirements have been waived or specifically listed as not applicable to the expenditure authority.

This approval authorizes Alaska to receive federal financial participation (FFP) for the provision of all Medicaid state plan and approved demonstration services—including a continuum of services to treat addictions to opioids and other substances—for Medicaid enrollees primarily diagnosed with opiate use disorder (OUD) and/or other substance use disorders (SUD) who are short-term residents in residential and inpatient treatment facilities that meet the definition of an Institution for Mental Diseases (IMD). The approval of this demonstration is a part of a comprehensive strategy Alaska has within its Medicaid section 1115 Behavioral Health Demonstration application submitted to CMS earlier this year. CMS will continue to engage with the state on the broader behavioral health request in the coming months, but CMS is not approving that request at this time. Under this demonstration, the state plans to pilot services under the SUD initiative in order to test, rigorously evaluate, and monitor the provision of the services under the SUD initiative, and use evaluation results from the demonstration to make strategic decisions prior to providing these services statewide and through the state plan authority.

CMS has determined that implementation of this demonstration in Alaska is likely to promote the objectives of the Medicaid program, as it is expected to improve health outcomes for Medicaid beneficiaries by increasing access to high quality OUD and other SUD care.

Specifically, the demonstration is expected to:

- Assist Alaska in increasing identification, initiation, and engagement of Medicaid beneficiaries diagnosed with OUD and other SUDs in treatment;
- Increase adherence to, and retention in, OUD/SUD treatment;
- Reduce overdose deaths, particularly those due to OUD; and
- Reduce inappropriate or preventable utilization of emergency departments and inpatient hospital settings through improved access to a continuum of care services in additional settings that, absent this demonstration, would be ineligible for payment for most Medicaid enrollees.

CMS and Alaska received public comments for this demonstration which were supportive of the state's demonstration offering a variety of services that address the behavioral health and SUD needs, as well as building on and enhancing options for all Alaska Medicaid beneficiaries, including the Alaska Native population. CMS appreciates the commenters' support of this demonstration.

In addition, Alaska submitted its SUD Implementation Plan Protocol (referred to hereinafter as the SUD Implementation Plan) as required by STC 21 for CMS approval. The SUD Implementation Plan describes information including the strategic approach and detailed project implementation plan, with timetables, programmatic content, and the key goals and objectives of the SUD-BHP demonstration. As per the STCs, the state has 90 calendar days, after the approval of this demonstration to collaborate with CMS to approve the SUD Implementation Plan. The state may not claim FFP for services provided in IMDs until CMS has approved the SUD Implementation Plan. Once approved, the SUD Implementation Plan will be incorporated into the STCs, and once incorporated, may be altered only with CMS approval.

CMS's approval of this demonstration is conditioned on compliance with the enclosed set of STCs which define anticipated federal involvement in the SUD-BHP demonstration. The approval is also subject to your written acknowledgement of the award and acceptance of the STCs within 30 calendar days of the date of this letter. Please send your written acceptance to your project officer, Mrs. Heather Ross, who is available to answer any questions concerning your section 1115(a) demonstration and may be contacted as follows:

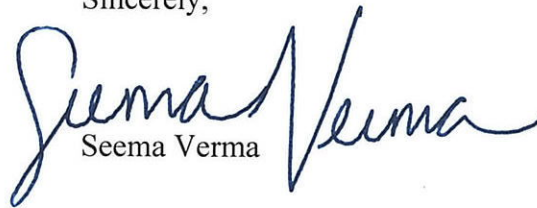
Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-01-16
7500 Security Boulevard
Baltimore, MD 21244-1850
Telephone: (410) 786-3666
E-mail: Heather.Ross@cms.hhs.gov

Official communication regarding official matters should be simultaneously sent to Mrs. Ross and Mr. David Meacham, Associate Regional Administrator for the Division of Medicaid and Children's Health Operations in our Seattle Regional Office. Mr. Meacham's contact information is as follows:

Mr. David Meacham
Associate Regional Administrator
Centers for Medicare & Medicaid Services
701 Fifth Avenue, Suite 1600
Seattle, WA 98104
Telephone: (206) 615-2356
E-mail: David.Meacham@cms.hhs.gov

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

Sincerely,


Seema Verma

Enclosures

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

NUMBER: 11-W-00318/0

TITLE: Alaska Substance Use Disorder and Behavioral Health Program (SUD-BHP)

AWARDEE: Alaska Department of Health and Social Services (DHSS)

The following expenditure authorities may only be implemented consistent with the approved Special Terms and Conditions (STCs) and shall enable Alaska 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 diseases (IMD).
- 2. Opioid Treatment Services (OTS) for Persons Experiencing an Opioid Use Disorder (OUD).** Expenditures for medication and counseling services to eligible individuals with severe opioid use disorder, in accordance with an individualized service plan determined by a licensed physician or licensed prescriber, and approved and authorized according to state requirements.
- 3. Intensive Outpatient Services.** Expenditures for intensive outpatient services provided to eligible individuals when determined to be medically necessary and in accordance with an individualized client plan.
- 4. Partial Hospitalization Services (PHP).** Expenditures for PHP services provided to eligible individuals specifically designed for the diagnosis or active treatment of a SUD to maintain the person's functional level and prevent relapse or inpatient hospitalization.
- 5. Medically Monitored Intensive Inpatient Services.** Expenditures for services provided in a residential setting or a specialty unit of an acute or psychiatric hospital. Individuals receiving Medicaid coverable services at this level of care require 24-hour services, professionally directed evaluation, observation, medical monitoring, and addiction treatment in an inpatient setting.
- 6. Medically Managed Intensive Inpatient Services.** Expenditures for services provided in a hospital setting (acute care or specialty) for individuals with acute medical, behavioral, or cognitive conditions. Medically managed services involve daily medical care and 24-hour nursing requiring the full resources of an acute care or psychiatric hospital.
- 7. Ambulatory Withdrawal Management Services.** Expenditures for outpatient services provided to eligible individuals at a mild withdrawal risk with a high commitment to withdrawal management process.

- 8. Clinically Managed Residential Withdrawal Management.** Expenditures for services provided in a social setting focusing on peer support programs, including daily individual and group therapies, support and health education services.
- 9. Medically Monitored Inpatient Withdrawal Management Services.** Expenditures for services provided in a freestanding withdrawal setting with inpatient beds, specializing in clinical consultation, for individuals experiencing severe withdrawal and needing clinical consultation and supervision for cognitive, biomedical, emotional and behavioral problems.
- 10. Medically Managed Intensive Inpatient Withdrawal Management Services.**
Expenditures for services provided in an acute care or psychiatric hospital in a patient unit, specializing in medical consultation, full medical acute services and intensive care for individuals experiencing severe, unstable withdrawal needs (usually hospital-based), including 24-hour nursing care and daily physician visits to modify withdrawal management regimen and manage medical instability.
- 11. Recovery Peer Support Services.** Expenditures for peer counseling support to help prevent relapse and promote recovery, and to support transition between levels of care for SUD.

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

NUMBER: 11-W-00318/0

TITLE: Alaska Substance Use Disorder and Behavioral Health Program (SUD-BHP)

AWARDEE: Alaska Department of Health and Social Services (DHSS)

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived in this list, shall apply to the demonstration, from date January 1, 2019 through December 31, 2023 unless otherwise specified. In addition, these waivers may only be implemented consistent with the approved Special Terms and Conditions (STCs).

Under the authority of section 1115(a)(1) of the Social Security Act (the Act), the following waivers of state plan requirements contained in section 1902 of the Act are granted in order to enable Alaska (the state) to carry out the Alaska Substance Use Disorder and Behavioral Health Program.

1. Statewide Operation Section 1902(a)(1)

To the extent necessary to enable the state to cover services within residential treatment for individuals with substance use disorder (SUD) and the comprehensive continuum of SUD services designed to maintain individuals in community settings on less than a statewide basis consistent with the phase-in schedule set forth in the approved implementation plan protocol required by the STCs.

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

To the extent necessary to enable the state to vary the amount, duration, and scope of services offered to individuals who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD) receiving treatment and withdrawal management services for substance use disorder (SUD) and the comprehensive continuum of SUD services designed to maintain individuals in community settings under this demonstration, regardless of eligibility.

**CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS (STC)**

NUMBER: 11-W-00318/0
TITLE: Alaska Substance Use Disorder and Behavioral Health Program (SUD-BHP)
AWARDEE: Alaska Department of Health and Social Services (DHSS)

I. PREFACE

The following are the Special Terms and Conditions (STC) for the “Alaska Behavioral Health Program” (BHP) section 1115(a) Medicaid demonstration (hereinafter BHP or “demonstration”), to enable the Alaska Department of Health and Social Services (hereinafter DHSS or “state”) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted waiver authorities and expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable (CNOM), 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 related to this demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted.

The STCs related to the programs for those state plan populations affected by the demonstration are effective from January 1, 2019 through December 31, 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: Reserved for Substance Use Disorder (SUD) Implementation Plan Protocol
- Attachment E: Reserved for SUD Claiming Protocol
- Attachment F: Reserved for SUD Monitoring Protocol

II. PROGRAM DESCRIPTION AND OBJECTIVES

The goal of this demonstration is for Alaska to maintain critical access to opioid use disorder (OUD) and other substance use disorder (SUD) treatment 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. The SUD initiative of the BHP demonstration is designed to be implemented all five years of the demonstration period. Alaska’s plan is to phase-in implementation of the SUD initiative across the state during the first two years, with approximately one-half of the state’s population being covered during Demonstration Year 1 and the other half of the state’s population covered in Demonstration Year 2. The state plans to pilot services under the SUD initiative in order to test, rigorously evaluate, and monitor the provision of the services under the SUD initiative, and use evaluation results from the demonstration to make strategic decisions prior to providing these services statewide and through the state plan authority.

The goal of the SUD initiative of the BHP demonstration is to increase access to a comprehensive continuum of SUD services designed to maintain individuals in community settings and to address long-standing gaps in services and needs related to the state’s opioid crisis. Approval of this demonstration is acknowledgement that, as relayed to CMS, the state faces significant challenges related to infrastructure, provider capacity, and workforce development—which are impediments to addressing the opioid crisis in the state. The SUD initiative of BHP will enhance the state’s ability to:

- Provide a continuum of SUD services—by both increasing the benefits offered to Medicaid recipients and using evidence-based SUD program standards; and
- Increase capacity by building provider networks and workforce throughout the state.

During the approval period, the state will leverage the authorities provided through this demonstration to achieve the following goals:

1. Increased rates of identification, initiation, and engagement in treatment
2. Increased adherence to and retention in treatment
3. Reduced 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 more appropriate and focused SUD use/misuse/abuse- related services
5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate
6. Improved access to care for physical health conditions among beneficiaries

Under the SUD demonstration, the state will address three major domains to accomplish these six goals:

1. Universally screen all Medicaid recipients, regardless of setting, using industry-recognized, evidence-based SUD screening instruments to identify symptoms and intervene as early as possible before use becomes dependence
2. Implement American Society of Addiction Medicine (ASAM) Criteria (3rd Edition) to match individuals with SUD with the services and tools necessary for recovery
3. Increase SUD treatment options for youth and adult Medicaid recipients, particularly non-residential, step-up and step-down treatment options

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.

- a. As part of the demonstration extension requests the state must provide documentation of compliance with the transparency requirements 42 CFR §431.412 and the public notice and tribal consultation requirements outlined in STC 15.
- b. Upon application from the state, CMS reserves the right to temporarily extend the demonstration including making any amendments deemed necessary to effectuate the demonstration extension including but not limited to bringing the demonstration into compliance with changes to federal law, regulation and policy.

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. 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.
- c. 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.

- d. 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.
- e. 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.
- f. 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 disenrolling 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

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 Alaska Medicaid recipients 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.

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

19. Substance Use Disorder/Opioid Use Disorder Program. Effective upon CMS' approval of the SUD/OD Implementation Protocol the demonstration benefit package for the

state’s Medicaid recipients must include SUD/ODU treatment services, including services provided in residential and inpatient treatment settings that qualify as an IMD, which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for the state’s Medicaid recipients residing in IMDs under the terms of this demonstration for coverage of medical assistance, including SUD/ODU benefits that would otherwise be matchable if the beneficiary were not residing in an IMD. Alaska 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 STC 21 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 coverage of SUD/ODU treatment services and withdrawal management during short term residential and inpatient stays in IMDs will expand the state’s current SUD/ODU benefit package available to all the state’s Medicaid recipients as outlined in 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: SUD/ODU Benefits Coverage with Expenditure Authority

SUD Benefit	Medicaid Authority	Expenditure Authority
Opioid Treatment Services for persons experiencing an Opioid Use Disorder	1115 expenditure authority	Services provided to individuals in IMDs
Intensive Outpatient Services	1115 expenditure authority	Services provided to individuals in IMDs
Outpatient Services	State plan (Individual services covered)	
Partial Hospitalization Program (PHP)	1115 expenditure authority	Services provided to individuals in IMDs
Early Intervention- Services	State plan	
Residential Treatment	1115 expenditure authority	Services provided to individuals in IMDs

Medically Monitored Intensive Inpatient Services	1115 expenditure authority	Services provided to individuals in IMDs
Medically Managed Intensive Inpatient Services	1115 expenditure authority	Services provided to individuals in IMDs
Ambulatory Withdrawal Management	1115 expenditure authority	Services provided to individuals in IMDs
Clinically Managed Residential Withdrawal Management	1115 expenditure authority	Services provided to individuals in IMDs
Medically Monitored Inpatient Withdrawal Management	1115 expenditure authority	Services provided to individuals in IMDs
Medically Managed Intensive Inpatient Withdrawal Management	1115 expenditure authority	Services provided to individuals in IMDs
Medication-Assisted Treatment (MAT)	State plan	Services provided to individuals in IMDs
Recovery Peer Support Services	1115 expenditure authority	Services provided to individuals in IMDs

The state attests that the services indicated in Table 1, above, as being currently covered under the Medicaid state plan authority are currently covered in Alaska’s state plan.

The state will attest that it will provide the Early and Periodic Screening, Diagnostic and Treatment services, EPSDT, to all eligible low-income infants, children and adolescents under age 21, as specified in Section 1905(r) of the Social Security Act (the Act).

The following service definition and provider qualifications are described for the approved SUD demonstration service pilots where separate expenditure authorities have been granted under this section 1115 demonstration.

- a. **Opioid Treatment Services (OTS) for persons experiencing an Opioid Use Disorder (OUD)** - Physician-supervised daily or several times weekly opioid agonist medication and counseling services provided to maintain multidimensional stability for those with severe opioid use disorder in accordance with an individualized treatment plan determined by a licensed physician or licensed prescriber and approved and authorized according to state requirements.

Component services include:

- i. Linkage to psychological, medical, and psychiatric consultation.
- ii. Access to emergency medical and psychiatric care through connections with more intensive levels of care.
- iii. Access to evaluation and ongoing primary care.

- iv. Ability to conduct or arrange for appropriate laboratory and toxicology tests including urine drug screenings.
- v. Availability of licensed physicians to evaluate and monitor use of, methadone, buprenorphine products or naltrexone products and of pharmacists and nurses to dispense and administer these medications.
- vi. Individualized, person-centered assessment and treatment.
- vii. Assessing, ordering, administering, reassessing, and regulating medication and dose levels appropriate to the individual; supervising withdrawal management from opioid analgesics, including buprenorphine products or naltrexone products; overseeing and facilitating access to appropriate treatment for opioid use disorder.
- viii. Medication for other physical and mental health illness is provided, as needed, either on-site or through collaboration with other providers.
- ix. Cognitive, behavioral, and other substance use disorder-focused therapies, reflecting a variety of treatment approaches, provided to the individual on an individual, group, and/ or family basis.
- x. Optional substance use care coordination provided, including integrating behavioral health into primary care and specialty medical settings through interdisciplinary care planning and monitoring individual progress and tracking individual outcomes; supporting conversations between buprenorphine-waivered practitioners and behavioral health professionals to develop and monitor individualized service plans; linking individuals with community resources to facilitate referrals and respond to social service needs; tracking and supporting individuals when they obtain medical, behavioral health, or social services outside the practice.
- xi. Referral for screening for infectious diseases such as HIV, hepatitis B and C, and tuberculosis at treatment initiation and then at least annually or more often based on risk factors.

Provider Qualifications- Providers qualified to be reimbursed for eligible services provided to eligible service recipients include licensed physicians, licensed physician assistants, licensed advanced nurse practitioners, licensed registered nurses supervised by a physician or advanced nurse practitioner, licensed practical nurses supervised by a physician or advanced nurse practitioner, mental health professional clinicians (AK Medicaid provider type including licensed clinical social workers, licensed marriage and family therapists, licensed master’s social workers, licensed clinical psychologists, licensed psychological associates, licensed professional counselors), substance use disorder counselors (AK certified Chemical Dependency Counselor I or II and Chemical Dependency Clinical Supervisor), and behavioral health clinical associates.

b. **Intensive Outpatient Services-** Intensive outpatient includes structured programming services provided to beneficiaries (a minimum of nine hours with a maximum of 19 hours a week for adults, and a minimum of six hours with a maximum of 19 hours a week for

adolescents) when determined to be medically necessary and in accordance with an individualized treatment plan. Treatment is focused on major lifestyle, attitudinal, and behavior issues which impair the individual's ability to cope with major life tasks without use of substances.

Components Services include:

- i. Individualized, person-centered assessment and clinically-directed treatment.
- ii. Cognitive, behavioral, and other substance use disorder-focused therapies, reflecting a variety of treatment approaches, provided to the individual on an individual, group, and/ or family basis
- iii. Appropriate drug screening
- iv. Psychoeducation Services
- v. Medication Services
- vi. Crisis Intervention Services
- vii. Recovery Support Services

Provider Qualifications-Providers qualified to be reimbursed for eligible services provided to eligible service recipients include licensed physicians, licensed physician assistants, licensed advanced nurse practitioners, mental health professional clinicians, substance use disorder counselors, and behavioral health clinical associates.

- c. **Partial Hospitalization Services (PHP)**-PHP services will be specifically designed for the diagnosis or active treatment of a SUD when there is a reasonable expectation for improvement or when it is necessary to maintain the person's functional level and prevent relapse or inpatient hospitalization. Services within the PHP are more clinically intense than IOP and, in addition to addressing major lifestyle, attitudinal, & behavior issues which impair the individual's ability to cope with major life tasks without the addictive use of alcohol and/or other drugs, have the capacity to treat individuals with substantial medical and psychiatric problems.

Component Services include:

- i. Individualized, person-centered assessment and clinically-directed treatment
- ii. Cognitive, behavioral, and other substance use disorder-focused therapies, reflecting a variety of treatment approaches, provided to the individual on an individual, group, and/ or family basis
- iii. Appropriate drug screening
- iv. Psychoeducation Services
- v. Medication Services
- vi. Crisis Intervention Services
- vii. Recovery Support Services

- viii. Occupational and recreational therapy services as appropriate

Provider Qualifications- Providers qualified to be reimbursed for eligible services provided to eligible service recipients include licensed physicians, licensed physician assistants, licensed advanced nurse practitioners, mental health professional clinicians, substance use disorder counselors, and behavioral health clinical associates.

- d. **Residential Treatment Services-** Treatment services delivered to residents of an institutional care setting, including facilities that meet the definition of an institution for mental diseases (IMD), are provided to Alaska Medicaid recipients with a SUD diagnosis when determined to be medically necessary and in accordance with an individualized service plan.
 - i. Residential treatment services are provided in an Alaska Department of Health and Social Services (DHSS) licensed facility that has been enrolled as a Medicaid provider and assessed/designated/certified by DHSS as delivering care consistent with ASAM or other nationally recognized, SUD-specific program standards for residential treatment facilities.
 - ii. Residential treatment services can be provided in settings of any size.
 - iii. 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.

Component services include:

- i. Clinically-directed therapeutic treatment to facilitate recovery skills, relapse prevention, and emotional coping strategies
- ii. Addiction pharmacotherapy and drug screening
- iii. Motivational enhancement and engagement strategies
- iv. Counseling and clinical monitoring
- v. Withdrawal management and related treatment designed to alleviate acute emotional, behavioral, cognitive, or biomedical distress resulting from, or occurring with, an individual's use of alcohol and other drugs
- vi. Regular monitoring of the individual's medication adherence
- vii. Recovery support services
- viii. Counseling services involving the beneficiary's family and significant others to advance the beneficiary's treatment goals, when (1) the counseling with the family member and significant others is for the direct benefit of the beneficiary, (2) the counseling is not aimed at addressing treatment needs of the beneficiary's family or significant others, and (3) the beneficiary is present except when it is clinically appropriate for the beneficiary to be absent in order to advance the beneficiary's treatment goals; and
- ix. Education on benefits of medication assisted treatment and referral to treatment as necessary.

Provider Qualifications- Providers qualified to be reimbursed for eligible services

provided to eligible service recipients include AK certified residential treatment facility providers. Until formal certification process undergoes regulatory review and approval process, provisional designation will be in place per AK SUD Implementation Plan Protocol.

- e. **Medically Monitored Intensive Inpatient Services-** These are services provided during a 24-hour professionally directed evaluation, observation, medical monitoring, and addiction treatment in an inpatient setting (hospital-based).

Component Services include:

- i. Individualized, person-centered assessment and medically-monitored treatment
- ii. Addiction pharmacotherapy and medication services
- iii. Appropriate drug screening
- iv. Cognitive behavioral and other substance-use disorder-focused therapies, reflecting a variety of treatment approaches, provided to the individual on an individual, group, or family basis
- v. Daily medical and nursing services
- vi. Counseling and clinical/medical monitoring
- vii. Daily treatment services focused on managing the individual's acute symptoms
- viii. Psychoeducation services

Provider Qualifications- Providers qualified to be reimbursed for eligible services provided to eligible service recipients include AK licensed general acute care, specialized psychiatric, Alaska Native tribal, and critical access hospitals.

- f. **Medically Managed Intensive Inpatient-** These are services provided during a 24-hour inpatient treatment requiring the full resources of an acute care or psychiatric hospital. Medically Managed Intensive Inpatient services differ from Medically Monitored Intensive Inpatient services due to the requirement of **medically directed** evaluation and treatment services provided in a 24-hour treatment setting under a defined set of policies, procedures, and individualized clinical protocols.

Component Services include:

- i. Individualized, person-centered assessment and medically directed & managed treatment
- ii. Addiction pharmacotherapy and medication services
- iii. Appropriate drug screening
- iv. Cognitive behavioral and other substance-use disorder-focused therapies, reflecting a variety of treatment approaches, provided to the individual on an individual, group, or family basis
- v. Daily medical and nursing services

- vi. Counseling and clinical/medical monitoring
- vii. Daily treatment services focused on managing the individual's acute symptoms
- viii. Psychoeducation services

Provider Qualifications- Providers qualified to be reimbursed for eligible services provided to eligible service recipients include AK licensed general acute care, specialized psychiatric, Alaska Native tribal, and critical access hospitals.

- g. **Ambulatory Withdrawal Management** - These are outpatient services that may be delivered in an office setting, a health care facility, an addiction treatment facility, or a patient's home for individuals at mild withdrawal risk and with a high commitment to withdrawal management process. Services delivered by physicians and nurses require training in managing intoxication and withdrawal states and clinical staff knowledgeable about the biopsychosocial dimensions of SUDs. Physicians are available via telephone or in- person for consultation; physician and emergency services consultation are available 24/7.

Component Services include:

- i. Individualized, person-centered Assessment
- ii. Physician and/or Nurse Monitoring
- iii. Management of Signs & Symptoms of Intoxication & Withdrawal
- iv. Medication Services
- v. Psychoeducation Services
- vi. Non-Pharmacological Clinical Support Services
- vii. Referral for Counseling Services

Provider Qualifications—Physicians, Physician Assistants, Advanced Nurse Practitioners, Registered Nurses supervised by a Physician or Advanced Nurse Practitioner, or Licensed Practical Nurses Supervised by a Physician or Advanced Nurse Practitioner.

- h. **Clinically Managed Residential Withdrawal Management**—These are services provided in a residential treatment setting that include supervision, observation, and support for individuals who are intoxicated or experiencing withdrawal and require 24-hour structure and support but do not require the medical and nursing care specified for medically monitored/managed inpatient withdrawal management services.

Component Services include:

- Individualized, person-centered Assessment
- Physician and/or Nurse Monitoring
- Management of Signs & Symptoms of Intoxication & Withdrawal

- Medication Services
- Patient Education Services
- Non-Pharmacological Clinical Support Services
- Referral for Counseling Services
- Recovery Support Services.

Provider Qualifications— providers qualified to be reimbursed for eligible services provided to eligible service recipients include AK certified residential treatment facility providers. Until formal certification process undergoes regulatory review and approval process, provisional designation will be in place per AK SUD Implementation Plan.

- i. **Medically Monitored Inpatient Withdrawal Management-** Services will consist of severe withdrawal and needs 24-hour nursing care and physician visits as necessary. This service is necessary because the patient is unlikely to complete withdrawal management without medical and nursing monitoring.

Component Services include:

- i. Individualized, person-centered assessment and medically monitored treatment
- ii. Addiction pharmacotherapy and medication services
- iii. Appropriate drug screening
- iv. Cognitive behavioral and other substance-use disorder-focused therapies, reflecting a variety of treatment approaches, provided to the individual on an individual, group, or family basis
- v. Daily medical and nursing services and monitoring
- vi. Management of signs and symptoms of intoxication and withdrawal
- vii. Counseling and clinical/medical monitoring
- viii. Daily treatment services focused on managing the individual’s acute symptoms
- ix. Psychoeducation services

Provider Qualifications- Providers qualified to be reimbursed for eligible services provided to eligible service recipients include AK licensed general acute care, specialized psychiatric, Alaska Native tribal, and critical access hospitals.

- j. **Medically Managed Intensive Inpatient Withdrawal Management-** Services are for severe, unstable withdrawal needs. This can include 24-hour nursing care and daily physician visits to modify withdrawal management regimen and manage medical instability.

Component Services include:

- i. Individualized, person-centered assessment and medically directed & managed treatment.

- ii. Addiction pharmacotherapy and medication services.
- iii. Appropriate drug screening.
- iv. Cognitive behavioral and other substance-use disorder-focused therapies, reflecting a variety of treatment approaches, provided to the individual on an individual, group, or family basis.
- v. Daily medical and nursing services.
- vi. Management of signs and symptoms of intoxication and withdrawal.
- vii. Counseling and clinical/medical monitoring.
- viii. Daily treatment services focused on managing the individual's acute symptoms.
- ix. Patient Education services.

Provider Qualifications-Providers qualified to be reimbursed for eligible services provided to eligible service recipients include AK licensed general acute care, specialized psychiatric, Alaska Native tribal, and critical access hospitals.

Recovery Peer Support Services: Peer recovery support services are designed and delivered by individuals in recovery from substance use disorder (peer recovery coach) to provide counseling support to help prevent relapse and promote recovery. Services can be provided by appropriately trained staff when working under the supervision of a competent behavioral health professional (as defined by the State). A peer recovery coach must be certified through the Alaska Department of Health and Social Services (DHSS) approved training program that provides peer support providers with a basic set of competencies necessary to perform the peer support function. The peer must demonstrate the ability to support the recovery of others from substance use disorders. Similar to other provider types, ongoing continuing educational requirements for peer support providers must be in place.

Provider Qualifications-Providers qualified to be reimbursed for eligible services provided to eligible service recipients include peer support providers must have lived an experience of substance use disorders or individuals with lived experience of SUD. and co-occurring mental disorders, work under the supervision of a competent mental health professional as defined by the state, complete training/certification as defined by the state and participate in continuing education.

20. SUD Services Claiming Methodology. Approved SUD Services for which FFP can be claimed solely to support SUD services listed in STC 19. Prior to claiming funding for any of the SUD services, the state must submit a claiming methodology protocol that CMS must approve prior to receiving FFP. The claiming methodology protocol must include expenditures claimed in accordance with CMS-approved claiming and documentation protocols to be specified in Attachment E. The state is not eligible to receive FFP for any of the SUD services until the protocol is approved. Upon CMS approval of the claiming protocol and SUD Implementation Plan Protocol required by STC 21, the state is eligible to receive FFP for the approved SUD services expenditures.

21. SUD Implementation Plan Protocol. The state must submit a SUD/ODU 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 SUD Implementation Plan Protocol, FFP will be available prospectively, not retrospectively. Failure to submit an Implementation Plan 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 SUD Implementation Plan 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:

- 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 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 accredited by the Council on Accreditation, the Commission on Accreditation for Rehabilitation Facilities, or the Joint Commission and consequently approved by the state pursuant to Title 7 of the Alaska Administrative Code, Chapter 70.990. The state must establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other, nationally recognized, SUD-specific program standards regarding, in particular, the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of 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 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 using the CMS SUD Monitoring Protocol template within 150 calendar days after approval of the 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 F. At a minimum, the SUD Monitoring Plan Protocol will include reporting relevant to each of the program implementation areas listed in STC 21. The SUD Monitoring Protocol must 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 31 of the demonstration. In addition, the SUD Monitoring Protocol must identify a baseline and a target to be achieved by the end of the demonstration. Where possible, baselines must 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 SUD Monitoring Protocol must be reported via the quarterly and annual monitoring reports.

23. Mid-Point Assessment. The state must conduct an independent mid-point assessment by November 1, 2020. The state must require that the assessor 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 state must require that the assessment include an examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plan Protocol, and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol. The state must require that the assessment 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 state must require that the mid-point assessment must 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 state must require the assessor 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 state must require the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS. The state must brief CMS on the report.

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

24. SUD Evaluation. The OUD/SUD Evaluation will be subject to the same requirements as the overall demonstration evaluation, as listed in sections VIII General Reporting Requirements and X Evaluation of the Demonstration of the STCs.

25. SUD 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, the Evaluation Design, including the SUD program 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.

26. 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 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 Quarterly

and Annual 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.

- 27. Evaluation Questions and Hypotheses Specific to the OUD/SUD Program.** 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 must have at least one evaluation question and hypothesis. The hypothesis testing must include, where possible, assessment of both process and outcome measures. Proposed measures must 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).
- 28. SUD Health Information Technology (Health IT).** The state must 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 must submit to CMS a plan to develop the infrastructure/capabilities. This “SUD Health IT Plan,” or assurance must be included as a section of the state’s “Implementation Plan” (see STC 21) to be approved by CMS. The SUD Health IT Plan must detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The SUD IT Plan must also be used to identify areas of SUD health IT ecosystem improvement.
- a. The SUD Health IT section of the Implementation plan must include implementation milestones and dates for achieving them (see Attachment F).
 - 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 must 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 must address how the state’s PDMP will enhance ease of use for prescribers and other state and federal stakeholders.² This must also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan must describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients’ history of controlled substance

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.*

prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.

- e. The SUD Health IT Plan must, 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 must 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 must 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 must include in its Monitoring Plan (see STC 22) an approach to monitoring its SUD Health IT Plan which will include performance metrics to be approved in advance by CMS.
- i. The state must monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in an addendum to its Annual Reports (see STC 36).
- j. As applicable, the state must 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.

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.

- 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 must 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 must use the federally-recognized ISA standards, barring no other compelling state interest.

VI. COST SHARING

- 29. Cost Sharing.** Cost sharing under this demonstration is consistent with the provisions of the approved state plan.

VII. DELIVERY SYSTEM

- 30.** The state's SUD/ODU Medicaid delivery system is based on a fee-for-Service (FFS) model for physical and behavioral health. The state delivers SUD services via a FFS delivery system for beneficiaries. Under the demonstration, Medicaid Section 1115 Behavioral Health Demonstration will continue to operate as approved in Section 1932(a) state plan authority for FFS.

VIII. GENERAL REPORTING REQUIREMENTS

- 31. Submission of Post-approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.
- 32. 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.
- 33. 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.
- 34. 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.
- 35. Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors’ in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative

match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 32.

IX. MONITORING

- 36. 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 must include a summary of progress made in regards to SUD Health IT requirements outlined in STC 28

37. 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 must 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 32.

38. Monitoring Calls. CMS will convene periodic conference calls with the states

- 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.

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

39. 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.

- 40. 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.
- 41. 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.
- 42. 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.
- 43. 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 must have at least one evaluation question and hypothesis. The hypothesis testing must include, where possible, assessment of both process and outcome measures. Proposed measures must 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).
- 44. 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 must be posted to the state's website with the application for public comment.

- a. The interim evaluation report must 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 must 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.

45. 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, November 1, 2018 – December 31, 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.

46. 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.

47. Public Access. The state must 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.

48. Additional Publications and Presentations. For a period of twelve (12) months following CMS approval of the final reports, CMS must 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 must be provided a copy including any associated press materials. CMS must 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.

XI. GENERAL FINANCIAL REQUIREMENTS

This project is approved for title XIX expenditures applicable to services rendered during the demonstration period.

49. 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-00304/0) assigned by CMS, including the project number extension which indicates the Demonstration Year (DY) in which services were rendered and by the Waiver Names identified in subparagraph (d).
- 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 must be reported as otherwise instructed in the State Medicaid Manual.
- c. Pharmacy Rebates. Pharmacy rebates must be reported on Form CMS 64.9 Base, and not allocated to any Form 64.0 or 64.9 Waiver
- 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 must be allocated to these forms based on the guidance which follows.
 - i. **SUD IMD FFS:** *Expenditures for all otherwise-allowable Medicaid services provided, were it not for the IMD prohibition, to otherwise-eligible individuals enrolled in fee-for-service during a month in which the beneficiary was a resident in an IMD for a primary diagnosis of SUD.*

- ii. **SUD Non-IMD FFS:** *Expenditures for all otherwise-allowable Medicaid services provided to eligible individuals enrolled in fee-for-service during a month in which the beneficiary was not a resident in an IMD for a primary diagnosis of SUD.*

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

Demonstration Year 1	January 1, 2019- December 31, 2019	12 months
Demonstration Year 2	January 1, 2020 - December 31, 2020	12 months
Demonstration Year 3	January 1, 2021 - December 31, 2021	12 months
Demonstration Year 4	January 1, 2022 - December 31, 2022	12 months
Demonstration Year 5	January 1, 2023 – December 31, 2023	12 months

f. **Budget Neutrality Specifications Manual.** The state must create and maintain a Budget neutrality Specifications Manual that describes in detail how the state compiles data on actual expenditures and member months related to budget neutrality, including methods used to extract and compile data from the state’s Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64 and in member month reports, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual must be made available to CMS on request.

50. Budget Neutrality Monitoring Tool. The state must provide CMS with quarterly budget neutrality status updates using the Budget Neutrality Monitoring Tool provided through the Performance Metrics Database and Analytics (PMDA) system. The tool incorporates the “Schedule C Report” for comparing demonstration’s actual expenditures to the budget neutrality expenditure limits described in Section IX. CMS will provide technical assistance, upon request.

51. Quarterly Annuals: 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.

52. 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. Disproportionate share hospital payments, behavioral health health homes payments, and graduate medical education payments are not expenditures under the demonstration and are therefore excluded from budget neutrality.

53. Administrative Costs. 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. Expenditures must be allocated to these forms based on the guidance which follows:

- a. ECM Capacity Building: *Expenditures for ECM capacity building payments.*
- b. ADM: *All other additional administrative costs that are directly attributable to the demonstration (for information only, excluded from budget neutrality).*

54. 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.

55. 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 44, 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 state’s Behavioral Health Demonstration and the member months must be subtotaled according to the MEGs defined in STC 55(d)(i).
- d. The required member month reporting MEG is:

- i. **SUD IMD FFS**: SUD IMD 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.
- ii. **SUD Non-IMD FFS**: SUD non-IMD Member Months are months of Medicaid eligibility during which the individual is receiving SUD services outside of an IMD under terms of the demonstration for any day during the month.

56. Standard Medicaid Funding Process. The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit, and separately report these expenditures by quarter for each federal fiscal year on the Form CMS-37 for both the Medical Assistance Payments (MAP) and State and Local Administration Costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within 30 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 shall reconcile expenditures reported on the Form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state t

57. 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.

58. 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.

59. State Certification of Funding Conditions. Under all circumstances, health care providers must retain 100 percent of the reimbursement amounts claimed by the state as demonstration expenditures. Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state government to return and/or redirect 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, and 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.

60. 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.

XII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

61. Limit on Title XIX Funding. The state must 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 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 XII.

62. 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 for all 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.

63. 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 75) 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 67 below.

64. Impermissible 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.

65. Main Budget Neutrality Test. *The PMPM cost estimates are based on actual 2016 spending for the IMD-stay projections—and historical expenditures from 2012 to 2017 for the non-IMD-stay SUD services, trended forward using trends based on the lower of state historical trends from Calendar Year 2012-2017 and the FFY 2018 President’s Budget trends.* The trend rates and per capita cost estimates for each MEG for each year of the demonstration are listed in the table below.

<i>MEG</i>	<i>TREND</i>	<i>DY 1 PMPM</i>	<i>DY 2 PMPM</i>	<i>DY 3 PMPM</i>	<i>DY 4 PMPM</i>	<i>DY 5 PMPM</i>
<i>SUD-IMD FFS</i>	4.5%	\$13,349	\$13,949	\$14,577	\$15,233	\$15,918
<i>SUD Non- IMD FFS</i>	4.5%	\$18.10	\$18.92	\$19.77	\$20.66	\$21.59

66. 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.

67. 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 Alaska 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.

68. Exceeding Budget Neutrality. The budget neutrality limits calculated in STC 58 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 must be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test must be based on the time period through the termination date.

69. Enforcement of Budget Neutrality. 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 plus:	1.5 percent
DY 1 through DY 3	Cumulative budget neutrality limit plus:	1.0 percent
DY 1 through DY 4	Cumulative budget neutrality limit plus:	0.5 percent
DY 1 through DY 5	Cumulative budget neutrality limit plus:	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 Plan Protocol	STC 21
150 days after SUD program approval date	SUD Monitoring Protocol	STC 22
180 days after approval date	Draft Evaluation Design	STCs 25 and 41
60 days after receipt of CMS comments	Revised Draft Evaluation Design	STCs 26 and 42
30 days after CMS Approval	Approved Evaluation Design published to state's website	STCs 42
November XX, 2020	Mid-Point Assessment	STC 23
One year prior to the end of the demonstration, or with renewal application	Draft Interim Evaluation Report	STC 44(c)
60 days after receipt of CMS comments	Final Interim Evaluation Report	STC 44(d)
18 months of the end of the demonstration	Draft Summative Evaluation Report	STC 45
60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	STC 45(a)
30 calendar days of CMS approval	Approved Final Summative Evaluation Report published to state's website	STC 45(b)
Monthly Deliverables	Monitoring Calls	STC 38
Quarterly Deliverables Due 60 days after end of each quarter, except 4 th quarter	Quarterly Monitoring Reports	STC 36
	Quarterly Expenditure Reports	STC 51
Annual Deliverables - Due 90 days after end of each 4 th quarter	Annual Reports	STC 36

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

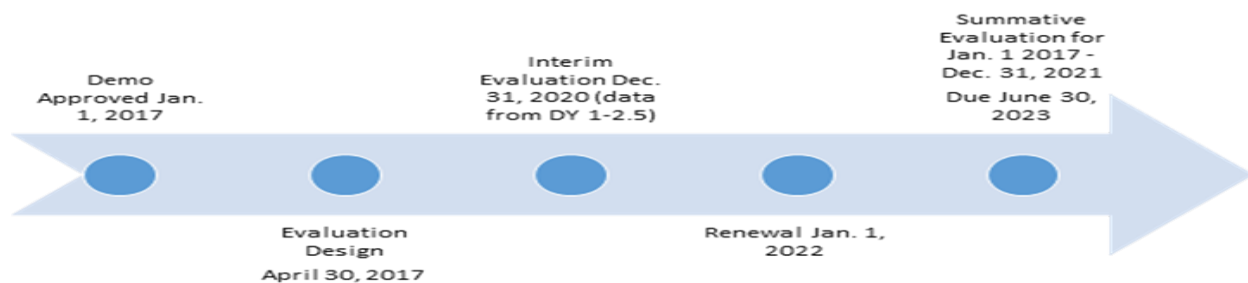
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, 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

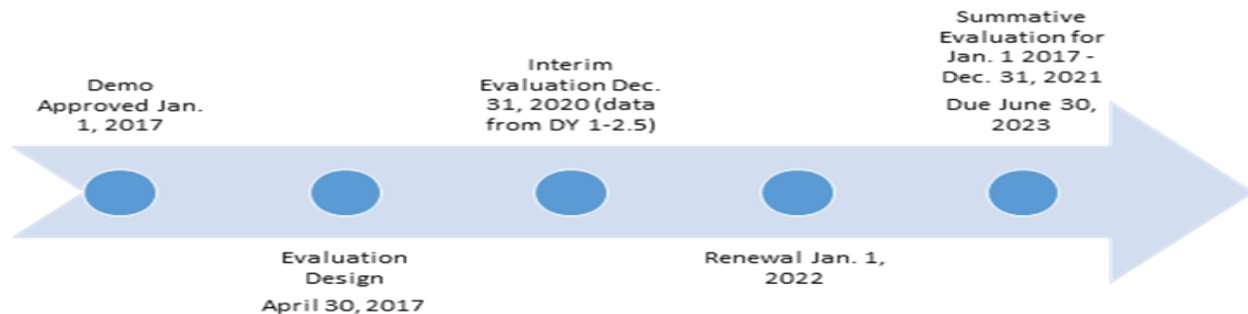
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved 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:
Reserved for Substance Use Disorder (SUD) Implementation Plan Protocol**

**ATTACHMENT E:
Reserved for SUD Claiming Protocol**

**ATTACHMENT F:
Reserved for SUD Monitoring Protocol**