

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



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**State Demonstrations Group**

APR 09 2019

Cynthia Beane  
Commissioner  
Bureau for Medical Services  
West Virginia Department of Health and Human Resources  
350 Capitol St., Room 251  
Charleston, WV 25301

Dear Ms. Beane:

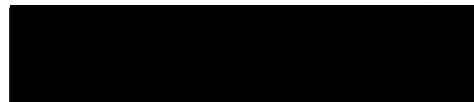
The Centers for Medicare & Medicaid Services (CMS) is issuing technical corrections to the West Virginia section 1115(a) Medicaid demonstration, titled "Creating a Continuum of Care for Medicaid Enrollees with Substance Use Disorders" (Project No. 11-W-00307/3), which was approved on October 6, 2017 under the authority of section 1115(a) of the Social Security Act ("the Act"). The technical corrections ensure that the Special Terms and Conditions (STC) reflect how the state is currently operating its demonstration.

Changes made include clarifying the criteria for the continuum of care model used in the demonstration and other non-substantial edits intended to correct and clarify the STC.

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

We look forward to continuing work with your staff on the administration of West Virginia's Creating a Continuum of Care for Medicaid Enrollees with Substance Use Disorders section 1115(a) demonstration.

Sincerely,



Angela D. Garner  
Director  
Division of System Reform Demonstrations

Cc: Francis McCullough, Director, Division of Medicaid Field Operations East  
Dan Belnap, CMS West Virginia State Lead

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

**NUMBER:** 11-W-00307/3

**TITLE:** West Virginia Continuum of Care for Medicaid Enrollees with Substance Use Disorders

**AWARDEE:** West Virginia Department of Health and Human Services

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by West Virginia for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period of this demonstration, be regarded as expenditures under the state's title XIX plan.

The following expenditure authorities may only be implemented consistent with the approved Special Terms and Conditions (STCs) and shall enable West Virginia to operate its section 1115 demonstration.

The expenditure authorities listed below promote the objectives of title XIX in the following ways:

- Improves health outcomes for Medicaid and other low-income populations in the state by covering treatment not otherwise covered by the state plan, and by making covered treatments available to previously excluded patients in institutions of mental disease (IMDs).

**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 SUD who are short-term residents in facilities that meet the definition of an institution for mental disease (IMD).

**2. Methadone Treatment.** Expenditures for services that could be covered under the Medicaid state plan; however, the state has elected to cover the services through expenditure authority instead.

**3. Peer Recovery Support Services.** Expenditures for services that could be covered under the Medicaid state plan; however, the state has elected to cover the services through expenditure authority instead.

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

**NUMBER:** 11-W-00307/3

**TITLE:** West Virginia Continuum of Care for Medicaid Enrollees with Substance Use Disorders

**AWARDEE:** West Virginia Department of Health and Human Services

**I. PREFACE**

The following are the amended Special Terms and Conditions (STCs) for West Virginia’s Substance Use Disorders (SUD) section 1115(a) Medicaid demonstration (hereinafter referred to as “demonstration”). The parties to this agreement are the West Virginia Department of Health and Human Services (“state”) and the Centers for Medicare & Medicaid Services (CMS). The STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state’s obligations to CMS during the life of the demonstration. The STCs were approved on October 6, 2017, for the period of January 1, 2018 through December 31, 2022.

The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description and Objectives
- III. General Program Requirements
- IV. Substance Use Disorder Demonstration
- V. General Reporting Requirements
- VI. Evaluation of the Demonstration
- VII. General Financial Requirements
- VIII. Monitoring Budget Neutrality for the Demonstration
- IX. Schedule of the State Deliverables during the Demonstration

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: SUD Monitoring Plan Protocol [RESERVED]

**II. PROGRAM DESCRIPTION AND OBJECTIVES**

The Substance Use Disorder (SUD) demonstration is a demonstration program to test a new paradigm for the delivery of SUD services for all Medicaid enrollees. The SUD program demonstrates how comprehensive and high quality substance use disorder care can improve the health of Medicaid recipients while decreasing other health care system (such as emergency department and inpatient hospital) costs. Critical elements of the SUD demonstration include

providing a continuum of care modeled after the American Society of Addiction Medicine Criteria (ASAM Criteria) or another comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for SUD treatment services, introducing policy and program guidance to ensure providers meet the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for standards of care, integrating SUD treatment services into a comprehensive managed care delivery system for those recipients receiving managed care under 1915(b) waiver authority; implementing utilization controls to improve care and ensure efficient use of resources; and implementing strategies to improve the quality of care through evidence-based best practices. This approach is expected to provide West Virginia Medicaid recipients with access to the care needed to achieve sustainable recovery.

Under this demonstration West Virginia expects to achieve the following to promote the objectives of title XIX:

- Improve quality of care and population health outcomes for Medicaid enrollees with SUD;
- Increase enrollee access to and utilization of appropriate SUD treatment services based on the ASAM Criteria or another comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines.
- Decrease medically inappropriate and avoidable utilization of high-cost emergency department and hospital services by enrollees with SUD; and
- Improve care coordination and care transitions for Medicaid enrollees with SUD.

### 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 Law, Regulation, and Policy.** All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly identified as not applicable in the expenditure authority documents (of which these terms and conditions are part), must apply to the demonstration.
3. **Changes in Medicaid Law, Regulation, and Policy.** The state must, within the time frames specified in law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or policy statement, affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is expressly identified as not applicable.
4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy Statements.** 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 budget neutrality agreement will be effective upon the implementation of the change.

- A. If mandated changes in the federal law require state legislation, the changes must take effect on the day such state legislation becomes effective, or on the day such legislation was required to be in effect under the federal law.
5. **State Plan Amendments.** The state shall not be required to submit title XIX state plan amendments for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid state plan is affected by a change to the demonstration, a conforming amendment to the state plan will be required, except as otherwise noted in these STCs.
  6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, enrollee rights, delivery systems, cost sharing, evaluation design, sources of non-federal share of funding and budget neutrality 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 Social Security Act (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 one hundred twenty (120) 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 failure by the state to submit required reports and other deliverables in a timely fashion according to the deadlines specified herein. 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 14, to reach a decision regarding the requested amendment;
    - B. A data analysis which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include total computable “with waiver” and “without waiver” expenditure estimates as well as the current federal share of the “with waiver” and “without waiver” estimates. The data analysis shall contain both summary and detailed level expenditure data through the current approval period using the most recent actual expenditures that illustrates 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. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation; and

D. If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.

8. **Extension of the Demonstration.** No later than twelve (12) months prior to the expiration date of the demonstration, the governor or chief executive officer of the state must submit to CMS notification that it expects to cover individuals under the Medicaid state plan or through some other type of coverage, a demonstration extension request, or a phase-out plan consistent with the requirements of STC 9.

As part of the demonstration extension request, the state must provide documentation of compliance with the transparency requirements at 42 CFR 431.412(c) and the public notice and tribal consultation requirements outlined in STC 14.

9. **Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.
- A. **Notification of Suspension or Termination:** The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit its notification letter and a draft phase-out plan to CMS no less than five (5) months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft plan to CMS, the state must publish on its website the draft plan for a thirty (30) day public comment period. In addition, if applicable, the state must conduct tribal consultation in accordance with its approved tribal consultation state plan amendment. Once the thirty (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.
- B. The state must obtain CMS approval of the phase-out plan prior to the implementation of the phase-out activities. Implementation of transition and phase-out activities must be no sooner than fourteen (14) days after CMS approval of the plan.
- C. **Phase-out Plan Requirements:** The state must include, at a minimum, in its 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.
- D. **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.

- E. **Federal Financial Participation (FFP):** If the project is terminated or any relevant waivers suspended by the state, FFP shall be limited to normal closeout costs associated with terminating the demonstration including services and administrative costs of disenrolling participants.
10. **CMS Right to Terminate or Suspend.** CMS may suspend or terminate, subject to adequate public notice, 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.
11. **Finding of Non-Compliance.** The state does not relinquish its rights to challenge the CMS finding that the state materially failed to comply.
12. **Withdrawal of Waiver Authority.** CMS reserves the right to withdraw waivers or expenditure authorities at any time it determines that continuing the waivers 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.
13. **Adequacy of Infrastructure.** The state must 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.
14. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the public notice procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

If applicable, the state must also comply with the tribal consultation requirements as set forth in section 1902(a)(73) of the Act and implemented in regulation at 42 CFR

431.408(b), and the tribal consultation requirements contained in the state’s approved Medicaid State Plan, when any program changes to the demonstration, either through amendment or extension, are proposed by the state.

15. **Federal Financial Participation (FFP).** No federal matching for expenditures for this demonstration will take effect until the effective date identified in the demonstration approval letter or as expressly stated within these STCs.

**IV. SUBSTANCE USE DISORDER (SUD) DEMONSTRATION**

16. **Program Description and Objectives.** The SUD demonstration is a demonstration program to test a new paradigm for the delivery of SUD services for all Medicaid enrollees, both those served via the managed care and fee-for-service delivery systems. No Medicaid state plan beneficiaries are excluded from the SUD demonstration. There are two (2) implementation dates of the SUD demonstration— January 1, 2018 for initial implementation, including coverage for methadone treatment services; and July 1, 2018 for full implementation, including residential treatment services, peer recovery support services, and withdrawal management services. Note: 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.

17. **SUD Demonstration Benefits.** The comprehensive SUD demonstration benefit package provides access to a full continuum of care for SUD treatment. Standard SUD services approved through the state plan benefit as well as SUD services approved through this demonstration will be available to all West Virginia Medicaid recipients who meet medical necessity criteria for services. The following service categories outlined in Table One (1) are included in the SUD demonstration benefit package for West Virginia Medicaid enrollees with the appropriate Medicaid authority designated:

**Table One: SUD Demonstration Benefits (with Expenditure Authority)**

ASAM Level of Care*	SUD Demonstration Benefit	Medicaid Authority	Costs Not Otherwise Matchable
N/A	Targeted Case Management	State plan	Services provided to short-term residents
N/A	Naloxone Administration Services	State plan	Services provided to short-term residents
0.5	Screening, Brief Intervention and Referral to Treatment	State plan	
1	Peer Recovery Support Services	Section 1115 demonstration	Services provided to short-term residents
1	Outpatient Services	State plan	
2.1	Intensive Outpatient Services	State plan	
2.5	Partial Hospitalization Services	State plan	

\*If not using ASAM Criteria, the level of care should be at the same level of the ASAM criteria.



3.1	Clinically Managed Low Intensity Residential Services	Section 1115 demonstration	Services provided to short-term residents
3.3	Clinically Managed Population-Specific High Intensity Residential Services	Section 1115 demonstration	Services provided to short-term residents
3.5	Clinically Managed High Intensity Residential Services	Section 1115 demonstration	Services provided to short-term residents
3.7	Medically Monitored Intensive Inpatient Services	State plan	Services provided to short-term residents
4	Medically Managed Intensive Inpatient Services	State plan	
1-WM	Ambulatory Withdrawal Management Services	State plan	
2-WM	Ambulatory Withdrawal Management Services	State plan	
3.2-WM	Clinically Managed Residential Withdrawal Management Services	Section 1115 demonstration	Services provided to short-term residents
3.7-WM	Medically Monitored Inpatient Withdrawal Management Services	State plan	Services provided to short-term residents
OTP	Opioid Treatment Program Services	Section 1115 demonstration	Services provided to short-term residents
OBOT	Office Based Opioid Treatment	State plan	Services provided to short-term residents

\*If not using ASAM Criteria, the level of care should be at the same level of the ASAM criteria.

The state attests that the services indicated in Table One (1), above, as being covered under Medicaid state plan authority are currently covered in the West Virginia Medicaid state plan. The following service definitions and provider qualifications are described for those SUD demonstration services, which are covered under this section 1115 demonstration.

### **Peer Recovery 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 a West Virginia Department of Health and Human Resources-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.

### **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 West

Virginia Medicaid recipients with an SUD diagnosis when determined to be medically necessary by the MCO utilization staff and in accordance with an individualized service plan. MCO utilization staff, physicians or medical directors will perform independent assessments to determine level of care and length of stay recommendations based upon the ASAM Criteria multidimensional assessment criteria or another comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines assessment criteria.

- a. Residential treatment services are provided in a West Virginia Bureau of Medical Services (BMS)-certified facility that has been enrolled as a Medicaid provider and assessed by BMS as delivering care consistent with ASAM Levels 3.1, 3.3, 3.5, and/or 3.7 or the equivalent level of care of the state's chosen other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines, and, for participation in the managed care delivery system, has been credentialed and enrolled by an MCO as a network provider. Each residential treatment provider will be certified as meeting the provider and service specifications described in the BMS policy manual consistent with the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for the requisite level or sublevel of care prior to participating in the West Virginia Medicaid program under this section 1115 demonstration. The MCOs will provide credentialing for ASAM Levels 3.1, 3.3, 3.5 and/or 3.7 or credentialing for the levels of care of the other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines contingent on the providers receiving certification from the state.
- b. Residential treatment services can be provided in settings of any size.
- c. The state's average length of stay for individuals admitted into all BMS-certified facilities at all levels of care is thirty (30) days.
- d. The implementation date for residential treatment services is July 1, 2018.
- e. 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.

Covered services include:

- a. Clinically-directed therapeutic treatment to facilitate recovery skills, relapse prevention, and emotional coping strategies.
- b. Addiction pharmacotherapy and drug screening;
- c. Motivational enhancement and engagement strategies;
- d. Counseling and clinical monitoring;

- e. 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;
- f. Regular monitoring of the individual's medication adherence;
- g. Recovery support services;
- h. 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,
- i. Education on benefits of medication assisted treatment and referral to treatment as necessary.

**Opioid Treatment Program Services (methadone treatment services)**

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 BMS-licensed methadone clinics in accordance with an individualized service plan determined by a licensed physician or licensed prescriber and approved and authorized according to state requirements.

Covered services include:

- a. Linkage to psychological, medical, and psychiatric consultation.
- b. Access to emergency medical and psychiatric care through connections with more intensive levels of care.
- c. Access to evaluation and ongoing primary care.
- d. Ability to conduct or arrange for appropriate laboratory and toxicology tests including urine drug screenings.
- e. 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.
- f. Individualized, person-centered assessment and treatment.
- g. Assessing, ordering, administering, reassessing, and regulating medication and dose levels appropriate to the individual; supervising withdrawal management from opioid analgesics, including methadone, buprenorphine products or naltrexone

- products; overseeing and facilitating access to appropriate treatment for opioid use disorder.
- h. Medication for other physical and mental health illness is provided, as needed, either on-site or through collaboration with other providers. 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.
  - i. 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.
  - j. 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.

**18. Incorporation of Industry Standards of Care.** Through revisions of its policy manual and contract requirements for managed care organizations (MCOs), BMS will establish standards of care for SUD demonstration services that incorporate industry standard benchmarks from the ASAM Criteria or another comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for patient assessment and placement, service and staffing specifications.

- a. Residential treatment services are provided in a BMS-certified facility that has been enrolled as a Medicaid provider and assessed by BMS as delivering care consistent with ASAM Levels 3.1, 3.3, 3.5, and/or 3.7 or another comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines, and, for participation in the managed care delivery system, has been credentialed and enrolled by an MCO as a network provider. Each residential treatment provider will be certified as meeting the provider and service specifications described in the BMS policy manual consistent with the ASAM Criteria or another comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for the requisite level or sublevel of care prior to participating in the West Virginia Medicaid program under this section 1115 demonstration.
- b. The MCOs will be responsible for credentialing all SUD demonstration service providers consistent with the key benchmarks from ASAM Criteria or from another comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines as set forth in the BMS policy manual and revised MCO contracts.

- c. All MCOs and SUD providers participating under this demonstration will incorporate the national patient assessment and placement guidelines as established in the ASAM Criteria or another comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines, into current assessment and level of care determination processes. The multidimensional assessment framework will be implemented as a standard component of the bio-psychosocial assessment and level of care determination process by January 1, 2018.

Between January 1, 2018 and December 1, 2018, providers will receive training and education on the ASAM or the other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines level of care criteria and the application of the ASAM Criteria or the other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines in the assessment process. MCOs will be required to provide evidence of initial and ongoing training of providers during site reviews conducted by the state. The state will review a sample of the provider network to corroborate the findings regarding training provided by the MCOs. If discrepancies are found, the state will review additional providers to ensure compliance and issue corrective action against the MCO. As part of a quality monitoring strategy, the state will review personnel and clinical records of a sample of the provider network to determine appropriate application and fidelity to the established assessment process.

19. **SUD Monitoring Plan Protocol.** The state must submit an SUD Monitoring Plan Protocol within 150 calendar days after approval of this demonstration. The SUD Monitoring Plan protocol must be developed in cooperation with CMS and is subject to CMS approval. The approved SUD Monitoring Plan Protocol will be incorporated here as Attachment H. At a minimum, the SUD Monitoring Plan Protocol will describe the data collection, reporting and analytic methodologies for performance measures and data points identified by the state and CMS for inclusion. The SUD Monitoring Plan Protocol will specify the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Subject Area V of the demonstration. In addition, for each performance measure, the SUD Monitoring Plan Protocol will identify a baseline, a target to be achieved by the end of the demonstration and an annual goal for closing the gap between baseline and target expressed as percentage points. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.

## **V. GENERAL REPORTING REQUIREMENTS**

20. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS will issue deferrals in the amount of \$5,000,000 (federal share) per deliverable 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) 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 submission 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 calendar 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; and
  - 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 deliverables(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, and timely and complete submission of required deliverables is necessary for effective testing, 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, which quarter the deferral applies to and how the deferral is released.

21. **Submission of Post-Approval Deliverables.** The state must submit all deliverables using the process stipulated by CMS and within the timeframes outlined within these STCs.

22. **Compliance with Federal Systems Innovation.** As federal systems continue to evolve and incorporate additional 1115 waiver 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, Transformed Medicaid Statistical Information System (T-MSIS), and other data elements that have been agreed to are provided; and
- C. Submit deliverables through the appropriate system as directed by CMS.

23. **Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state

shall cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration.

This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state shall include in its contracts with entities that collect, produce or maintain data and files for the demonstration, that they shall make such data available for the federal evaluation as is required by the state 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 20.

24. **Cooperation with Federal Learning Collaboration Efforts.** The state will cooperate with improvement and learning collaboration efforts by CMS.
25. **Quarterly and Annual Operational Reports.** The state must submit three (3) Quarterly Reports and one (1) compiled Annual Report each demonstration year (DY). The information for the fourth quarterly report should be reported as distinct information within the Annual Report. The Quarterly Reports are due no later than sixty (60 days) following the end of each demonstration quarter. The compiled Annual Report is due no later than ninety (90) days following the end of the DY.
  - A. The Quarterly and Annual Reports will include all required elements 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).
  - B. The Quarterly and Annual 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.
    1. Operational Updates - The reports shall provide sufficient information to document key operational and other 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 lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held.
    2. Performance Metrics – Any required monitoring and performance metrics must be included in writing in the Quarterly and Annual Reports. Information in the reports will follow the framework provided by CMS and be provided in a structured manner that supports federal tracking and analysis.
    3. Budget Neutrality and Financial Reporting Requirements – The state must provide an updated budget neutrality workbook that includes established

baseline and member months data with every Quarterly and Annual Report that meets all the reporting requirements for monitoring budget neutrality set forth in section VII. General Financial Requirements of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly expenditures associated with the populations affected by this demonstration on the Form CMS-64.

Evaluation Activities and Interim Findings. 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. The state shall specify, for CMS approval, a set of performance and outcome metrics, including their specifications, reporting cycles, level of reporting (e.g., the state, health plan and provider level, and segmentation by population) to support rapid cycle assessments in trends for monitoring and evaluation of the demonstration.

**26. Additional Demonstration Annual Operational Report Requirements.** The Annual Report shall meet the requirements in 42 C.F.R. 431.428, which address both the content of the report and the publication of the draft and final reports on the State's public website. In addition to the fourth quarter information and the aggregated components of the Quarterly Reports, the Annual Report must, at a minimum, include the requirements outlined below:

- A. Items included in the Quarterly Reports must be summarized to reflect the operation/activities throughout the DY;
- B. Total annual expenditures for the demonstration population for each DY, with administrative costs reported separately;
- C. Total contributions, withdrawals, balances, and credits; and
- D. Yearly enrollment reports for demonstration enrollees for each DY (enrollees include all individuals enrolled in the demonstration) that include the member months, as required to evaluate compliance with the budget neutrality agreement.

**27. Close Out Operational Report.** Within one hundred twenty (120) days prior to the expiration of the demonstration, the state must submit a draft Close Out Report to CMS for comments.

- A. The draft Close Out Report must comply with the most current Guidance from CMS.
- B. The state will present to and participate in a discussion with CMS on the Close-Out Report.
- C. The state must take into consideration CMS' comments for incorporation into the final Close-Out Report.
- D. The Final Close-Out Report is due to CMS no later than thirty (30) 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 20.

**28. State Data Collection.** The state must collect data and information necessary to oversee service utilization and rate setting by provider/plan, comply with the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) and the Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set), collectively referred to as the CMS Child and Adult Core Measure Sets for Medicaid and CHIP, and comply with other existing federal measure sets.

- A. The state will use this information in ongoing monitoring of individual well-being, provider/plan performance, and continuous quality improvement efforts, in addition to complying with CMS reporting requirements.
- B. The state must maintain data dictionary and file layouts of the data collected.
- C. The raw and edited data will be made available to CMS within thirty (30) days of a written request.

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

- A. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration.
- 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.
- D. Areas to be addressed during the monitoring call include, but are not limited to:

1. Transition and implementation activities;
2. Stakeholder concerns;
3. Operations and performance;
4. Enrollment;
5. Cost sharing;
6. Quality of care;
7. Beneficiary access;
8. Benefit package and wrap around benefits;
9. Audits;
10. Lawsuits;
11. Financial reporting and budget neutrality issues;
12. Progress on evaluation activities and contracts;
13. Related legislative developments in the state; and
14. Any demonstration changes or amendments the state is considering.

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

## VI. EVALUATION OF THE DEMONSTRATION

31. **Independent Evaluator.** At the beginning of the demonstration period, the state must 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 accord with the CMS-approved, Draft Evaluation Design, which will meet the requirements described in 42 C.F.R. 431.424 and the guidance provided in Attachment B: “Developing the Evaluation Design.” For scientific integrity, every effort should be made to follow the approved methodology. State evaluation must follow the approved methodology; however, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.
32. **Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A of these STCs. The state must submit, for CMS comment and approval, a Draft Evaluation Design with implementation timeline, for the demonstration to CMS 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 may choose to use the expertise of the independent party in the development of the Draft Evaluation Design.
33. **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 Reports and Annual Reports.
34. **Evaluation Questions and Hypotheses.** Consistent with attachments A and B of these STCs the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. CMS recommends hypotheses include an assessment of the objectives of SUD section 1115 demonstrations, to include (but is not limited to): initiation and compliance with treatment, appropriate utilization of health services (emergency department and inpatient hospital settings), and a reduction in key outcomes such as deaths due to overdose.

Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS’s Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

35. **Evaluation Budget.** A budget for 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 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, if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.
36. **Evaluation Requirements.** The demonstration evaluation will meet the prevailing standards of scientific evaluation and academic rigor, as appropriate and feasible for each aspect of the evaluation, including standards for the evaluation design, conduct, and interpretation and reporting of findings. In addition, the evaluation design plan will include a description of how the effects of the demonstration will be isolated from those other changes occurring in the state at the same time through the use of comparison or control groups, regarding significant aspects of the demonstration.
- A. The demonstration evaluation will use the best available data; use controls and adjustments for and reporting of the limitations of data and their effects on results; and discuss the generalizability of results.
- B. The state shall arrange with an independent entity to conduct the evaluation. The evaluation design shall discuss the state's process for arranging with an independent entity to conduct the evaluation, including a description of the qualifications the entity must possess, how the state will ensure no conflict of interest, and a budget for evaluation activities.
37. **State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the final Evaluation Design, the interim evaluation, and/or the summative evaluation.
38. **State Must Separately Evaluate Components of the Demonstration.** The outcomes from each evaluation component must be integrated into one programmatic summary that describes whether the state met the demonstration goal, with recommendations for future efforts regarding all components.
39. **Draft Interim Evaluation Reports.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Report should be posted to the state's website with the application for public comment. Also refer to Attachment B for additional information on the Interim Evaluation Report.
- A. The interim evaluation report will discuss evaluation progress and present findings to date as per the approved evaluation design.
- B. For demonstration authority that expires prior to the overall demonstration's

- expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
- C. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions, hypotheses and how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
  - D. The state must submit the final Interim Evaluation Report sixty (60) 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.
40. **Summative Evaluation Report.** The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within eighteen (18) months of the end of this approval period. The draft Summative Evaluation Report must include the information in the approved Evaluation Design. Refer to Attachment B for additional information on the evaluation report.
- A. Unless otherwise agreed upon in writing by CMS, the state shall submit the final Summative Evaluation Report within sixty (60) 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 thirty (30) days of approval by CMS.
41. **Public Access.** The state shall post the final documents (e.g., Quarterly and Annual Reports, Final Operational Report, approved Evaluation Design, Final Interim Evaluation Report(s), Final Summative Evaluation Report(s), and the Final Evaluation Report) on the state's Medicaid website within thirty (30) days of approval by CMS.
42. **Additional Publications and Presentations.** For a period of twenty-four (24) months following CMS approval of the final reports, CMS will be notified prior to presentation of other reports and related publications (including, for example, journal articles), by the state, contractor, or any other third party (an entity which is not the state or contractor) over which the state Medicaid agency has control. Prior to release of these reports, articles and other publications, CMS will be provided a copy including any associated press materials. CMS will be given thirty (30) 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.

## XII. GENERAL FINANCIAL REQUIREMENTS

43. **Quarterly Expenditure Reports.** The state must complete quarterly expenditure reports 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, for services provided through this demonstration and that are subject to budget neutrality. CMS shall provide FFP for allowable demonstration expenditures only as long as they do not exceed the pre-defined limits on the costs incurred as specified in section VIII (Monitoring Budget Neutrality).
44. **Reporting Expenditures Subject to the Title XIX Budget Neutrality Expenditure Limit.** The following describes the reporting of expenditures subject to the budget neutrality limit:
- 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 budget neutrality expenditure limit must be reported each quarter on separate Forms CMS-64.9 Waiver and/or CMS-64.9P Waiver, identified by the demonstration project number (11-W-00307/3) assigned by CMS, including the project number extension, which indicates the DY in which services were rendered.
  - b. **Cost Settlements.** For monitoring purposes, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (form CMS-64.9P Waiver) for the summary sheet line 10B, in lieu of lines 9 or 10C. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual.
  - c. **Pharmacy Rebates.** The state may propose a methodology for assigning a portion of pharmacy rebates to the demonstration services, in a way that reasonably reflects the actual rebate-eligible pharmacy utilization of those populations, and which reasonably identifies pharmacy rebate amounts with DYs. Use of the methodology is subject to the approval in advance by the CMS Regional Office, and changes to the methodology must be approved in advance by the Regional Office. A portion of pharmacy rebates assigned to the demonstration using the approved methodology will be reported on the appropriate Forms CMS-64.9 Waiver for the demonstration and not on any other CMS-64.9 form to avoid double-counting. Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.
  - d. **Use of Waiver Forms.** For each DY, separate Forms CMS-64.9 Waiver and/or CMS-64.9P Waiver shall be submitted reporting expenditures for individuals enrolled in the demonstration, subject to the budget neutrality limit (Section VIII of these

STCs). The state must complete separate waiver forms for the following eligibility group/waiver names:

- i. EG 1 – “SUD IMD” – This EG corresponds to Expenditure Authority #1 (Residential Treatment for Individuals with SUD) which includes all medical assistance expenditures including residential treatment costs with dates of service in a month when the beneficiary was a patient in an IMD.
- ii. EG 2 – “Methadone and Peer Support” – This EG corresponds to Expenditure Authorities #2 (Methadone Treatment) and #3 (Peer Recovery Support Services) which includes the PMPM cost of methadone and peer recovery support services.

45. **Title XIX Administrative Costs.** Administrative costs will not be included in the budget neutrality agreement, but the state must separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on Forms CMS-64.10 Waiver and/or CMS-64.10P Waiver. Administrative costs that are directly attributable to the demonstration must be reported under waiver name "SUD Admin."

46. **Claiming Period.** All claims for expenditures subject to the budget neutrality expenditure limit (including any cost settlements) must be made within two (2) years after the calendar quarter in which the state made the expenditures. 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 two (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 CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.

47. **Reporting Member Months.** The following describes the reporting of member months for the demonstration:

- a. For the purpose of calculating the budget neutrality expenditure limit, the state must provide to CMS, as part of the quarterly and annual reports as required under STC 25, the actual number of eligible member months for all demonstration expenditures. The state must submit a statement accompanying the quarterly and annual reports, certifying the accuracy of this information.
- b. The term “eligible member months” refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, for EG 1 “IMD”/ Expenditure Authority #1 Residential Treatment for Individuals with SUD, member months are months of Medicaid eligibility during which the individual is an inpatient in an IMD under the terms of the demonstration for any day during the month. For EG 2 “Methadone and Peer Support,” member months are all Medicaid eligible member months for Medicaid populations eligible for the SUD demonstration

that are not EG 1 “IMD” member months.

48. **Standard Medicaid Funding Process.** The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable Medicaid expenditures on the quarterly Form CMS-37. In addition, the estimate of matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each FFY on the Form CMS-37 (narrative section) 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 thirty (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.
49. **Extent of Federal Financial Participation for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS shall provide FFP at the applicable federal matching rates for the demonstration as a whole as outlined below, subject to the budget neutrality limits described in section VIII.
- a. Administrative costs, including those associated with the administration of the demonstration; and
  - b. Net expenditures and prior period adjustments, made under approved Expenditure Authorities granted through section 1115(a)(2) of the Act, with dates of service during the operation of the demonstration and consistent with the applicable STC requirements.
50. **Sources of Non-Federal Share.** The state must certify that matching non-federal share of funds for the demonstration are state/local monies. The state further assures that such funds shall 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 shall be addressed within the time frames set by CMS.
  - b. Any amendments that impact the financial status of the program shall require the state to provide information to CMS regarding all sources of the non-federal share of funding.
51. **State Certification of Funding Conditions.** The state must certify that the following conditions for non-federal share of demonstration expenditures are met:



- a. Units of government, including governmentally operated health care providers, may certify that state or local tax dollars have been expended as the non-federal share of funds under the demonstration.
- b. To the extent the state utilizes certified public expenditures (CPEs) as the funding mechanism for title XIX (or under section 1115 authority) payments, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
- c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for payments under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such tax revenue (state or local) used to satisfy demonstration expenditures. The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.
- d. The state may use intergovernmental transfers to the extent that such funds are derived from state or local tax revenues and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments. Under all circumstances, health care providers must retain one hundred (100) percent of the claimed expenditure. Moreover, no pre-arranged agreements (contractual or otherwise) exist between health care providers and state and/or local 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, 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.

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

## VIII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

53. **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 approved demonstration service expenditures incurred during the period of approval of the demonstration. The limit is determined by using a per capita cost method, and budget neutrality expenditure caps are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. The data supplied by the state to CMS to set the annual caps is subject to review and audit, and if found to be inaccurate, will result in a modified

budget neutrality expenditure limit. CMS’ assessment of the state’s compliance with these annual limits will be done using the Schedule C report from the CMS-64.

54. **Risk.** The state must be at risk for the per capita cost (as determined by the method described below) for demonstration eligibles under this budget neutrality agreement, but not for the number of demonstration eligibles. Because CMS provides FFP for all demonstration eligibles, West Virginia must not be at risk for changing economic conditions that impact enrollment levels. However, by placing West Virginia at risk for the per capita costs for current eligibles, CMS assures that the federal demonstration expenditures do not exceed the level of expenditures had there been no demonstration.

55. **Budget Neutrality Expenditure Limit.** The budget neutrality test includes an allowance for hypothetical services. The expected costs of the hypothetical services are reflected in the “without waiver” budget neutrality expenditure limit. The state must not accrue budget neutrality “savings” from the hypothetical services.

	<b>Trend</b>	<b>DY 1</b>	<b>DY 2</b>	<b>DY 3</b>	<b>DY 4</b>	<b>DY 5</b>
<b>SUD IMD PMPM</b>	5.4%	\$2,807.11	\$2,958.69	\$3,118.46	\$3,286.86	\$3,464.35
<b>Methadone and Peer Supports PMPM</b> Note: The DY 1 PMPM includes six (6) rather than twelve (12 months of peer supports; and, as a result, the PMPM for this EG is lower in DY 1.	5.4%	\$1.85	\$3.32	\$3.50	\$3.69	\$3.89

56. **Composite Federal Share Ratio.** The federal share of the budget neutrality expenditure limit is calculated by multiplying the limit times the Composite Federal Share. The Composite Federal Share is the ratio calculated by dividing the sum total of federal financial participation (FFP) received by the state on actual demonstration expenditures during the approval period, as reported through the Medicaid Budget and Expenditure System/State Children’s Health Insurance Program Budget and Expenditure System (MBES/CBES) and summarized on Schedule C with consolidation of additional allowable demonstration offsets such as, but not limited to, premium collections and pharmacy rebates, by total computable demonstration expenditures for the same period as

reported on the same forms. 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-upon method.

57. **Future Adjustments to the Budget Neutrality Expenditure Limit.** CMS reserves the right to adjust the budget neutrality expenditure limit to be consistent with enforcement of impermissible provider payments, health care related taxes, new federal statutes, or policy interpretations implemented through letters, memoranda, or regulations with respect to the provision of services covered under the demonstration.
58. **Enforcement of Budget Neutrality.** CMS will enforce budget neutrality over the life of this demonstration rather than on an annual basis. However, if the state’s expenditures exceed the calculated cumulative budget neutrality expenditure cap by the percentage identified below for any of the demonstration years, the state must submit a corrective action plan to CMS for approval.

<b>Demo Year</b>	<b>Cumulative Target Definition</b>	<b>Percentage</b>
DY 1	DY 1 budget limit amount plus:	1.0 percent
DY 2	DYs 1 through 2 combined budget limit amount plus:	1.0 percent
DY 3	DYs 1 through 3 combined budget limit amount plus:	1.0 percent
DY 4	DYs 1 through 4 combined budget limit amount plus:	0.5 percent
DY 5	DYs 1 through 5 combined budget limit amount plus:	0 percent

**IX. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION**

<b>Date – Specific</b>	<b>Deliverable</b>	<b>STC Reference</b>
150 days after approval March 4, 2018	Submit SUD Monitoring Plan Protocol	STC 19
180 days after approval April 3, 2018	Submit draft Evaluation Design	STC 32
60 days after CMS comments received	Submit revised Evaluation Design	STC 33
09/01/2022	Submit Draft Close Out Report	STC 27
<b>Annual</b>	By March 31 - Draft Annual Report	STC 25
<b>Annual</b>	Within 30 days of receipt of CMS comments – Final Annual Report	STC 25, 26
<b>Quarterly</b>	Quarterly Progress Reports	STC 25

## **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**

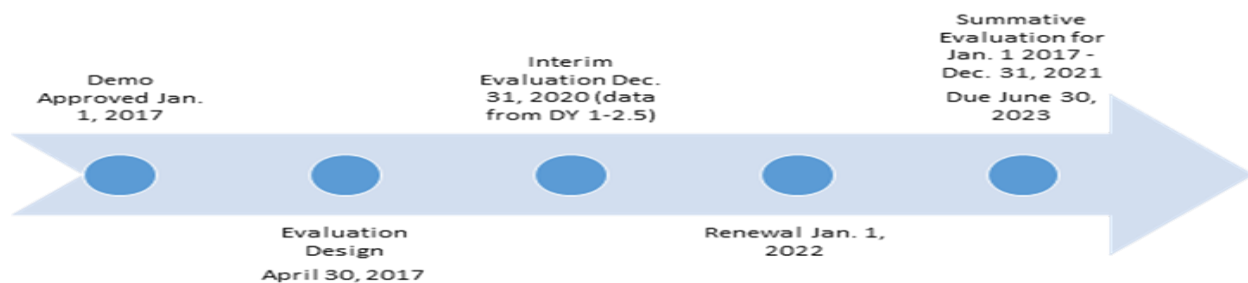
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, 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
<b>Hypothesis 1</b>				
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
<b>Hypothesis 2</b>				
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**

- A. Independent Evaluator.** The process the state will use for obtaining an independent entity to conduct the analysis and write the Evaluation Report, including a description of the qualifications the entity must possess. As soon as known, this section should be updated to include:
- a. Information about the organization conducting the evaluation;

- b. Contact information for the organization, including how to obtain a copy of the evaluation;
- c. The name and contact information of the Principal Investigator; and
- d. Curriculum Vitae of the Principal Investigator.

**B. 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. This includes “No Conflict of Interest” signed conformation statements.

**C. 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.

**D. 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.

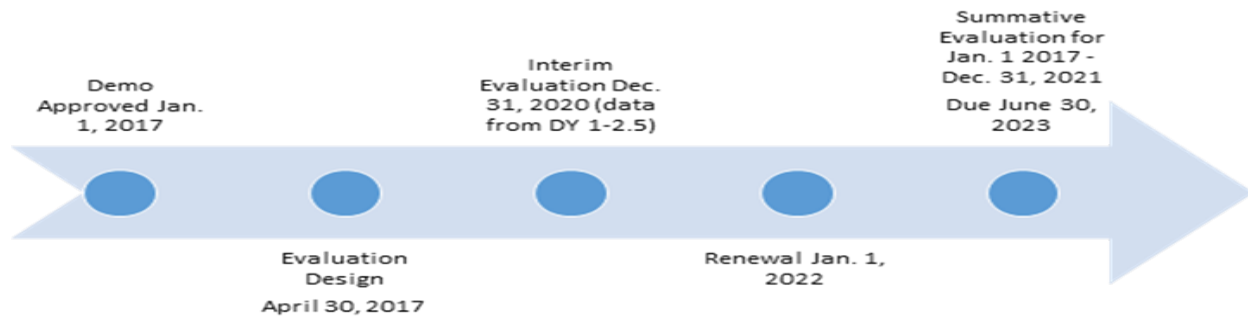
The format for the Interim and Summative Evaluation reports is as follows:

- 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: SUD Monitoring Plan Protocol**  
**[To be incorporated after CMS approval]**