
APPENDIX B: GOALS, RESEARCH QUESTIONS, AND ANALYTIC APPROACHES FOR EVALUATING SECTION 1115 SUBSTANCE USE DISORDER DEMONSTRATIONS

This appendix provides detailed recommendations for evaluations of section 1115 demonstrations for individuals with substance use disorders (SUD). This document should be used as a basis for states' discussions with their independent evaluators, and is not intended to represent the entirety of concerns states may have as they prepare their final evaluation designs. CMS is available to provide additional assistance to states if necessary.

This appendix is intended to supplement the document entitled Evaluation Design Guidance for Section 1115 Demonstrations for Beneficiaries with SMI/SED or SUD. The guidance in these documents does not change the existing guidance for SUD demonstrations.

1. Section 1115 demonstrations for SUD

On November 1, 2017, CMS published a State Medicaid Director (SMD) letter providing guidance on section 1115 demonstrations to improve access to and quality of treatment for Medicaid beneficiaries with SUD. Through this new policy, states have the flexibility to develop innovative solutions to address the state-specific SUD-related matters and to phase in a range of strategies over time.

2. Goals of the SUD demonstrations

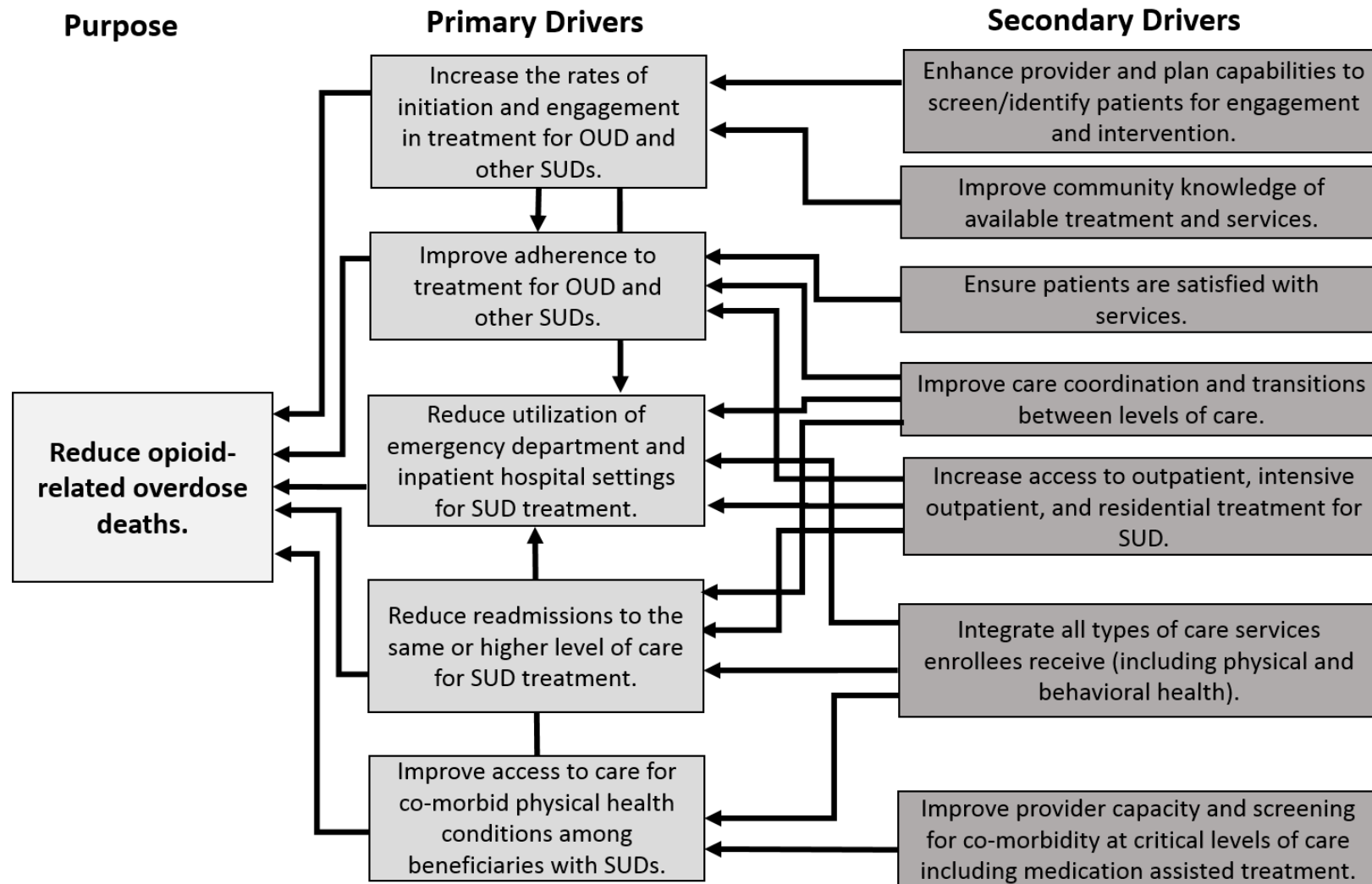
States should articulate goals of their demonstrations, including goals specified in the SMD letter as well as state-specific policy goals for their changes in service delivery systems for SUD populations. The goals specified in the SMD letter for SUD demonstrations include:

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

3. Sample driver diagram for SUD demonstrations

CMS expects states to include either a logic model or a driver diagram for the demonstration. In Figure B.1, we present a sample driver diagram for an SUD demonstration in which the purpose is to reduce opioid-related overdose deaths.

Figure B.1. Substance use disorder: Example driver diagram



In this sample driver diagram, the primary drivers are system components or factors which contribute directly to achieving the aim. Secondary drivers are actions, interventions, or lower-level components that are necessary to achieve the primary drivers. As shown in the example, secondary drivers may relate to one or multiple primary drivers. The example also illustrates that primary drivers may also relate to other primary drivers, but all primary drivers have a direct relational impact on the demonstration's overall goal—reducing opioid-related overdose deaths.¹

Note that a sample logic model using an example for SMI/SED demonstration types is presented in Appendix A.

4. Hypotheses and research questions for SUD

Core evaluation questions, hypotheses, recommended data sources, and analytic approaches for SUD demonstrations are provided in Table B.1. The driver diagram mentioned above is intended to be a framework for developing and refining evaluation questions and hypotheses. Using the example driver diagram, the five primary drivers and seven secondary drivers support hypotheses for the following three basic evaluation questions: (1) Did access to and utilization of SUD treatment services increase? (2) Did enrollees receiving SUD treatment services realize improved health outcomes? And as a result, (3) Were opioid-related overdose deaths reduced?

Table B.1 shows how drivers (primary and secondary) should align with the evaluation hypotheses under each evaluation question. CMS expects the state to report on the measures in Table B.1 as applicable to the demonstration goals and hypotheses; however, the state should add measures as applicable for its state-specific programs or components. The state should confirm the data sources it will use to test each hypothesis in Table B.1. Additionally, states are asked to demonstrate patterns and trends of reduced Medicaid costs associated with their SUD 1115 demonstration. Specific requirements of the cost analysis are detailed at the end of Table B.1, and in Appendix C.

Note that evaluation questions should include an assessment of both processes and outcomes. Measures should be specified with the measure name, measure number from nationally recognized forums (if applicable), numerator and denominator, and exclusions.

¹ If more detailed technical assistance related to driver diagrams is needed, additional tools and support can be found at: <https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf>.

Table B.1. Summary of key evaluation questions, hypotheses, data sources, and analytic approaches (to be modified as appropriate to accommodate state’s specific demonstration design)

Driver	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question: <i>Does the demonstration increase access to and utilization of SUD treatment services?</i>						
Demonstration Goal: Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs.						
Evaluation Hypothesis: The demonstration will increase the percentage of beneficiaries who are referred and engage in treatment for OUD and other SUDs.						
Primary Driver <i>(Increase the rates of initiation and engagement in treatment for OUD and other SUDs)</i>	Initiation and engagement of alcohol and other drug dependence treatment ^a	NQF #0004	Initiation: number of patients who began initiation of treatment through an inpatient admission, outpatient visits, intensive outpatient encounter or partial hospitalization within 14 days of the index episode start date	Patients who were diagnosed with a new episode of alcohol or drug dependency during the first 10 and ½ months of the measurement year	Claims data	Descriptive statistics (frequencies and percentages); chi square tests of significance comparing target population to baseline and to the comparison group
	Initiation and engagement of alcohol and other drug dependence treatment ^a	NQF #0004	Engagement: Initiation of treatment and two or more inpatient admissions, outpatient visits, intensive outpatient encounters or partial hospitalizations with any alcohol or drug diagnosis within 30 days after the date of the initiation encounter	Patients who were diagnosed with a new episode of alcohol or drug dependency during the first 10 and ½ months of the measurement year	Claims data	Descriptive statistics (frequencies and percentages); chi square tests of significance comparing target population to baseline and to the comparison group

Driver	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Secondary Drivers <i>(Enhance provider and plan capabilities to screen/identify patients for engagement and intervention. Improve community knowledge of available treatment and services)</i>	Providers offering screening services for SUD and/or OUD and/or referral to treatment	NBHQF Goal 3A	Number of providers offering screening, services, and/or referral to treatment	Number of providers	Claims data or provider survey	Descriptive statistics (frequencies and percentages); chi square tests of significance comparing target population to baseline and to the comparison group
	Referral after screening positive for SUD and/or OUD	None	Number of enrollees who screen positive and are referred for services	Number of demonstration beneficiaries	Claims data or provider survey	Descriptive statistics (frequencies and percentages); chi square tests of significance comparing target population to baseline and to the comparison group
Secondary Drivers <i>(Enhance provider and plan capabilities to screen/identify patients for engagement and intervention. Improve community knowledge of available treatment and services)</i>	Receipt of care following referral for SUD and/or OUD	None	Number of enrollees who are referred to care and receive services	Number of demonstration beneficiaries	Claims data or provider survey	Descriptive statistics (frequencies and percentages); chi square tests of significance comparing target population to baseline and to the comparison group
	Community knowledge of available treatment and services	None	Beneficiary survey	Beneficiary survey	Beneficiary Survey	Descriptive statistics

Driver	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Demonstration Goal: Increased adherence to and retention in treatment for OUD and other SUDs.						
Evaluation Hypothesis: The demonstration will increase the percentage of beneficiaries who adhere to treatment of OUD and other SUDs.						
Primary Drivers <i>(Increase the rates of initiation and engagement in treatment for OUD and other SUDs. Improve adherence to treatment for OUD and other SUDs)</i>	Continuity of pharmacotherapy for OUD ^a	NQF #3175	Number of participants who have at least 180 days of continuous pharmacotherapy with a medication prescribed for OUD without a gap of more than seven days	Individuals who had a diagnosis of OUD and at least one claim for an OUD medication	Claims data	Descriptive statistics; chi square tests of significance comparing target population to baseline and to the comparison group
	Percentage of beneficiaries with an SUD diagnosis (including beneficiaries with an OUD diagnosis) who used SUD services per month ^a	None	Number of enrollees who receive a service during the measurement period by service type	Number of enrollees	Claims data	Descriptive statistics; chi square tests of significance comparing target population to baseline and to the comparison group
Secondary Drivers <i>(Increase access to outpatient, intensive outpatient, and residential treatment for SUD. Improve care coordination and transitions between levels of care)</i>	Time to treatment	NBHQF Goal 1	Sum of (date of clinical assessment- date of 1 st contact)	Number of clinical assessments	Claims data	Descriptive statistics (frequencies and percentages, measures of central tendency); T-Test and chi square tests of significance comparing target population to baseline and to the comparison group

Driver	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
	Rate of continuation of treatment	NBHQF Goal 1	Sum of (date of first treatment service-date of clinical assessment)	Number of enrollees receiving treatment	Claims data	Descriptive statistics (frequencies and percentages, measures of central tendency); T-Test and chi square tests of significance comparing target population to baseline and to the comparison group
	Length of engagement in treatment	NBHQF Goal 1	Number of clients completing 4 th treatment session within 30 days	Number of enrollees receiving treatment	Claims data	Descriptive statistics (frequencies and percentages, measures of central tendency); T-Test and chi square tests of significance comparing target population to baseline and to the comparison group
Secondary Driver <i>(Ensure patients are satisfied with services)</i>	Patient experience of care	CCBHC	Consumer Assessment of Healthcare Providers (CAHPS); Experience of Care and Health Outcomes Survey (ECHO)	CAHPS; ECHO	Beneficiary survey	Descriptive statistics

Driver	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Demonstration Goal: Reduced utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.						
Evaluation Hypothesis: The demonstration will decrease the rate of emergency department and inpatient visits within the beneficiary population for SUD.						
Primary Driver (<i>Reduced utilization of emergency department and inpatient hospital settings for SUD treatment</i>)	Emergency department visits for SUD-related diagnoses and specifically for OUD ^{a,b}	None	The number of ED visits for SUD during the measurement period	Beneficiaries enrolled in Medicaid for at least one month (30 consecutive days) during the measurement period.	Claims data	Descriptive statistics; chi square tests of significance comparing target population to baseline and to the comparison group
	Inpatient admissions for SUD and specifically OUD ^a	None	Number of beneficiaries with an inpatient admission for SUD and specifically for OUD	Total number of beneficiaries/1,000 member months	Claims data	Descriptive statistics; chi square tests of significance comparing target population to baseline and to the comparison group
Evaluation Question: Do enrollees receiving SUD services experience improved health outcomes?						
Demonstration Goal: Improved access to care for physical health conditions among beneficiaries.						
Evaluation Hypothesis: The demonstration will increase the percentage of beneficiaries with SUD who experience care for comorbid conditions.						
Primary Driver (<i>Improve access to care for co-morbid physical health conditions among beneficiaries with SUD</i>)	Access to preventive/ ambulatory health services for adult Medicaid beneficiaries with SUD ^a	NCQA	Number of beneficiaries with SUD who had an ambulatory or preventive care visit during the measurement period	Number of beneficiaries with an SUD diagnosis	Claims data	Descriptive statistics; chi square tests of significance comparing target population to baseline and to the comparison group
	Tobacco use screening and follow-up for people with alcohol or other drug dependence	NQF #2600	Number of beneficiaries with alcohol or other drug dependence screened for tobacco use	Total number of beneficiaries	Claims data	Descriptive statistics; chi square tests of significance comparing target population to baseline and to the comparison group

Driver	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Secondary Drivers <i>(Improve provider capacity and screening for co-morbidity at critical levels of care including medication assisted treatment. Integrate all types of care services enrollees receive – including physical and behavioral health)</i>	Preventive care and screening	NQF #2152	Patients who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user	All patients aged 18 years and older seen for at least two visits or at least one preventive visit during the measurement period	Claims data and/or administrative data	Descriptive statistics; chi square tests of significance comparing target population to baseline and to the comparison group
	Substance use disorders: depression screening	NQMC: 004006	Patients with SUD who are screened for depression	All patients with SUD	Claims data and/or administrative data	Descriptive statistics; chi square tests of significance comparing target population to baseline and to the comparison group
	Care coordination	None	Provider survey: Behavioral Health Integration Capacity Assessment (BHICA)	BHICA	Provider Survey	Descriptive statistics
Demonstration Goal: Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate.						
Evaluation Hypothesis: Among beneficiaries receiving care for SUD, the demonstration will reduce readmissions to SUD treatment.						
Primary Driver <i>(Reduce readmissions to the same or higher level of care for SUD)</i>	Plan All-Cause Readmissions ^b	None	At least one acute unplanned readmission for any diagnosis within 30 days of the date of discharge from the index hospital stay, that is on or between the second day of the measurement year and the end of the measurement year	Medicaid beneficiaries age 18 and older with a discharge from an acute inpatient stay (index hospital stay) on or between January 1 and December 1 of the measurement year	Claims data	Descriptive statistics; chi square tests of significance comparing target population to baseline and to the comparison group

Driver	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Secondary Drivers <i>(Improve care coordination and transitions between levels of care. Increase access to outpatient, intensive outpatient, and residential treatment for SUD. Integrate all types of care services enrollees receive)</i>	Remission at 30 days post treatment (self-reported drug use)	None	Beneficiary Survey	Beneficiary Survey	Beneficiary Survey	Descriptive statistics
	Remission at 1 year post treatment (self-report drug use; second initiation of treatment)	None	Beneficiary Survey	Beneficiary Survey	Beneficiary Survey	Descriptive statistics
Evaluation Question: Are rates of opioid-related overdose deaths impacted by the demonstration?						
Demonstration Goal: Reduction in overdose deaths, particularly those due to opioids.						
Evaluation Hypothesis: The demonstration will decrease the rate of overdose deaths due to opioids.						
Primary Driver <i>(Reduce opioid-related opioid overdose deaths)</i>	Use of opioids at high dosage in persons without cancer ^a	NQF #2940	Number of beneficiaries with opioid prescription claims where the morphine equivalent dose for 90 consecutive days or longer is greater than 120 mg	Number of beneficiaries with two or more prescription claims for opioids filled on at least two separate dates, for which the sum of the days' supply is greater than or equal to 15	Claims and administrative data	Descriptive statistics; chi square tests of significance comparing target population to baseline and to the comparison group
	Rate of overdose deaths, specifically overdose deaths due to any opioid ^a	None	Number of overdose deaths per month and per year	Number of beneficiaries/1,000	Claims and administrative data	Descriptive statistics; chi square tests of significance comparing target population to baseline and to the comparison group

Driver	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
	Concurrent use of opioids and benzodiazepines ^a	None	Number of beneficiaries with concurrent use of prescription opioids and benzodiazepines	Number of beneficiaries with two or more prescription claims for opioids filled on two or more separate days, for which the sum of the supply is 15 or more days	Claims and administrative data	Descriptive statistics; chi square tests of significance comparing target population to baseline and to the comparison group

Additional Required Evaluation Topic: Demonstrate patterns and trends in Medicaid costs associated with SUD 1115 demonstration: States will conduct analyses that document total costs as well as cost drivers measured on a per member per month basis (PMPM) throughout the pre- and post-demonstration periods. The recommended cost categories include: 1) total Medicaid costs and total federal Medicaid costs, 2) SUD-IMD costs, other SUD costs, and non-SUD costs, and 3) inpatient costs, non-ED outpatient costs, ED outpatient costs, pharmacy costs, and long-term care costs to be obtained from state data warehouse and data submitted to the states directly by facilities including IMDs. Please refer to the companion technical guidance document (Attachment C: Approaches to Analyzing Costs Associated with Section 1115 Demonstrations for Beneficiaries with SMI/SED or SUD) that further discusses cost data sources, methodologies for creating an analytic file to examine changes in overall costs and individual cost components, and regression modeling considerations. The cost categories are designed to illustrate how costs and types of costs change as a result of the SUD 1115 demonstration.

^a Denotes a metric that is also part of the Monitoring Protocol Technical Assistance.

^b Denotes a metric that was revised or added since CMS released the initial guidance.

5. Identifying beneficiaries with an SUD diagnosis and/or treatment using Medicaid Data

This section provides instructions for obtaining codes from the Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set) Measure IET-AD: Initiation and Engagement of Alcohol and Other Drug (AOD) Dependence Treatment.² The most recent version is available at <https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-core-set/index.html>.

- a. Click on link titled, “2019 Adult Core Set HEDIS Measures Value Set Directory” (or most recent available year)
- b. Accept license agreement, download zip file, open Excel file
- c. Use tab: “adult value sets to codes”
- d. To identify an SUD diagnosis or treatment, use the following codes located in the Excel spreadsheet:

Type of visit	Value sets used	Types of code included
An outpatient visit, intensive outpatient visit, or partial hospitalization with an AOD diagnosis	IET Stand Alone Visits Value Set with AOD Dependence Value Set	CPT/HCPCS/UBREV with ICD9/ICD10
	IET Visits Group 1 Value Set with IET POS Group 1 Value Set and AOD Dependence Value Set	CPT with POS and ICD9/ICD10
	IET Visits Group 2 Value Set with IET POS Group 2 Value Set and AOD Dependence Value Set	CPT with POS and ICD9/ICD10
	A detoxification visit (Detoxification Value Set)	HCPCS/ICD9PCS/ICD10PCS/UBREV
	An ED visit (ED Value Set) with an AOD diagnosis (AOD Dependence Value Set)	CPT/UBREV with ICD9/ICD10
An acute or non-acute inpatient discharge with either an AOD diagnosis. Identify all acute and non-acute inpatient stays	AOD Dependence Value Set) or an AOD procedure code (AOD Procedures Value Set with (Inpatient Stay Value Set)	ICD9/ICD10 or ICD9PCS/ICD10PCS with UBREV

² The “Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set) Technical Specifications and Resource Manual for Federal Fiscal Year 2019 Reporting” is available at <https://www.medicaid.gov/medicaid/quality-of-care/downloads/medicaid-adult-core-set-manual.pdf>. Measure IET-AD: Initiation and Engagement of Alcohol and Other Drug (AOD) Dependence Treatment is described on pp. 90-98.