

Section 1115 Substance Use Disorder (SUD) Demonstration:
Guide for Developing Implementation Plan Protocols

Overview: This template is meant to assist states that are developing an implementation plan for applications for a new section 1115 substance use disorder (SUD) demonstration project pursuant to the State Medicaid Directors’ letter #17-003 issued on November 1, 2017, “Strategies to Address the Opioid Epidemic”. States have the option of submitting their implementation plan as part of their application or as a post-approval protocol. If a state chooses to use a post-approval protocol, the timeframe for submitting the protocol will be specified in the Special Terms and Conditions (STCs) agreement between CMS and the state. Submission of the information provided in this template or the attachments does not guarantee approval of a state’s demonstration request. CMS will work with states to identify any additional information necessary to consider approval of implementation plans and demonstration requests.

This template was designed to help states ensure demonstration implementation plans meet the goals and milestones established by CMS aimed at improving quality, accessibility, and outcomes of SUD treatment services in the most cost-effective manner. In addition, this template is intended to help states describe plans for improving the state’s SUD Health Information Technology (IT) infrastructure to enhance the state’s prescription drug monitoring program (PDMP). This template was also developed to facilitate an efficient review process. States should add narrative responses to the information requested in the sections below that are applicable to their specific plans for improving treatment, and complete the input boxes provided. We will continue to improve this guide based on input from states. The state’s SUD Health IT Plan should be recorded in Attachment A.

The STCs developed for these demonstrations generally require states to submit an implementation plan within 90 calendar days after approval of the OUD/SUD demonstration. The state may not claim FFP for services provided in Institutions for Mental Diseases (IMDs), including residential treatment facilities, until CMS has approved a state’s implementation plan.

As the state is developing its implementation plan, the state may access strategic design support through the Medicaid Innovation Accelerator Program (IAP). If your state is interested in receiving strategic design support through the Medicaid IAP related to implementation plan development, please contact tyler.sadwith@cms.hhs.gov.

Please submit completed implementation plans electronically to your CMS section 1115 Project Officer.

CMS' New Opioid and Other SUDs 1115 Demonstration Initiative:

Goals and Milestones to be Addressed in State Implementation Plan Protocols

CMS is committed to working with states to provide a full continuum of care for people with opioid use disorder (OUD) and other SUDs and in supporting state-proposed solutions for expanding access and improving outcomes in the most cost-effective manner possible.

Goals:

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

Milestones:

1. Access to critical levels of care for OUD and other SUDs;
2. Widespread use of evidence-based, SUD-specific patient placement criteria;
3. Use of nationally recognized, evidence-based, SUD program standards to set residential treatment provider qualifications;
4. Sufficient provider capacity at each level of care, including MAT;
5. Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD; and
6. Improved care coordination and transitions between levels of care.

Section I – Milestone Completion

This section should contain information detailing state strategies for meeting the six milestones over the course of the demonstration. Specifically, this section should:

1. Include a summary of how the state already meet each milestone and any actions needed to be completed by the state to meet each milestone including the persons or entities responsible for completing actions;
2. Describe the timelines and activities the state will undertake to achieve the milestones; and
3. Provide an overview of future plans to improve beneficiary access to SUD services and promote quality and safety standards.

Milestones

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

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

- Outpatient Services;
- Intensive Outpatient Services;
- Medication assisted treatment (medications as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state);
- Intensive levels of care in residential and inpatient settings; and
- Medically supervised withdrawal management

Below is a table that can be included in a state’s implementation plan to describe plans to improve access to SUD treatment services for Medicaid beneficiaries including a variety of services at different levels of intensity across a continuum of care. **Suggestions regarding information to include are provided in the table below.**

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current SUD treatment services covered by the state in each level of care. For services currently covered in the state plan, list the benefit	Provide an overview of planned SUD treatment services to be covered by the state in each level of care: indicate whether planned services will be added to the state	Provide a list of action items needed to be completed to meet milestone requirements, if any. Include persons or entities responsible for completion of

	category and page location; for services currently covered in a demonstration, include the program name and Special Term and Condition number.	plan or authorized through the 1115.	each action item. Include timeframe for completion of each action item.
Coverage of outpatient services			
Coverage of intensive outpatient services			
Coverage of medication assisted treatment (medications as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state)			
Coverage of intensive levels of care in residential and inpatient settings			
Coverage of medically supervised withdrawal management			

Additional Suggestions for Milestone Table on Access to Critical Levels of Care for OUD and Other SUDs

For each level of care in the table, it would be helpful to provide information on the discrete services and provider qualifications (practitioner and provider type) for each service. This section should include information on current and intended actions and coverage, and associated

timelines, for the service categories needed to meet the *Access to Critical Levels of Care for OUD and Other SUDs* milestone. This milestone must be met within 12 to 24 months of demonstration approval or other timeframe in accordance with the STCs. States should also provide additional detail on when the state expects to meet the criteria not yet achieved for this milestone.

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

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

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

Below is a table that states can use to identify the state’s plan to increase the use of evidence-based, SUD-specific placement criteria to provide treatment that reflects diverse patient needs and evidence-based clinical guidelines. **Suggestions regarding information to include are provided in the table below.**

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current state use of evidence-based, SUD-specific patient placement criteria and utilization management approach to ensure placement in appropriate level of care and receipt of services recommended for that level of care	Provide an overview of planned state implementation of requirement that providers use an evidence-based, SUD-specific patient placement criteria and use of utilization management to ensure placement in appropriate level of care and receipt of services recommended for that level of care	Specify a list of action items needed to be completed to meet milestone requirements. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item

Implementation of requirement that providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools that reflect evidence-based clinical treatment guidelines			
Implementation of a utilization management approach such that (a) beneficiaries have access to SUD services at the appropriate level of care			
Implementation of a utilization management approach such that (b) interventions are appropriate for the diagnosis and level of care			
Implementation of a utilization management approach such that (c) there is an independent process for reviewing placement in residential treatment settings			

Additional Suggestions for Milestone Table on *Use of Evidence-based, SUD-Specific Patient Placement Criteria*

It would be helpful to include in this table information on current and intended actions and associated timelines needed to meet the *Use of evidence-based, SUD-specific patient placement criteria* milestone. This milestone must be met within 12-24 months of demonstration approval or other timeframe in accordance with the STCs. States should also provide additional detail on when the state expects to meet the criteria not yet achieved for this milestone.

The following bullets highlight information it would be helpful to include in the above table.

- Regarding implementation of a requirement that providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools that reflect evidence-based clinical treatment guidelines --
 - Describe which evidence-based, SUD-specific patient placement criteria are used to assess treatment needs and develop recommendations for placement in appropriate levels of care; and
 - Describe how these criteria are established as requirements, e.g. in managed care contracts, policy manuals or other guidance.

- Regarding implementation of a utilization management approach –
 - Describe state or health plan oversight activities to ensure beneficiaries have access to SUD services at the appropriate level of care;
 - Describe state or plan activities to ensure interventions being provided are appropriate for the diagnosis and level of care; and
 - Describe current use of or future plans to use a third-party (independent of treating providers) to review appropriateness of placement in residential treatment settings including the process that is or will be used and the type and frequency of reviews conducted.

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

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

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

- Implementation of a state process for reviewing residential treatment providers to assure compliance with these standards; and

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

Below is a table states can use to detail how the state currently incorporates nationally recognized, SUD-specific program standards into their provider qualifications for residential treatment facilities through their licensure requirements, policy manuals, managed care contracts, or other guidance and any plans to implement additional standards. In addition, it would be helpful to include a description of how the standards currently in use by the state compare to the ASAM Criteria or other nationally recognized, SUD specific standards that the state has chosen as the model. **Suggestions regarding information to include are provided in the table below.**

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current provider qualifications for residential treatment facilities and how these compare to nationally recognized SUD-specific program standards, e.g., the ASAM Criteria	Provide an overview of planned use of nationally recognized SUD-specific program standards in improving provider qualifications for residential treatment facilities.	Specify a list of action items needed to be completed to meet milestone requirements. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item
Implementation of residential treatment provider qualifications in licensure requirements, policy manuals, managed care contracts, or other guidance. Qualification should meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding, in particular, the types of services, hours of clinical			

care, and credentials of staff for residential treatment settings			
Implementation of a state process for reviewing residential treatment providers to ensure compliance with these standards			
Implementation of requirement that residential treatment facilities offer MAT on-site or facilitate access off site			

Additional Suggestions for Milestone Table on Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities

It would be helpful to include in this table information on current and intended actions and associated timelines needed to meet the *Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities* milestone. This milestone must be met within 12 to 24 months of demonstration approval or other timeframe in accordance with the STCs. States should also provide additional detail on when the state expects to meet the criteria not yet achieved for this milestone.

The following bullets highlight information it would be helpful to include in the above table.

- Regarding implementation of residential treatment provider qualifications that meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards:
 - Identify which nationally recognized, SUD-specific program standards will be used as a model;
 - Describe what standards are in place now;
 - Describe the particular criteria for the types of services, hours of clinical care, and credentials of staff for residential treatment settings that are in place now and those which will be implemented as part of any new provider qualifications for residential treatment facilities that the state is planning to put in place.
- Describe the use of a state process for reviewing residential treatment providers to assure compliance with these standards; and

- Indicate whether the state currently has in place a requirement that residential treatment facilities offer MAT on-site or facilitate access off site, and, if not, describe the state’s plans to implement such a requirement and plans to work with residential treatment providers in the state to facilitate compliance with this requirement.

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

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

Below is a table that states can use to detail how the state will assess provider capacity at the critical levels of care listed in Milestone 1 as well as state strategies to build this provider capacity infrastructure. **Suggestions regarding information to include are provided in the table below.**

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current provider capacities throughout the state to provide SUD treatment at each of the critical levels of care listed in Milestone 1.	Provide an overview of planned improvements to provider availability and capacity intended to improve Medicaid beneficiary access to treatment throughout the State at each of the critical levels of care listed in Milestone 1.	Specify a list of action items needed to be completed to meet milestone requirements. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item
Completion of assessment of the availability of providers enrolled in Medicaid and accepting new patients in the following critical levels of care			

<p>throughout the state (or at least in participating regions of the state) including those that offer MAT:</p> <p>Outpatient Services;</p> <p>Intensive Outpatient Services;</p> <p>Medication Assisted Treatment (medications as well as counseling and other services);</p> <p>Intensive Care in Residential and Inpatient Settings;</p> <p>Medically Supervised Withdrawal Management.</p>			
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Additional Suggestions for Milestone Table on *Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment*

It would be helpful to include in this table information on current and intended actions, including associated timelines, to meet the milestone of *Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment*. This milestone must be met within 12 months of demonstration approval or other timeframe in accordance with the STCs. States should also provide additional detail on when the state expects to meet the criteria not yet achieved for this milestone.

The following list describes additional information it would be helpful to include in the above table regarding an assessment of the availability of providers enrolled in Medicaid and accepting new patients in the critical levels of care throughout the state (or at least in participating regions of the state) including those that offer MAT:

- Anticipated penetration rate and geographic distributions of providers at each level of care; and
- Plans for enhancement of capacity based on assessments of provider availability.

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

To meet this milestone, states must ensure that the following criteria are met:

- Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse;
- Expanded coverage of and access to naloxone for overdose reversal; and
- Implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs.

Below is a table states can use to detail the variety of strategies that the state has put in place to address prescription drug abuse and opioid use disorders as well as plans to implement additional strategies. **Suggestions regarding information to include are provided in the table below.**

(Note that Attachment A includes a suggested table for detailing the state’s plans for improving its SUD health IT infrastructure to improve its PDMP.)

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current treatment and prevention strategies to reduce opioid abuse and OUD in the state.	Provide an overview of planned strategies to prevent and treat opioid abuse and OUD.	Specify a list of action items needed to be completed to meet milestone requirements as detailed above. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item
Implementation of opioid prescribing guidelines along with other interventions to prevent opioid abuse			
Expanded coverage of, and access to, naloxone for overdose reversal			

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

Additional Suggestions for Milestone Table on *Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD*

It would be helpful to include in this table information on current and intended actions and associated timelines needed to meet the *Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD* milestone. This milestone may be met over the course of the demonstration. States should also provide additional detail on when the state expects to meet the criteria not yet achieved for this milestone.

6. Improved Care Coordination and Transitions between Levels of Care

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

Below is a table states can use to detail the current state procedures for care coordination and transitions between levels of care to insure seamless transitions of care and collaboration between services. It would also be helpful to describe plans for expanding these procedures and improving this infrastructure. **Suggestions regarding information to include are provided in the table below.**

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities	Provide an overview of current care coordination services and transition services across levels of care.	Provide an overview of planned improvements to care coordination services and transition services across levels of care.	Specify a list of action items needed to be completed to meet milestone requirements. Include persons or entities responsible for completion of each action item. Include timeframe for

			completion of each action item
Additional policies to ensure coordination of care for co-occurring physical and mental health conditions			

Additional Suggestions for Milestone Table on *Improved Care Coordination and Transitions between Levels of Care*

It would be helpful to include in this table information on current and intended actions and associated timelines to meet the Improved Care Coordination and Transitions between Levels of Care milestone. This milestone must be met within 12 to 24 months of demonstration approval or other timeframe in accordance with the STCs. States should also provide additional detail on when the state expects to meet the criteria not yet achieved for this milestone

Regarding implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities, it would be helpful to include the following information in the table above:

- Current content of specific policies to ensure these procedures;
- Specific plans to help beneficiaries attain or maintain a sufficient level of functioning outside of residential or inpatient facilities; and
- Current policies or plans to improve care coordination for co-occurring physical and mental health conditions;

Section II – Implementation Administration

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

Name and Title:

Telephone Number:

Email Address:

Section III – Relevant Documents

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

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

Section I.

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

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

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

- a. Health IT.Gov in “Section 4: Opioid Epidemic and Health IT.”¹
- b. CMS 1115 Health IT resources available on “Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability” and, specifically, the “1115 Health IT Toolkit” for health IT considerations in conducting an assessment and developing their Health IT Plans.²

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

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

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

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

- Enhancing the health IT functionality to support PDMP interoperability; and

¹ Available at <https://www.healthit.gov/playbook/opioid-epidemic-and-health-it>.

² Available at <https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html>.

- Enhancing and/or supporting clinicians in their usage of the state’s PDMP.

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

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

Table 1. State Health IT / PDMP Assessment & Plan

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p><i>5. Implementation of comprehensive treatment and prevention strategies to address Opioid Abuse and OUD, that is:</i></p> <p><i>--Enhance the state’s health IT functionality to support its PDMP; and</i></p> <p><i>--Enhance and/or support clinicians in their usage of the state’s PDMP.</i></p>	<p><i>Provide an overview of current PDMP capabilities, health IT functionalities to support the PDMP, and supports to enhance clinicians’ use of the state’s health IT functionality to achieve the goals of the PDMP.</i></p>	<p><i>Provide an overview of plans for enhancing the state’s PDMP, related enhancements to its health IT functionalities, and related enhancements to support clinicians’ use of the health IT functionality to achieve the goals of the PDMP.</i></p>	<p><i>Specify a list of action items needed to be completed to meet the HIT/PDMP milestones identified in the first column. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item</i></p>
Prescription Drug Monitoring Program (PDMP) Functionalities			
Enhanced interstate data sharing in order to better track patient specific prescription data			
Enhanced “ease of use” for prescribers and other state and federal stakeholders			
Enhanced connectivity between the state’s PDMP and any statewide, regional or local health information exchange			

Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns ³ (see also “Use of PDMP” #2 below)			
Current and Future PDMP Query Capabilities			
Facilitate the state’s ability to properly match patients receiving opioid prescriptions with patients in the PDMP (i.e. the state’s master patient index (MPI) strategy with regard to PDMP query)			
Use of PDMP – Supporting Clinicians with Changing Office Workflows / Business Processes			
Develop enhanced provider workflow / business processes to better support clinicians in accessing the PDMP prior to prescribing an opioid or other controlled substance to address the issues which follow			
Develop enhanced supports for clinician review of the patients’ history of controlled substance prescriptions provided through the PDMP—prior to the issuance of an opioid prescription			
Master Patient Index / Identity Management			
Enhance the master patient index (or master data management service, etc.) in support of SUD care delivery.			

³ Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015. MMWR Morb Mortal Wkly Rep 2017;66:265–269. DOI: <http://dx.doi.org/10.15585/mmwr.mm6610a1>.

Overall Objective for Enhancing PDMP Functionality & Interoperability			
Leverage the above functionalities / capabilities / supports (in concert with any other state health IT, TA or workflow effort) to implement effective controls to minimize the risk of inappropriate opioid overprescribing—and to ensure that Medicaid does not inappropriately pay for opioids			

Attachment A, Section II – Implementation Administration

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

Name and Title:

Telephone Number:

Email Address:

Attachment A, Section III – Relevant Documents

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