comprehensive delivery system. The objectives of Heritage Health include:

- Improved health outcomes;
- Enhanced integration of services and quality of care;
- Emphasis on person-centered care, including enhanced preventive and care management services;
- Reduced rates of costly and avoidable care; and
- Improved financially sustainable system.

Nebraska Medicaid contracts with three health plans for the administration of the Heritage Health program: Nebraska Total Care (Centene), UnitedHealthCare Community Plan, and WellCare of Nebraska.

A driving force behind the creation of Heritage Health was the desire to improve care coordination and simplify service delivery for Medicaid beneficiaries. Prior to the launch of Heritage Health, a beneficiary struggling with substance use, physical health problems, and mental health conditions who also required prescription drugs navigated three separate programs in order to receive the full array of benefits and services the individual required. Through the integration of Medicaid services, Heritage Health removes barriers to addressing all the health needs of each beneficiary with a streamlined, person- centered approach. The SUD demonstration builds on these recent changes.

Table 3 Milestones for 1115 Demonstrations Addressing Opioids and Other Substances

	Milestones	Specifications and Proposed Timeframes
1	Access to Critical Levels of Care for OUD and other SUDs	Coverage of a) outpatient, b) intensive outpatient services, c) medication- assisted treatment (medications as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state), d) intensive levels of care in residential and inpatient settings, and e) medically supervised withdrawal management *Proposed Timeframe: Within 12 to 24 months of demonstration approval*
2	Use of Evidence-based, SUD-specific Patient Placement Criteria	1. Implementation of requirement that 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 *Proposed Timeframe: Within 12 to 24 months of demonstration approval* 2. Implementation of a utilization management approach such 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. *Proposed Timeframe: Within 24 months of demonstration approval*
3	Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities	1. 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, evidence-based SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings *Proposed Timeframe: Within 12 to 24 months of demonstration approval* 2. Implementation of state process for reviewing residential treatment providers to assure compliance with these standards *Proposed Timeframe: Within 24 months of demonstration approval* 3. Requirement that residential treatment facilities offer MAT on site or facilitate access off site *Proposed Timeframe: Within 12 to 24 months of demonstration approval*
4	Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment for OUD	Completion of 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. Expanded telehealth reporting requirements *Proposed Timeframe: Within 12 months of demonstration approval*
5	Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD	1. Implementation of opioid prescribing guidelines along with other interventions to prevent opioid abuse *Proposed Timeframe: Over the course of the demonstration* 2. Expanded coverage of, and access to, naloxone for overdose reversal *Proposed Timeframe: Over the course of the demonstration* 3. Implementation of strategies to increase utilization and improve functionality, of prescription drug monitoring programs *Proposed Timeframe: Over the course of the demonstration*
6	Improved Care Coordination and Transitions between Levels of Care	Implementation of policies to ensure residential and inpatient facilities link beneficiaries, especially those with OUD, with community-based services and supports following stays in these facilities. *Proposed Timeframe: Within 12 to 24 months of demonstration approval*

B. EVALUATION QUESTIONS & HYPOTHESES

The objective of this SUD demonstration project is to improve the State of Nebraska's ability to provide a full continuum of care for people experiencing SUD by improving access to evidence-based SUD treatment, and by improving the quality of available SUD treatment. By doing so, the State seeks to maintain or reduce the cost of care for beneficiaries with SUD. Accordingly, the evaluation questions are:

1. Did the demonstration increase access to health care for beneficiaries with SUD?
2. Did the demonstration improve the quality of SUD treatment?
3. Did the demonstration maintain or reduce total cost of care?

The driver diagrams below illustrate how the three program aims are to be achieved by demonstration activities (secondary drivers). The six CMS-required demonstration goals are primary drivers of increased Access and Quality. Each primary driver represents a testable hypothesis about the impact of the demonstration activities leading to the aim. Table 4 specifies the measures that will be used to assess each hypothesis.

The first aim, access, is targeted through expanded coverage and capacity for SUD treatment. These activities align with CMS Milestones 1 and 4 (Fig. 1). Specifically, the state will add coverage for medically monitored intensive inpatient withdrawal management for adults at ASAM level 3.7-WM, include methadone as a covered form of MAT, and educate providers about the availability of coverage for IMD stays >15 days. Furthermore, residential providers will be required to expand their treatment methods by either offering MAT onsite or facilitating access to MAT off-site. The demonstration also plans to introduce expanded reporting requirements to encourage the use of telehealth for SUD treatment, and will add SUD-specific provider capacity reporting requirements for MCOs that include the number of participating providers accepting new patients by level of care and those that offer MAT. The evaluation hypothesis is that the expanded coverage will increase access to the specified services, which will be reflected in increased utilization, and capacity building activities will increase the number of people receiving any treatment, as well as the number of available providers and beds providing SUD services. An additional hypothesis is that as beneficiaries increasingly receive appropriate SUD services, they will also be more likely to access care for physical health conditions, reflected in increased utilization of ambulatory and preventive care by beneficiaries with SUD.

The second aim, quality, is anticipated to improve as a result of the implementation of several waiver components as well as the expanded coverage (Fig. 2). In order to accomplish Milestone 2, widespread use of evidence-based, SUD-specific patient placement criteria, the demonstration will update MCO contract language to include a requirement that assessment tools used when authorizing or reviewing inpatient stays be based on evidence based clinical treatment guidelines. The demonstration also plans to add SUD treatment specific requirements to the existing annual audit tool used to review all contracted MCOs' compliance with this new contract language. As part of the plan to achieve milestone 3, the demonstration plans to update MCO contract language to include a requirement that the MCOs perform reviews of residential treatment providers to assure all standards regarding service type and expectations, hours of care, and staffing requirements. These changes will be complemented by policy

interventions associated with Milestone 5, which include Implementation of opioid prescribing guidelines, expanded coverage of, and access to, naloxone for overdose reversal, and reforms to prescription drug monitoring programs. In addition, new language will be added to MCO contracts clarifying requirements for the inclusion of policies that link beneficiaries, especially those with OUD, with community-based services and supports following inpatient stays in treatment facilities, including specific timeframes for Care Management contact post discharge from an inpatient stay related to an SUD, in alignment with Milestone 6.

The evaluation hypothesizes that as the demonstration promotes standardized assessment and placement for patients, establishes qualifications for residential providers, and implements processes to assure compliance with treatment standards, these activities in combination will improve the appropriateness and continuity of care for SUD patients, reflected in higher rates of initiation and engagement in treatment, and in greater adherence and retention in treatment, reflected in continuity of MAT. The evaluation further hypothesizes that by promoting evidence-based assessment and referral, the demonstration will support better matching of patients to appropriate treatment settings, and hence improved quality will be reflected in lower rates of ED use and hospital readmission for patients with SUD, and reduced rates of overdose mortality.

The third aim, cost maintenance, is an intended outcome of treating patients in the most appropriate setting and improving follow-up (Fig.3). Improved continuity of care and rates of MAT engagement are expected to enable more individuals to be stabilized in SUD treatment, and to be less frequently in crisis and in need of acute care. As discussed above, improved access is anticipated to increase the utilization of SUD services including IMD stays and outpatient services. It is hypothesized that any increase in claims for treatment, and in longer IMD stays, that result from the demonstration will be balanced by reductions in ED visits and hospital admissions for beneficiaries with SUD. Reduced cost may occur as a result of reduced hospitalizations specifically for SUD, but may also include reduced need for care for comorbid physical or behavioral health conditions that were poorly managed due to untreated SUD and low engagement in primary care. Therefore, the evaluation will test the hypothesis that overall hospital utilization will be reduced for beneficiaries with SUD, as well as the narrower hypothesis that admissions and ED visits specifically for SUD will be reduced. Ultimately, total cost of care for beneficiaries with SUD will be analyzed to test the hypothesis that the increased cost of SUD treatment is balanced by reduced acute care utilization.

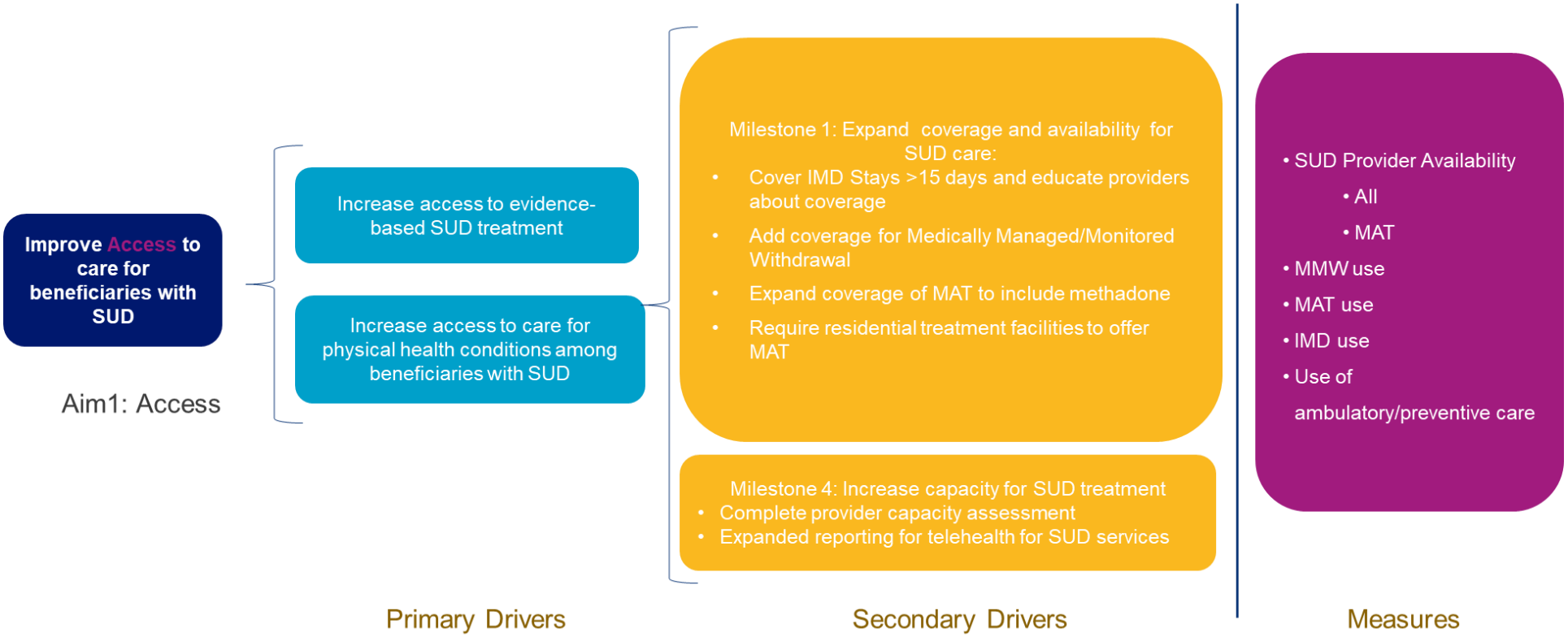

Figure 1 Driver Diagram, Access

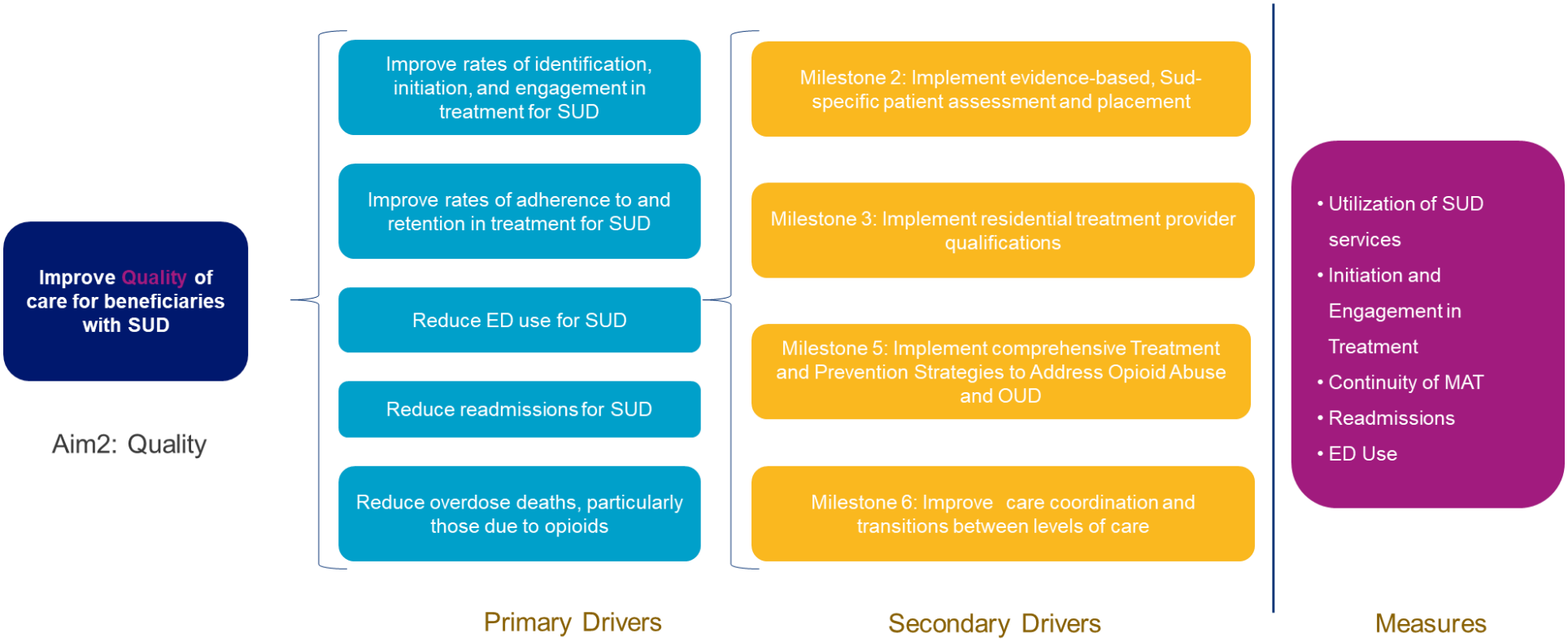

Figure 2 Driver diagram, Quality

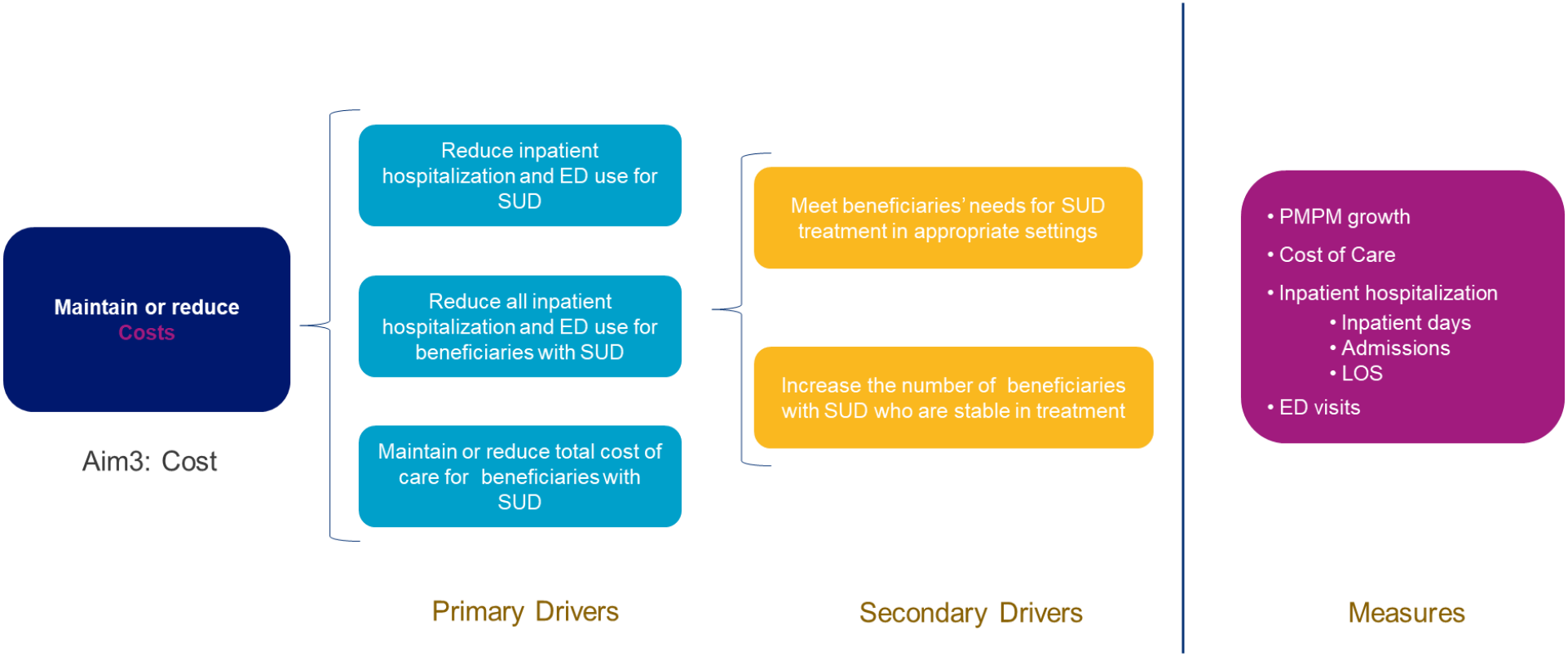

Figure 3 Driver diagram, Cost

Table 4 Evaluation Hypotheses and Measures

Hypothesis	Measure Description	Measure type/Steward	Numerator	Denominator	Data Source	Analytic Approach
Aim 1: Improve Access to health care for beneficiaries with SUD						
Evaluation Question: Did the demonstration improve access to health care for beneficiaries with SUD?						
Demonstration goal/Primary Driver: Increase Access to evidence-based SUD treatment						
The demonstration will increase access to evidence-based SUD treatment, reflected in increased utilization.	Number of beneficiaries receiving any SUD treatment service	CMS-constructed	Number of beneficiaries aged 19-64 with a claim for any services for SUD treatment	Total number of beneficiaries aged 19-64	Claims	Descriptive statistics; ITS Regression
	Number of beneficiaries who use residential services for SUD	CMS-constructed	Number of beneficiaries who use residential services for SUD	Number of beneficiaries aged 19-64 with a claim for residential services for SUD	Claims	Descriptive statistics; ITS Regression
	Number of beneficiaries who use withdrawal management services	CMS-constructed	Number of beneficiaries aged 19-64 with a claim for withdrawal management	Total number of beneficiaries aged 19-64 with SUD	Claims	Descriptive statistics; ITS Regression
	Number of beneficiaries who have a claim for MAT for SUD	CMS-constructed	Number of beneficiaries aged 19-64 with a claim for MAT	Total number of beneficiaries aged 19-64 with SUD	Claims	Descriptive statistics; ITS Regression
	Number of IMD stays for SUD	CMS-constructed	Number of IMD stays for beneficiaries aged 19-64 with SUD	Total number of beneficiaries aged 19-64 with SUD	Claims	Descriptive statistics; ITS Regression
	Number of days of IMD treatment for SUD	CMS-constructed	Number of days of IMD treatment for SUD	Total number of beneficiaries aged 19-64 with SUD	Claims	Descriptive statistics; ITS Regression
	Average LOS of IMD stays for SUD	CMS-constructed	Total number of days of IMD treatment for beneficiaries aged 19-64 with SUD	Number of IMD stays for beneficiaries aged 19-64 with SUD	Claims	Descriptive statistics; ITS Regression
The demonstration will increase access to evidence-based SUD treatment, reflected in increased capacity.	Number of providers enrolled in Medicaid and qualified to deliver SUD services	CMS-constructed	Number of providers enrolled in Medicaid and qualified to deliver SUD services	--	Provider enrollment database; Claims	Descriptive Statistics
	Number of providers enrolled in Medicaid and qualified to deliver MAT for SUD services	CMS-constructed	Number of providers enrolled in Medicaid and qualified to deliver MAT for SUD services	--	Provider enrollment database; Claims	Descriptive Statistics
	Number of beds available in IMD facilities providing SUD services	State-identified (DHHS)	Number of beds available in IMD facilities providing SUD services	--	MCO reporting	Descriptive Statistics

	Number of outpatient facilities offering detoxification	Survey question (SAMHSA)	Number of outpatient facilities offering detoxification	Number of adult residents[11]	N-SSATS	Descriptive Statistics
	Number of facilities offering opioid-specific detoxification	Survey question (SAMHSA)	Number of facilities offering opioid-specific detoxification		N-SSATS	Descriptive Statistics
	Opioid Treatment Programs (OTPs)	Survey question (SAMHSA)	Number of facilities offering Opioid Treatment Programs (OTPs)		N-SSATS	Descriptive Statistics
	Outpatient facilities offering OTPs	Survey question (SAMHSA)	Number of outpatient facilities offering OTPs		N-SSATS	Descriptive Statistics
	Residential (non-hospital) facilities offering OTPs	Survey question (SAMHSA)	Number of residential (non-hospital) facilities offering OTPs		N-SSATS	Descriptive Statistics
	Medication-assisted opioid therapy provided at facilities with OTPs	Survey question (SAMHSA)	Number of facilities with OTPs offering medication-assisted opioid therapy		N-SSATS	Descriptive Statistics
	Any type of medication assisted therapy (MAT)	Survey question (SAMHSA)	Number of facilities offering any type of medication assisted therapy (MAT)		N-SSATS	Descriptive Statistics
	Needing but not receiving treatment at a specialty facility for illicit drug/SUD in the past year	Survey question (SAMHSA)	Estimated rate[12]	--	NSDUH	Descriptive Statistics
Demonstration goal/Primary Driver: Increase Access to care for physical health conditions among beneficiaries with SUD.						
The demonstration will increase access to care for physical health conditions among beneficiaries with SUD	The percentage of Medicaid beneficiaries with SUD who had an ambulatory or preventive care visit.	Quality measure (HEDIS)	Number of unique beneficiaries with SUD diagnosis, and specifically those with OUD, who have a claim for an ambulatory or preventive care visit in the past 12 months	Total number of beneficiaries aged 19-64 with SUD/OUD	Claims	Descriptive statistics; ITS Regression

[11] N-SSATS measures will be used as reported (number of facilities) for comparison of demonstration years to baseline. For comparison to national benchmarks, a ratio of facilities to the size of the adult population will be calculated.

[12] The NSDUH reports estimated prevalence for each survey question. For detailed methodology, see Substance Abuse and Mental Health Services Administration. (2019). Results from the 2018 National Survey on Drug Use and Health: Detailed tables. Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/

Aim 2: Improve Quality of Care for Beneficiaries with SUD

Evaluation Question: Did the demonstration improve the quality of SUD treatment?

Demonstration Goal/Primary Drivers: Improve rates of identification, initiation, engagement, adherence, and retention in treatment for SUD

The demonstration will Improve rates of identification, initiation, and engagement, in treatment for SUD	Percentage of beneficiaries who initiated treatment within 14 days of a new SUD diagnosis	Quality measure NCQA; NQF #0004; Medicaid Adult Core Set; Adjusted HEDIS measure	Beneficiaries with a claim for treatment within 14 days	Total number of beneficiaries aged 19-64 with a new diagnosis of SUD	Claims	Descriptive statistics; ITS Regression
	Percentage of beneficiaries who initiated treatment and who had two or more additional services for SUD within 34 days of the initiation visit.		Beneficiaries with two or more claims for SUD treatment within 34 days	Total number of beneficiaries aged 19-64 with a new diagnosis of SUD	Claims	Descriptive statistics; ITS Regression
The demonstration will improve rates of adherence to and retention in treatment for SUD	Continuity of pharmacotherapy for OUD	Quality measure USC; NQF #3175	Beneficiaries who have at least 180 days of continuous treatment	Total number of beneficiaries aged 19-64 receiving MAT for OUD	Claims	Descriptive statistics; ITS Regression
The demonstration will reduce ED use for SUD	Number of ED visits for SUD	DHHS	Total number of claims for ED visits for SUD	Total number of beneficiaries aged 19-64	Claims	Descriptive statistics; ITS Regression
The demonstration will reduce readmissions for SUD	30-Day Readmission	CMS-constructed	Number of acute inpatient stays among beneficiaries with SUD followed by an acute readmission within 30 days	Number of acute inpatient stays among beneficiaries with SUD	Claims	Descriptive statistics; ITS Regression
The demonstration will reduce overdose deaths, particularly those due to opioids	Rate of overdose deaths, overall, and due to opioids	CDC	Total number of overdose deaths; Total number of deaths due to opioid overdose	Total adult population of the state	National Center for Health Statistics	Descriptive statistics;

Aim 3: Maintain or reduce costs

Evaluation Question: Did the demonstration maintain or reduce total cost of care?

Demonstration Goal/Primary Driver: Reduce inpatient hospitalization and ED use for SUD

The demonstration will reduce inpatient hospitalization and ED use for SUD	Number of inpatient stays for SUD	CMS-constructed	Number of beneficiaries aged 19-64 with a claim for an inpatient stay for SUD	Total number of beneficiaries aged 19-64	Claims	Descriptive statistics; ITS Regression
	Number of days of inpatient hospitalization for SUD	CMS-constructed	Total number of days of inpatient treatment for SUD for beneficiaries aged 19-64	Total number of beneficiaries aged 19-64	Claims	Descriptive statistics; ITS Regression
	Average LOS of inpatient hospitalization for SUD	CMS-constructed	Total number of days of inpatient treatment for SUD for beneficiaries aged 19-64	Total number of beneficiaries aged 19-64	Claims	Descriptive statistics; ITS Regression
	Number of ED visits for SUD	CMS-constructed	Total number of claims for ED visits for SUD for beneficiaries aged 19-64	Total number of beneficiaries aged 19-64	Claims	Descriptive statistics; ITS Regression

Demonstration Goal/Primary Driver: Reduce inpatient hospitalization and ED use for beneficiaries with SUD

The demonstration will reduce inpatient hospitalization and ED use for beneficiaries with SUD	Number of inpatient stays for any cause	CMS-constructed	Number of beneficiaries aged 19-64 with a claim for an inpatient stay for SUD	Total number of beneficiaries aged 19-64 with SUD	Claims	Descriptive statistics; ITS Regression
	Number of days of inpatient for any cause	CMS-constructed	Total number of days of inpatient treatment for SUD for beneficiaries aged 19-64	Total number of beneficiaries aged 19-64 with SUD	Claims	Descriptive statistics; ITS Regression
	Average LOS of inpatient hospitalization for any cause	CMS-constructed	Total number of days of inpatient treatment for SUD for beneficiaries aged 19-64	Total number of beneficiaries aged 19-64 with SUD	Claims	Descriptive statistics; ITS Regression
	Number of ED visits for any cause	CMS-constructed	Total number of claims for ED visits for SUD for beneficiaries aged 19-64	Total number of beneficiaries aged 19-64 with SUD	Claims	Descriptive statistics; ITS Regression
Demonstration Goal/Primary Driver: Reduce or maintain total cost of care for beneficiaries with SUD						
The demonstration will reduce or maintain total cost of SUD-related care	PMPM Cost for SUD treatment	CMS-constructed	PMPM cost of all claims for any SUD diagnosis for beneficiaries age 19-64	Total number of beneficiaries aged 19-64 with SUD	Claims	Descriptive statistics; ITS Regression
The demonstration will reduce or maintain total cost of care	PMPM Cost	CMS-constructed	PMPM cost for beneficiaries age 19-64 with SUD	Total number of beneficiaries aged 19-64 with SUD	Claims	Descriptive statistics; ITS Regression

C.METHODOLOGY

The evaluation will employ mixed methods to investigate the demonstration's impact on access, quality, and cost. For each of the three aims, quantitative analysis of claims and other reported metrics will test the evaluation hypotheses described in Table 4. Additional insight into quality and access will be derived from analysis of national survey data, and from qualitative sources including key informant interviews.

1.Evaluation design

The primary approach for testing evaluation hypotheses will be an Interrupted Time Series (ITS) analysis of claims and administrative data. ITS regression will be used to compare the trend in each outcome during the 24-month pre-demonstration period to the period from demonstration launch until the end of the demonstration. Unlike a simple pre-post design, ITS can analyze trends over time in outcome variables. This will allow for greater sensitivity to changes in outcomes that may have been increasing or decreasing at baseline. Additionally, stratification by region, demographics, and other populations of interest will be used to investigate whether disparities exist and if so whether they have been reduced. Subgroup analysis will be performed for gender, race/ethnicity, pregnant women, beneficiaries dually eligible for Medicare, and presence of a co-occurring mental health diagnosis.

Quality and access to SUD treatment will be investigated in more depth through semi-structured interviews with providers and administrators. These interviews will provide a nuanced picture of implementation successes and challenges, and perceived impact.

National survey data will be used to supplement these approaches. The National Survey of Substance Abuse Treatment Services (N-SSATS) will be used to identify increases in the number of facilities offering detoxification and MAT/OTP services. The ratio of facilities offering each service to the size of the adult population will be used as a crude metric of system capacity for comparison to the national ratio. The National Survey of Drug Use and Health (NSDUH) will be used to determine whether the demonstration reduces the rate of needing but not receiving SUD services, which will be compared to the national rate. While national benchmarks are an imperfect comparison, and neither survey crosswalks these measure with Medicaid enrollment, these two datasets will provide context for Nebraska's results.

2.Target and Comparison Populations

The population studied will be adult Medicaid beneficiaries aged 19-64 who have an SUD diagnosis, including those who become eligible as a result of the expansion of Nebraska's Heritage Health program. DHHS anticipates an increase of approximately twofold in the number of adult beneficiaries beginning October 1, 2020 with the launch of the HHA expansion (Table 5). Current actuarial projections do not predict that the expansion population will differ significantly in acuity or prevalence of SUD from the existing adult population. Because Nebraska Medicaid is rarely the primary payer for beneficiaries aged $\geq$65, older adults are not specifically targeted by this demonstration, and data for this population is expected to be incomplete. Similarly, adolescents under age 19 will have access to services provided under the waive authority, but are not specifically targeted, and will not be included in the evaluation analysis.

Table 5 Evaluation Population Size

Estimated population size Unique individuals per year			
	Total Adult Beneficiaries	SUD Dx	OUD Dx
Pre-demonstration (Average 2018-19)	83,500	4,949	770
Demonstration* (Estimated)	175,349	10,392	1617

Because all Medicaid beneficiaries are eligible for services under the waiver, no true comparison population is available for this demonstration. Using the ITS approach, the comparison is of post-waiver trends to pre-waiver trends. For additional context, comparisons of statewide outcomes to national trends and other states will be made, but are not considered a true counterfactual, as other states are different at baseline, and many also are implementing similar programs.

The analysis will employ a repeated cross-sectional approach, including all member months for a given quarter. This will include all adult beneficiaries who were enrolled during the quarter, regardless of duration. Individuals who have an SUD diagnosis or claim (as defined in CMS guidance) in the previous 12 months will be included in the evaluation population. Two years of claims data prior to the demonstration period will be used to identify individuals to be included in the pre-demonstration period, in order to more accurately identify beneficiaries with an SUD condition. Individuals who are identified as having received an SUD-related service through the Division of Behavioral Health[13] during the past 12 months will also be included.

3.Evaluation Period

The evaluation period will include 24 months prior to the launch of the demonstration as a baseline. The formal launch date, July 9, 2019, marked the beginning of a ramp-up period when waiver provisions were being disseminated and newly implemented. Coverage for IMD stays >15 days was available immediately, but MMW and MAT/OTP coverage required extensive preparation. Table 1 shows the dates when new services were first offered. Because MMW and MAT/OTP services are expected to be offered beginning around Oct 1, 2020, the demonstration should not be considered fully launched until that time. The evaluator will conduct sensitivity analysis examining the demonstration years separately to detect a delay in the demonstration's impact. Heritage Health Expansion will launch October 1, 2020, beginning inclusion of the newly eligible adult population. Sensitivity analysis will also consider the post-expansion period separately as the influx of new beneficiaries, and broader changes to the system, may alter the impact of the demonstration. The evaluation period will end at the close of the demonstration in June 2024, resulting in a 60-month post-intervention period.

[13] DHHS is currently investigating the feasibility and legal authority to use data from DBH to improve the accuracy of identifying the target population.

Table 6 Overall timeframe and duration of the pre-intervention and post-intervention periods.

Evaluation period	Calendar Dates	Duration
Pre-Intervention	July 9 2017 - July 8 2019	24 months
Post Intervention	July 9 2019-June 30 2024	60 months

4.Evaluation Measures

Measures that will be used for evaluation of Access, Quality, and Cost are summarized in Driver Diagrams, and described in detail in Table 4, Evaluation Hypotheses and Measures.

Access will be assessed through two categories of measures: utilization and capacity. Utilization measures will be drawn from claims for the specific SUD services listed. Capacity measures will be drawn from the state's provider enrollment database, and from MCO non-claims reporting, to determine numbers of Medicaid-enrolled facilities providing SUD services. Additional measures from SAMHSA surveys will be used to compare the state's progress on access to national benchmarks. The National Survey of Substance Abuse Treatment Services (N-SSATS) will be used to investigate whether the state's capacity for providing SUD treatment services increases during the demonstration through the addition of new services at residential treatment facilities. The national ratio of facilities to adult population size will serve as a benchmark. As shown in Table 2, compared to the US at large, the state has fewer facilities offering detoxification and MAT/OTP services relative to adult population size. This is a crude metric of system capacity, because number of facilities does not take into account the capacity of those facilities, or the number of individuals needing treatment. However, because Nebraska currently has so few facilities offering these services, it is anticipated that the addition of Medicaid coverage will increase this number, which will be reflected in a higher ratio of facilities to the size of the adult population. Another national benchmark for comparison is the rate of needing but not receiving SUD treatment, as reported in the National Survey on Drug Use and Health (NSDUH). In 2018, NE's rate was similar to the US (2.51, 95%CI 1.98 - 3.18 NE, vs 2.54, 95% CI 2.42 - 2.66 US) despite lower SUD prevalence.[14] If the demonstration succeeds in increasing access to SUD treatment, the rate of needing but not receiving is expected to decrease.

Quality will be assessed using standard SAMHSA measures of initiation and engagement in treatment, retention in treatment, and continuity of treatment. All are derived from claims. Downstream measures of quality (reflecting outcomes not avoided by treatment) are ED visits, readmissions, and overdose deaths. Overdose deaths will be derived from CDC reports, as the state does not track this information in sufficient detail. This will not allow the identification of Medicaid beneficiaries so the rate will be for the state rather than the demonstration target population.

[14] Substance Abuse and Mental Health Services Administration. (2019). Results from the 2018 National Survey on Drug Use and Health: Detailed tables. Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/

Three types of cost measures are included in Table 4; acute care (ED or inpatient hospital use) for SUD by any beneficiary, acute care for any cause by a beneficiary with SUD, and total cost of care for beneficiaries with SUD. Cost of acute care for SUD is hypothesized to decrease as a result of wider access to and participation in SUD treatment. All beneficiaries are included in the denominator for this measure. Because unmanaged SUD can worsen other conditions, leading ED visits or inpatient admissions, cost of all acute care for beneficiaries with SUD will also be tracked to determine whether stabilizing these individuals in treatment reduces these costs as well. Finally, total cost of care for beneficiaries with SUD, including care for SUD and other causes, in all settings, will be included to assess whether the costs of providing SUD treatment are balanced by reduced costs in other services.

5.Data Sources

Secondary Data

The measures used for evaluation are listed in Table 4. Most are derived from claims and administrative data and will be reported to CMS as part of the approved SUD waiver monitoring protocol. National survey data from NSDUH and N-SSATS will be obtained from SAMHSA. Overdose mortality data will be obtained from the CDC/National Center for Health Statistics.

Claims Data

MCO claims data is submitted at least weekly, and uploaded monthly to the state's data warehouse. Late or incomplete submissions have not been common, and have been resolved promptly, rarely impacting the monthly upload.

The Nebraska Medicaid program is also in the development process for a new data warehouse and business intelligence technology platform. Development for this Data Management and Analytics (DMA) project began in February of 2018 and is scheduled for go-live in November 2020. For example, currently contracted Heritage Health plans submit pharmacy encounter data based on Nebraska's proprietary pharmacy encounter format. The proprietary format is necessitated by the limitations of the state's legacy MMIS system. With the completion of the DMA project, Heritage Health plans will submit encounter data utilizing a NCPDP standard transaction format. The NCPDP standard format will provide the Nebraska Medicaid program with significantly more information about each pharmacy encounter than is currently captured within the proprietary format. While the changeover presents some risk, the state expects that the new DMA platform will have a positive impact on this demonstration, allowing for more detailed data collection and reporting that facilitates both implementation and evaluation.

Primary Data

Key Informant Interviews

Qualitative data will be gathered through document review and key informant interviews. Semi-structured key informant interviews with lasting 30-45 minutes will be conducted by phone or videoconference, with privacy protections in accordance with CMS guidelines. Interviews will be recorded and transcribed. Interview guides will be developed by the IE in collaboration with DHHS for providers, and for state administrators involved in implementation of the waiver demonstration.

As appropriate, interviews will explore program implementation, and topics drawn from the Access and Quality driver diagrams; examples are shown in Table 7.

Based on the unique count of NPI numbers with specialty 26 (psychiatry/mental health/substance abuse) for providers billing Medicaid, excluding those who are not billing independently, Nebraska had 506 SUD provider access points as of November 2019. An informative sample of providers will be drawn from this pool, with attention to diversity in region, role, and facility type, e.g. residential or outpatient. Two waves of interviews will be conducted, in order to explore changes over the course of implementation (Table 8). Where possible, providers who participated in wave 1 will be re-interviewed for wave 2. Where the original interviewee is not available, another provider from the same facility will be interviewed if one is available; otherwise, the evaluator will seek to interview another provider with the same specialty practicing in a similar institutional setting. For administrators, the evaluator will seek to include the same roles – which may or not be the same individuals – in wave 2 as in wave 1. Interviewees will be compensated for their participation with a gift card.

Table 7 Example Topics to be Included in Key Informant Interviews

Research Question	Demonstration Goals	Example topics
1.In what ways did (or did not) the demonstration increase access to health care for beneficiaries with SUD?	• Access to evidence-based SUD treatment • Access to care for physical health conditions	• Perceived impact of new rules on the ease of placing patients in appropriate settings • Perceived impact of new rules on the availability of a full continuum of care for SUD, including MAT services • Existing or planned growth in capacity due to rule changes or SUD IMD demonstration authority.
2.In what ways did (or did not) the demonstration improve the quality of SUD treatment?	• Identification, initiation, and engagement in treatment for SUD • Adherence to and retention in treatment for SUD • Reduced ED visits and readmissions • Reduced OD deaths	• Perceived impact of new rules on ease of engaging and retaining beneficiaries in treatment for SUD • Perceived impact of rule revisions on discharge planning in residential care settings and service delivery post-discharge
3.What changes might make the demonstration more effective in achieving program goals of increased access and improved quality?	• Implementation challenges and successes	• Provider familiarity with new rules for coverage • Perceived impact of rule changes on administrative burden • Suggestions for improvements or course corrections

Table 8 Key Informant Interviews

	Number of interviews
Wave 1 (Demonstration year 2)	
Providers	30-35
Administrators	8-12
Wave 2 (Demonstration year 4)	
Providers	30-35
Administrators	8-12
Total	76-94

MCO non-claims reporting

All MCOs receiving Nebraska Medicaid payments are required to submit templated reports including non-claims data, quality measures, and qualitative information on required activities. New reporting requirements will include ASAM critical levels of care including IMD stays MAT/OTP. MCOs will be required to submit reports on an ad hoc basis throughout the demonstration.

During the demonstration period, all MCOs will be required to conduct an assessment of provider capacity, and report the results to the state. Currently MCOs are required to report SUD/BH health network capacity and access at a county level. Each MCO submits a standard set of required data that includes number and average distance from providers by county, and by classification (urban, rural, frontier). New requirements currently under development will mandate reporting of this same information decomposed by critical (ASAM) level of care including MAT/OTP.

Provider Enrollment Database

All providers must be listed in the state's provider enrollment database before MCOs can contract with them for Medicaid-reimbursed services. The state's list of Medicaid-enrolled providers is updated at least weekly. The number of providers offering SUD treatment or specific services will be obtained by linking claims data to the provider enrollment database.

6.Analytic Methods

Descriptive statistics

The IE will use descriptive statistical methods to generate summary tables of population size and characteristics, outcomes for the pre and post demonstration periods, and distribution of outcomes by demographic characteristics and relevant subgroupings. Data will be analyzed using standard tests as rates, proportions, frequencies, and measures of central tendency (e.g., mean, median, mode). These tables will be used to develop a quantitative picture of the population, to describe raw trends, and to identify characteristics that will be included as covariates in regression modeling. Prior to performing regression analysis, the expansion and non-expansion populations will be compared using t-tests to confirm that the two groups do not differ significantly in demographic or clinical characteristics that would make the comparison to baseline inappropriate. ANOVA/MANOVA tests will be used as a first pass comparison of mean outcomes for demonstration years to pre-demonstration years. For metrics derived from NSDUH and N-SSATS survey data, results for Nebraska will be compared to national results for each year based on the reported confidence interval (NSDUH) or by calculating a ratio of number of facilities to adult population size (N-SSATS).

ITS regression modeling

The evaluation will use ITS analysis to test for different linear effects in the pre-demonstration and post-demonstration periods. The function for an example outcome C is described in table 9 below.

Table 9 Interrupted Time Series function

Equation	
$$C = \beta 0 + \beta 1 * TIME + \beta 2 * POST + \beta 3 * (TIME * POST) + \beta i * COVAR + \varepsilon$$	
Variable	Description
TIME	A count variable that starts with the first quarter pre-demonstration period data and ends with the last quarter of post-demonstration period data.
POST	An indicator variable that equals 1 if the month occurred on or after demonstration start date.
COVAR	A set of covariates, such as age, gender, race, dual Medicare-Medicaid enrollment, and month.

The marginal effect and standard error for each term will be derived and reported. The average marginal effect of the interaction term (β3*TIME*POST) represents the apparent difference between the pre- and post-demonstration periods. Table 4 indicates the hypothesis for each outcome.

Qualitative analysis

Qualitative analysis will be used for key informant interview transcripts. The goal of the analysis is to identify perceptions of providers and administrators regarding the ways the demonstration did or did not achieve the program goals of increased access and improved quality. These perceptions will be used in combination with quantitative analysis to understand demonstration impact, and also to identify challenges or potential course corrections for consideration by the state.

The research questions to be addressed are:

1. In what ways did (or did not) the demonstration increase access to health care for beneficiaries with SUD?
2. In what ways did (or did not) the demonstration improve the quality of SUD treatment?
3. What changes might make the demonstration more effective in achieving program goals of increased access and improved quality?

As shown in Table 7, interviews will address these questions by probing for perspectives on the implementation and outcomes of the demonstration. Thematic analysis using a coding tree derived from the access and quality driver diagrams will be used to excerpt transcripts. Additional themes that arise during coding will be added to the analysis. Results of the research questions 1 and 2 will be used to add context to the quantitative findings regarding access and quality. Results of research question 3 will be reported as a distinct section, and will inform the Evaluation Report chapter on Lessons Learned and Recommendations.

D. CHALLENGES AND METHODOLOGICAL LIMITATIONS

1. Lack of a true comparison group

The target population for the demonstration is Nebraska Medicaid beneficiaries with SUD. A true comparison group for this demonstration would be an equivalent population of Medicaid beneficiaries who are not offered the services provided through the waiver. Because all beneficiaries with SUD are eligible for the demonstration, a true comparison group is not available. Nebraska residents not eligible for Medicaid, and residents of other states, are different in demographics and acuity, and will have access to a varied range of SUD services depending on their coverage or uninsured status. The most rigorous method available is the interrupted time series regression, which will compare trends during the demonstration period to trends in the pre-intervention time period.

2. Expansion of Medicaid population

Beginning in Oct 2020, the expansion of Heritage Health is expected to grow the Nebraska Medicaid adult population from approximately 64,000 individuals to approximately 117,000 during the first year, and 144,000 in the second year, with more gradual increases in following years. If the prevalence of SUD stays unchanged, this is expected to increase the number of individuals with SUD from approximately five thousand to over ten thousand unique individuals per year. The large influx of individuals who were not eligible during the pre-demonstration

period is a limitation to the interpretation of the ITS comparison. Current actuarial models suggest that the expansion population is not significantly different from the non-expansion adult population in acuity or key variables, which mitigates concerns about the differences between the pre and post demonstration time periods. To further mitigate this limitation, the evaluator will conduct the ITS modeling with and without the expansion population to determine whether the result changes when they are included.

3. Sample size

The number of Nebraska Medicaid beneficiaries with SUD (See Table 5) is estimated at 10,392 unique individuals per year during the demonstration period, which may not be large enough to conduct statistical analysis on all subgroups of interest. Moreover, evaluation measures are with few exceptions collected for the full SUD population, but some may be most applicable to individuals with OUD, which represents only 16% of the SUD population. The estimated 1617 individuals with OUD per year may not be enough to drive change for the full evaluation population. For this reason, the evaluator will analyze the OUD subgroup separately as well, to determine whether changes can be detected specifically among individuals with OUD. The small size of the OUD sample may limit sensitivity and significance of the results.

4. Identification of beneficiaries with SUD

Individuals will be included in the evaluation if they have an SUD diagnosis or claim within the previous 12 months, based on CMS guidelines. Individuals with an SUD that has not resulted in a diagnosis or treatment will not be detected. Because some beneficiaries transition on and off Medicaid, a full 12 months of claims may not be available for all individuals, and there is a risk of missing individuals who have SUD due to incomplete data. This is especially true for individuals newly eligible as a result of HHA expansion. This is likely to lead to an under-identification of beneficiaries with an SUD, but is preferable to excluding individuals who lack 12 months of continuous data. In order to mitigate the under-identification, DHHS is investigating the feasibility and legal authority to use data from the Division of Behavioral Health which could identify newly enrolled individuals who received an SUD-related service in the past 12 months.

The failure to detect individuals who have SUD but are not identified due to incomplete data has a similar effect as failure to detect individuals with undiagnosed SUD. Incomplete identification will reduce the sample size, and could alter the characteristics of the population, which should be considered in interpretation of the results.

5. Data availability

Overdose prevention is not a primary target of the demonstration, but the frequency of lethal overdose may be reduced because of improved access to and quality of SUD treatment. Overdose mortality was not tracked in Nebraska during the pre-demonstration period, so no baseline is available in state data. Data from the CDC will be used to measure fatal overdose, which will produce a rate for the state adult population as a whole, rather than specific to Medicaid beneficiaries. For 2018, the CDC and NIDA reported a rate of 7.4 per 100,000 for all

overdoses, and 3.3 for opioid overdoses.[1516] Because the rate is low at baseline, and the demonstration target population is only a portion of the population contributing to the state rate, any impact of the demonstration on overdose rates among the target population may be too small for the evaluation to detect.

[15] National Center for Health Statistics, 2019. Retrieved from https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm

[16] NIDA. 2020, July 2. Nebraska: Opioid-Involved Deaths and Related Harms. Retrieved from https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/nebraska-opioid-involved-deaths-related-harms on 2020, July 15

ATTACHMENTS

A. Independent Evaluator

Procurement for an evaluation contractor to assist the State in executing its SUD demonstration evaluation plan will be pursuant to the State of Nebraska procurement guidelines with resulting agreement contingent upon approval from Nebraska's Governor and Executive Council. The State retains responsibility for monitoring the SUD delivery system, mid-point assessment of the program's effectiveness and overall demonstration performance. To mitigate any potential conflict of interest, the evaluation contractor is responsible for:

- Secondary analysis of data collected for monitoring purposes;
- Benchmarking performance to national standards;
- Evaluating changes over time;
- Interpreting results; and
- Producing evaluation reports.

As part of the focused IMD evaluation, the evaluator is responsible for final measure selection, identifying, if viable, other State systems that may serve as comparisons, conducting all data analysis, measuring change overtime and developing sensitivity models as necessary to address study questions.

The State anticipates one procurement for all evaluation activities and the production of required CMS reports. The successful bidder will demonstrate, at a minimum, the following qualifications:

- The extent to which the evaluator can meet State RFP minimum requirements;
- The extent to which the evaluator has sufficient capacity to conduct the proposed evaluation, in terms of technical experience and the size/scale of the evaluation;
- The evaluator's prior experience with similar evaluations;
- Past references; and
- Value, e.g., the assessment of an evaluator's capacity to conduct the proposed evaluation with their cost proposal, with consideration given to those that offer higher quality at a lower cost.

Consistent with the requirements of 42 CFR § 431.420, Nebraska DHHS will select and retain an independent evaluator to complete the independent evaluation of the demonstration required under 42 CFR § 431.424. DHHS will utilize the State of Nebraska's procurement process to contract with this evaluator and promote an independent evaluation, through the general requirements for each state contractor as well as project-specific standards. These include requirements for third-party contractors to avoid conflicts of interest, adhere to the project's designated scope of work, and maintain professional independence from Department staff and others. Each bidding party will submit a proposal to DHHS that attests to present satisfaction of these requirements, and DHHS Procurement staff and MLTC will work with the evaluator to identify and address concerns that arise during the administration of the contract. By requiring initial satisfaction of these standards by the contracting party in order to be awarded the contract, as well as ongoing maintenance of the requirements during the term of service, DHHS will be in a position to receive an objective evaluation report that is the product of a fair, impartial, and conflict-free evaluation.

B. Budget

Table B1 shows the total estimated cost for evaluation activities through the demonstration years and two years beyond.

Table B1 Budget for Evaluation Activities

	Total Estimated Cost							
Evaluation Activity	DY1 7/1/2019-6/30/2020	DY2 7/1/2020-6/30/2021	DY3 7/1/2021-6/30/2022	DY4 7/1/2022-6/30/2023	DY5 7/1/2023-6/30/2024	POST Y6 7/1/2024-6/30/2025	POST Y7 7/1/2025-6/30/2026	**Total**
Project Management (e.g. regular project meetings, status updates and ad hoc discussions)	$0	$14,976	$19,968	$34,528	$19,968	$19,968	$19,968	$129,376
Semi-Structured Interviews Data Collection and Analysis	$0	$18,678	$118,144	$8,424	$115,024	$0	$0	$260,270
Quantitative Data Collection, Cleaning and Analysis	$0	$40,123	$53,498	$53,498	$53,498	$40,123	$0	$240,739
Interim Evaluation Report Generation	$0	$0	$0	$135,824	$21,029	$0	$0	$156,853
Summative Evaluation Report Generation	$0	$0	$0	$0	$0	$0	$204,464	$204,464
Total	$0	$73,778	$191,610	$232,274	$209,518	$60,091	$224,432	$991,702

C. Timeline and Milestones

Table C1 Timeline and Milestones for Evaluation

		DY1	DY2	DY3	DY4	DY5	POST Y6	POST Y7
Milestones	**Dates**	**7/1/2019-6/30/2020**	**7/1/2020-6/30/2021**	**7/1/2021-6/30/2022**	**7/1/2022-6/30/2023**	**7/1/2023-6/30/2024**	**7/1/2024-6/30/2025**	**7/1/2025-6/30/2026**
Evaluation Design	4/30/2020	X						
Procurement of IE	TBD		X					
Data Collection	10/1/2020-6/30/2024		X	X	X	X	X (runout)	
Analysis	Ongoing		X	X	X	X	X	X
KII Wave 1	7/1/2021-12/30/2021			X				
Interim Evaluation Report	6/30/2023				X			
KII Wave 2	7/1/2021-12/30/2021					X		
Summative Evaluation Report	1/30/2026							X