

# Evaluation Design Technical Assistance Guide for Section 1115 Demonstrations: Substance Use Disorder Demonstrations

This document provides technical assistance for evaluating section 1115 substance use disorder (SUD) demonstrations. It includes a description of the goals (Section 1), an example logic model (Section 2) linking demonstration activities to expected outcomes, hypotheses, and research questions (Sections 3 and 4), and provides guidance on identifying beneficiaries (Section 5). It also presents data sources (Section 6), analytic methods (Section 7), and analytic approaches (Tables 2 and 3).

The Centers for Medicare & Medicaid Services (CMS) provides evaluation technical assistance guides for several other common demonstration components.<sup>1</sup> States with multiple policies in their demonstration should consult relevant policy-specific evaluation technical assistance guides to develop comprehensive evaluation designs aligned with special terms and conditions (STCs) requirements.

## 1. Demonstration goals

On November 1, 2017, CMS published guidance on section 1115 demonstrations for improving access to and quality of treatment for Medicaid beneficiaries with SUD (state Medicaid director letter [SMDL] #17-003).<sup>2</sup> The SUD demonstration opportunity provides states flexibility to create innovative, state-specific solutions for SUD treatment. The goals of section 1115 SUD demonstrations include:

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

## 2. Example logic model for SUD demonstrations

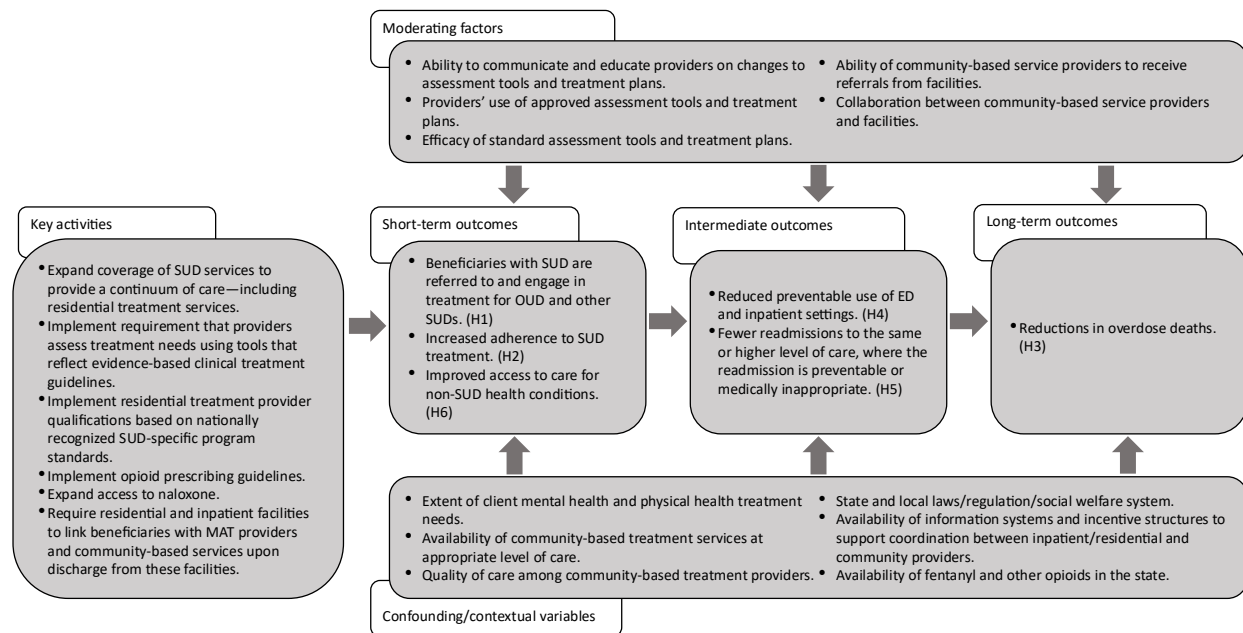
Figure 1 shows an example logic model. It depicts how the demonstration affects outcomes, accounting for moderating and confounding or contextual factors. A state's logic model should reflect the specific SUD services the demonstration offers and any other relevant state-specific context of activities.

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<sup>1</sup> These resources are available to states on the Medicaid.gov website: <https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html>.

<sup>2</sup> See: <https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd17003.pdf>.

**Figure 1. Example logic model for section 1115 SUD demonstrations**



ED = emergency department; H = hypothesis; MAT = medication assisted treatment; SUD = substance use disorder.

### 3. Research questions related to demonstration implementation

To understand the implementation of SUD demonstrations and opportunities to improve demonstration operations, the state should specify a set of implementation questions. These questions can provide context for analyses that address hypotheses and assess progress toward demonstration goals. For example, collaboration and coordination between inpatient health care providers and community-based providers is likely to affect—and should inform interpretation of—demonstration outcomes. It is also useful to document facilitators and barriers to success experienced by program administrators, staff, and participants. Qualitative data collected from states that have implemented SUD demonstrations indicates that there have been several common challenges in the implementation of SUD demonstrations. The challenges include lack of provider familiarity with the Medicaid program and with American Society of Addiction Medicine (ASAM) patient placement criteria, insufficient provider capacity, and the logistics of developing new reimbursement rates and policies for Medicaid programs.<sup>3</sup>

Table 2 lists implementation questions along with recommended measures, data sources, and analytic approaches. To answer the implementation questions, the state can leverage data it has already presented in the implementation plan and monitoring reports to assess program implementation approaches, trends, and lessons learned.<sup>4</sup> The state should also consider collecting additional data

<sup>3</sup> See: <https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/sud-1115-rcr-impl-chalngs.pdf>.

<sup>4</sup> For example, the state could synthesize data from SUD demonstration monitoring metrics to understand trends in the number of beneficiaries with a SUD diagnosis who are receiving SUD services. The state could also reconstruct the monitoring metrics for different cohorts of beneficiaries or different time horizons to yield the most actionable evidence given its demonstration evaluation design and implementation experience.

through interviews, surveys, and/or focus groups with key entities<sup>5</sup> and beneficiaries to understand their experiences with the demonstration, develop a deeper understanding of barriers and facilitators, and inform the moderating factors and contextual factors affecting demonstration outcomes.

*Primary Implementation Question 1:* Which key entities are collaborating to implement and operationalize the demonstration, and what are their main roles? How and why have the roles or participation of those key entities changed during the demonstration?

*Primary Implementation Question 2:* What strategies implemented during the demonstration do key program staff identify as most effective for achieving the goals of the demonstration?

*Primary Implementation Question 3:* What are barriers for key program staff implementing the demonstration, and what strategies have they used to overcome barriers? What are facilitators for key program staff implementing the demonstration, and what suggestions do they have for improving the demonstration?

*Primary Implementation Question 4:* What challenges have providers experienced in providing services as part of the demonstration, and what strategies have they used to overcome challenges? What aspects of the demonstration have worked well for providers, and what suggestions do they have for improving the demonstration?

*Primary Implementation Question 5:* What facilitators and barriers to participation do beneficiaries experience,<sup>6</sup> and what does this information suggest about the need for refinements to demonstration implementation or design more broadly? What are beneficiaries' experiences with accessing and receiving SUD services?

*Primary Implementation Question 6 (for evaluations of demonstration extensions):* How have the experiences of key program staff and providers changed during the extension period of the demonstration? Have they experienced new challenges or successes? Which, if any, new aspects of the demonstration were most effective for achieving the goals of the demonstration?

#### **4. Hypotheses and research questions related to demonstration outcomes**

The following hypotheses and research questions are consistent with CMS's expectations for evaluating SUD demonstrations. Table 3 presents Hypotheses 1 through 6 and corresponding research questions, along with recommended outcome measures, measure stewards, data sources, comparison groups (where applicable), and analytic approaches. In addition to the hypotheses and research questions listed below, the state should evaluate demonstration costs. The document titled *Evaluation Technical Assistance Guide for Section 1115 Demonstrations: Assessing Demonstration Costs* provides research questions, measures

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<sup>5</sup> Key entities may include health care providers, community partners, and state program administrators.

<sup>6</sup> Participation refers to the mechanism through which beneficiaries come into contact with the demonstration, which could include being screened, referred to services, and receiving services.

and data sources, and analytical methods for assessing costs in conjunction with demonstration goals and outcomes.<sup>7</sup>

**Hypothesis 1:** The demonstration will increase the percentage of beneficiaries who are referred to and engage in treatment for opioid disorder (OD) and other SUDs.

*Primary Research Question 1.1:* How does the demonstration impact the share of Medicaid beneficiaries who have a SUD diagnosis?

*Primary Research Question 1.2:* How does the demonstration impact the share of Medicaid beneficiaries with a SUD diagnosis who receive any SUD treatment?

*Subsidiary Research Question 1.2a:* How does utilization vary by service type?

*Primary Research Question 1.3:* How does the demonstration impact SUD provider availability (including medication assisted treatment [MAT] providers)?

**Hypothesis 2:** The demonstration will increase adherence to treatment of OD and other SUDs.

*Primary Research Question 2.1:* How does the demonstration affect the percentage of beneficiaries who adhere to SUD and OD treatment (including continuity of pharmacotherapy and/or receiving follow-up care after an ED visit for SUD or OD)?

**Hypothesis 3:** The demonstration will decrease the rate of overdose deaths, particularly those due to opioids.

*Primary Research Question 3.1:* How does the demonstration impact the use of opioids at high dosage and concurrently with benzodiazepines?

*Primary Research Question 3.2:* How does the demonstration impact the rate of overdose deaths due to opioids among Medicaid beneficiaries?

**Hypothesis 4:** The demonstration will decrease the rate of ED and inpatient visits within the beneficiary population for SUD.

*Primary Research Question 4.1:* How does the demonstration impact the rate of ED visits and inpatient admissions among beneficiaries with SUD?

**Hypothesis 5:** Among beneficiaries receiving care for SUD, the demonstration will reduce readmissions to SUD treatment.

*Primary Research Question 5.1:* How does the demonstration impact the rate of readmissions for SUD to the same or higher level of care among beneficiaries with SUD?

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<sup>7</sup> This resources is available to states on the Medicaid.gov website: <https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html>.

**Hypothesis 6:** The demonstration will improve access to care for physical health conditions among beneficiaries.

*Primary Research Question 6.1:* How does the demonstration impact the percentage of beneficiaries with SUD who receive care for comorbid conditions?

*Primary Research Question 6.2:* How does the demonstration impact the percentage of beneficiaries with SUD who receive ambulatory preventive care?

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

States can use codes from the “Adult Health Care Quality Measures for Medicaid (Adult Core Set) Measure IET-AD: Initiation and Engagement of Alcohol and Other Drug (AOD) Dependence Treatment” to identify beneficiaries with a SUD diagnosis.<sup>8</sup> To identify a SUD diagnosis or treatment, states can use the value sets in Table 1.

**Table 1. Value sets to identify beneficiaries with a SUD diagnosis**

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	CPT/HCPCS/UBREV with ICD-9/ICD-10
	IET Visits Group 1 Value Set with IET POS Group 1 Value Set	CPT with POS and ICD-9/ICD-10
	IET Visits Group 2 Value Set with IET POS Group 2 Value Set	CPT with POS and ICD-9/ICD-10
	A detoxification visit (Detoxification Value Set)	HCPCS/ICD-9-PCS/ICD-10-PCS/ UBREV
	An ED visit (ED Value Set)	CPT/UBREV with ICD-9/ICD-10
An acute or non-acute inpatient discharge with an AOD diagnosis. Identify all acute and non-acute inpatient stays	Inpatient Stay Value Set	ICD-9/ICD-10 or ICD-9-PCS/ICD-10-PCS with UBREV

CPT = Current Procedural Terminology; ED = emergency department; HCPCS = Healthcare Common Procedure Coding System; ICD-9/10 = 9/10th revision of the International Classification of Diseases; ICD-9-PCS/ICD-10-PCS = ICD 9/10 procedure codes; IET = Initiation and Engagement of Substance Use Disorder Treatment; POS = place of service; UBREV = Uniform Billing Revenue Code.

## 6. Data sources

SUD demonstration evaluations can largely rely on data sources described in the *Evaluation Design and Reporting for Section 1115 Demonstrations* document, including survey data and Medicaid administrative data.<sup>9</sup> The National Survey on Drug Use and Health (NSDUH) can also be a key data source. Sponsored

<sup>8</sup> The most recent version is available at <https://www.medicaid.gov/medicaid/quality-of-care/quality-of-care-performance-measurement>.

<sup>9</sup> This resources is available to states on the Medicaid.gov website: <https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html>.

by the Substance Abuse and Mental Health Services Administration, the NSDUH is a nationwide study of substance use, mental health, and other health-related issues in the United States. Each year, the NSDUH interviews approximately 70,000 people ages 12 and older who reside in households or noninstitutionalized group quarters. Other potentially relevant surveys include the Behavioral Risk Factor Surveillance System, which surveys adults ages 18 and older about health behaviors such as alcohol and tobacco use and generates state-level estimates, and the National Substance Use and Mental Health Services Survey, which is an annual survey of service providers. Legal opioid transactions by geographic area are recorded in the Automated Reports and Consolidated Ordering System (ARCOS) database maintained by the United States Drug Enforcement Administration.

## **7. Methods for testing demonstration hypotheses**

The research questions in Section 4 cover demonstration features typically approved by CMS in SUD demonstrations. CMS expects the state to adopt the suggested research questions with appropriate modifications for the state-specific demonstration. The research questions address the evaluation hypotheses, in alignment with the anticipated goals of SUD demonstrations.

For each of the outcome measures in Table 2, states should use the most rigorous comparison strategy and associated analytic approach feasible to obtain estimates of causal demonstration impacts. From more to less rigorous, these approaches include the following:

1. A regression model based on a randomized controlled trial comparing beneficiaries participating in the SUD demonstration to beneficiaries randomized to a control group that is not participating in the demonstration
2. A difference-in-differences regression model comparing beneficiaries participating in the SUD demonstration to similar beneficiaries in a state without a SUD demonstration
3. An interrupted time series regression model (if multiple pre-demonstration data points about SUD service use are available) or a pre-post comparison (if multiple pre-demonstration data points about SUD service use are unavailable or of poor quality)
4. Descriptive trend analyses over the course of the demonstration (if data about SUD service use are unavailable or are of poor quality in the pre-demonstration period and in non-demonstration states)

**Table 2. Suggested measures, data sources, and analytic approaches for research questions related to demonstration implementation**

Data sources	Measures and analytic approach
<b>Primary Implementation Question 1:</b> Which key entities are collaborating to implement and operationalize the demonstration, and what are their main roles? How and why have the roles or participation of those key entities changed during the demonstration?	
<ul style="list-style-type: none"> <li>• Memoranda of understanding with key partners</li> <li>• Interviews with Medicaid agency staff</li> <li>• Monitoring reports</li> </ul>	<ul style="list-style-type: none"> <li>• Descriptive qualitative analysis of roles of these key entities in the demonstration and how roles have changed over time</li> </ul>
<b>Primary Implementation Question 2:</b> What strategies implemented during the demonstration do key program staff identify as most effective for achieving the goals of the demonstration?	
<ul style="list-style-type: none"> <li>• Monitoring reports</li> <li>• Interviews with Medicaid agency staff, SUD providers, facility/practice administrators, and community partners</li> </ul>	<ul style="list-style-type: none"> <li>• Descriptive qualitative analysis to identify themes associated with the effectiveness of strategies implemented to achieve the goals of the demonstration and any obstacles hindering effectiveness</li> </ul>
<b>Primary Implementation Question 3:</b> What are barriers for key program staff implementing the demonstration, and what strategies have they used to overcome barriers? What are facilitators for key program staff implementing the demonstration, and what suggestions do they have for improving the demonstration?	
<ul style="list-style-type: none"> <li>• Review of program documentation</li> <li>• Interviews with Medicaid agency and other state staff involved with the demonstration or demonstration services</li> </ul>	<ul style="list-style-type: none"> <li>• Descriptive qualitative analysis of facilitators and barriers in implementation, key program staff's strategies for overcoming barriers, and key program staff's suggestions for improving the demonstration</li> </ul>
<b>Primary Implementation Question 4:</b> What challenges have providers experienced in providing services as part of the demonstration, and what strategies have they used to overcome challenges? What aspects of the demonstration have worked well for providers, and what suggestions do they have for improving the demonstration?	
<ul style="list-style-type: none"> <li>• Interviews with SUD providers and facility/practice administrators</li> <li>• Review of facility or practice documentation</li> </ul>	<ul style="list-style-type: none"> <li>• Descriptive qualitative analysis to identify challenges experienced by providers in providing demonstration services to demonstration participants</li> </ul>
<b>Primary Implementation Question 5:</b> What facilitators and barriers to participation do beneficiaries experience, and what does this information suggest about the need for refinements to demonstration implementation or design more broadly? What are beneficiaries' experiences with accessing and receiving SUD services?	
<ul style="list-style-type: none"> <li>• Interviews or focus groups with affected beneficiaries</li> </ul>	<ul style="list-style-type: none"> <li>• Descriptive qualitative analysis to identify barriers experienced by patients in receiving demonstration services</li> </ul>
<b>Primary Implementation Question 6:</b> How have the experiences of key program staff and providers changed during the extension period of the demonstration? Have they experienced new challenges or successes? Which, if any, new aspects of the demonstration were most effective for achieving the goals of the demonstration?	
<ul style="list-style-type: none"> <li>• Monitoring reports</li> <li>• Interviews with Medicaid agency staff, SUD providers, facility/practice administrators, and community partners</li> </ul>	<ul style="list-style-type: none"> <li>• Descriptive qualitative analysis of experiences of key program staff and providers to identify changes in their experiences and in the demonstration that were most effective</li> </ul>

ED = emergency department; MAT = medication assisted treatment; OUD = opioid use disorder; PDMP = prescription drug monitoring program; SUD = substance use disorder

**Table 3. Suggested measures, data sources, comparison strategies, and analytic approaches**

Outcome measure	Measure steward, endorsement	Data source
<b>Hypothesis 1:</b> <i>The demonstration will increase the percentage of beneficiaries who are referred to and engage in treatment for OUD and other SUDs.</i>		
<b>Primary Research Question 1.1:</b> How does the demonstration impact the share of Medicaid beneficiaries who have a SUD diagnosis?		
Percentage of beneficiaries with a SUD diagnosis (including beneficiaries with an OUD diagnosis) who used SUD services per month	None	Medicaid administrative data
<b>Primary Research Question 1.2:</b> How does the demonstration impact the share of Medicaid beneficiaries with a SUD diagnosis who receive any SUD treatment?		
Percentage of new SUD episodes that result in the initiation of treatment through an inpatient SUD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or medication treatment within 14 days of the diagnosis	NCQA, CMIT #394, Milestone 6 monitoring metric	Medicaid administrative data
Percentage of beneficiaries of new substance use disorder episode who initiated treatment and were engaged in ongoing SUD treatment including medications for AUD or OUD within 34 days of the initiation visit	NCQA, CMIT #394, Milestone 6 monitoring metric	
<b>Subsidiary Research Question 1.2a:</b> How does utilization vary by service type?		
Percentage of beneficiaries who during the measurement period used the following SUD services: <ul style="list-style-type: none"> <li>Any SUD treatment</li> <li>Outpatient services</li> <li>Medication-assisted treatment</li> <li>Residential treatment</li> <li>Acute inpatient</li> </ul>	Milestone 1 monitoring metrics	Medicaid administrative data
<b>Primary Research Question 1.3:</b> How does the demonstration impact SUD provider availability (including MAT providers)?		
Percentage of Medicaid providers offering screening services for SUD or OUD or referral to treatment	NBHQF Goal 3A	Medicaid administrative data or provider survey
Percentage of demonstration beneficiaries who screen positive for SUD or OUD and are referred for services	None	



Outcome measure	Measure steward, endorsement	Data source
<b>Hypothesis 2:</b> <i>The demonstration will increase adherence to treatment of OUD and other SUDs.</i>		
<b>Primary Research Question 2.1:</b> How does the demonstration affect the percentage of beneficiaries who adhere to SUD and OUD treatment (including continuity of pharmacotherapy and/or receiving follow-up care after an ED visit for SUD or OUD)?		
Percentage of adults 18 years of age and older with pharmacotherapy for OUD who have at least 180 days of continuous treatment	NCQA, CMIT #164	Medicaid administrative data
Percentage of discharges for patients age 18 and older who had a visit to the ED with a primary diagnosis of SUD during the measurement year and who had follow-up with a corresponding primary diagnosis of alcohol or other drug dependence within 7 and 30 days of discharge	NCQA, CMIT #265, Milestone 6 monitoring metric	
<b>Hypothesis 3:</b> <i>The demonstration will decrease the rate of overdose deaths, particularly those due to opioids.</i>		
<b>Primary Research Question 3.1:</b> How does the demonstration impact the use of opioids at high dosage and concurrently with benzodiazepines?		
Percentage of beneficiaries age 18 and older with concurrent use of prescription opioids and benzodiazepines. Beneficiaries with a cancer diagnosis, sickle cell disease diagnosis, or in hospice or palliative care are excluded.	PQA, CMIT #150	Medicaid administrative data
<b>Primary Research Question 3.2:</b> How does the demonstration impact the rate of overdose deaths due to opioids among Medicaid beneficiaries?		
Percentage of beneficiaries age 18 and older who received prescriptions for opioids with an average daily dosage greater than or equal to 90 morphine milligram equivalents over a period of 90 days or more	PQA, CMIT #740	Medicaid administrative data
Percentage of overdose deaths due to any opioid during the measurement period among adult Medicaid beneficiaries living in a geographic area covered by the demonstration.	None	Medicaid administrative data, state mortality data source
<b>Hypothesis 4:</b> <i>The demonstration will decrease the rate of ED and inpatient visits within the beneficiary population for SUD.</i>		
<b>Primary Research Question 4.1:</b> How does the demonstration impact the rate of ED visits and inpatient admissions among beneficiaries with SUD?		
Total number of ED visits for SUD-related diagnoses for OUD per 1,000 beneficiary-months	Milestone 5 monitoring metric	Medicaid administrative data
Number of inpatient admissions for SUD-related diagnoses for OUD per 1,000 beneficiary-months	Milestone 5 monitoring metric	

Outcome measure	Measure steward, endorsement	Data source
<b>Hypothesis 5:</b> Among beneficiaries receiving care for SUD, the demonstration will reduce readmissions to SUD treatment.		
<b>Primary Research Question 5.1:</b> How does the demonstration impact the rate of readmissions for SUD to the same or higher level of care among beneficiaries with SUD?		
The rate of all-cause readmissions from an acute inpatient stay during the measurement period among beneficiaries	Milestone 6 monitoring metric	Medicaid administrative data
Remission at 30 days post treatment (self-reported drug use)	None	Beneficiary Survey
Remission at 1 year post treatment (self-report drug use; second initiation of treatment)	None	
<b>Hypothesis 6:</b> The demonstration will improve access to care for physical health conditions among beneficiaries.		
<b>Primary Research Question 6.1:</b> How does the demonstration impact the percentage of beneficiaries with SUD who receive care for comorbid conditions?		
Access to preventive/ ambulatory health services for adult Medicaid beneficiaries with SUD	NCQA, CMIT #36 (adapted)	Medicaid administrative data
Tobacco use screening and follow-up for people with alcohol or other drug dependence	None	Medicaid administrative data, and/or electronic health records
<b>Primary Research Question 6.2:</b> How does the demonstration impact the percentage of beneficiaries with SUD who receive ambulatory preventive care?		
Percentage of patients aged 18 years and older 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	NCQA, CMIT #597	Medicaid administrative data, and/or electronic health records
Care coordination	None	Provider Survey: Behavioral Health Integration Capacity Assessment
Percentage of beneficiaries with a SUD diagnosis (including beneficiaries with an OUD diagnosis) who used were screened for hepatitis C or HIV (if applicable)	None	Medicaid administrative data

AUD = alcohol use disorder; CMIT = Centers for Medicare & Medicaid Services Measure Inventory Tool; ED = emergency department; MAT = medication assisted treatment; NBHQF = National Behavioral Health Quality Framework; NCQA = National Committee for Quality Assurance; OUD = opioid use disorder; PQA = Pharmacy Quality Alliance; SUD = substance use disorder.