ENTERS FOR MEDICARE & MEDICAID SERVICES

EXPENDITURE AUTHORITY

NUMBER: 11-W-10024/7

TITLE: Nebraska Substance Use Disorder Program

AWARDEE: Nebraska Department of Health and Human Services, Division of Medicaid and Long-Term Care

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Nebraska for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from July 1, 2019 through June 30, 2024, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

The following expenditure authorities may only be implemented consistent with the approved Special Terms and Conditions (STCs) and shall enable Nebraska to operate the above-identified section 1115(a) demonstration.

Residential Treatment for Individuals with Substance Use Disorder (SUD). Expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an Institution for Mental Diseases (IMD).

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS (STCs)

NUMBER: 11-W-10024/7

TITLE: Nebraska Substance Use Disorder

AWARDEE: Nebraska Department of Health and Human Services
Division of Medicaid and Long-Term Care

I. PREFACE

The following are the STCs for the Nebraska Substance Use Disorder section 1115(a) Medicaid demonstration (hereinafter "demonstration"), to enable the Nebraska Department of Health and Human Services, Division of Medicaid and Long-Term Care (hereinafter "state") to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on those expenditure authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS related to the demonstration. These STCs neither grant additional expenditure authorities, nor expand upon those separately granted. These STCs are effective from July 1, 2019 to June 30, 2024 unless otherwise specified. The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Eligibility and Enrollment
V. Demonstration Programs and Benefits
VI. Cost Sharing
VII. Delivery System
VIII. General Reporting Requirements
IX. Monitoring
X. Evaluation of the Demonstration
XI. General Financial Requirements under title XIX
XII. Monitoring Budget Neutrality for the Demonstration
XIII. Schedule of Deliverables for the Demonstration Period

Additional attachments have been included to provide supplementary information and guidance for specific STCs.

- Attachment A: Developing the Evaluation Design
- Attachment B: Preparing the Interim and Summative Evaluation Reports
- Attachment C: SUD Implementation Plan
- Attachment D: SUD Monitoring Protocol

- Attachment E: SUD Evaluation Design

II. PROGRAM DESCRIPTION AND OBJECTIVES

The goal of this demonstration is for the state to maintain and enhance access to opioid use disorder (OUD) and other substance use disorder (SUD) services and continue delivery system improvements for these services to provide more coordinated and comprehensive treatment of Medicaid beneficiaries with SUD. This demonstration will provide the state with authority to provide high-quality, clinically appropriate treatment to beneficiaries with SUD while they are short-term residents in residential and inpatient treatment settings that qualify as IMDs. It will also support state efforts to implement models of care focused on increasing support for individuals in the community and home, outside of institutions, and improve access to a continuum of SUD evidence-based services at varied levels of intensity. This continuum of care shall be based on the American Society of Addiction Medicine (ASAM) criteria and/or other nationally recognized assessment and placement tools that reflect evidence-based clinical treatment guidelines.

During the demonstration period, the state seeks to achieve the following goals:

1. Increased rates of identification, initiation, and engagement in treatment for SUD;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. 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;
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 with SUD.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).

2. **Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
   a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.

   b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

5. **State Plan Amendments**. The state will not be required to submit title XIX or XXI State Plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP State Plan is affected by a change to the demonstration, a conforming amendment to the

appropriate State Plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP State Plans govern.

6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP State Plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

    a. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;

    b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;

    c. A data analysis which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable “with waiver” and “without waiver” status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the “with waiver” expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;

    d. An up-to-date CHIP allotment worksheet, if necessary;

    e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions,

as well as the oversight, monitoring and measurement of the provisions.

8. **Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer of the state in accordance with the requirements of 42 Code of Federal Regulations (CFR) 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit a phase-out plan consistent with the requirements of STC 9.

9. **Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.

    a. Notification of Suspension or Termination: The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

    b. Transition and Phase-out Plan Requirements: The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.

    c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.

    d. Transition and Phase-out Procedures: The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210 and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain

benefits as required in 42 CFR §431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

e. Exemption from Public Notice Procedures 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).

f. Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid State Plan.

g. Federal Financial Participation (FFP). If the project is terminated or any relevant waivers suspended by the state, FFP must be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

10. **Withdrawal of Waiver or Expenditure Authority.** CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX and title XXI. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

11. **Adequacy of Infrastructure.** The state will ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.

12. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR section 431.408 prior to submitting an application to extend the demonstration. For applications to amend the

demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 7 or extension, are proposed by the state.

13. **Federal Financial Participation.** No federal matching funds for expenditures for this demonstration, including for administrative and medical assistance expenditures, will be available until the SUD Implementation Plan is approved.

14. **Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The state Medicaid agency must exercise oversight of all delegated functions to operating agencies, MCOs, and any other contracted entities. The single state Medicaid agency is responsible for the content and oversight of the quality strategies for the demonstration.

15. **Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.101(b)(5).

IV. ELIGIBILITY AND ENROLLMENT

16. **Eligibility Groups Affected by the Demonstration.** Under the demonstration, there is no change to Medicaid eligibility. Standards and methodologies for eligibility remain set forth under the State Plan and are subject to all applicable Medicaid laws and regulations.

V. DEMONSTRATION PROGRAMS AND BENEFITS

17. **Opioid Use Disorder/Substance Use Disorder Program.** Under this demonstration, Nebraska Substance Use Disorder Program beneficiaries will have access to high quality, evidence-based SUD treatment services, ranging from medically supervised withdrawal management for SUDs to ongoing care for these conditions in cost-effective community-

based settings. The state will work to improve care coordination and care for co-occurring physical and mental health conditions. Nebraska will be expected to achieve a statewide average length of stay of 30 days in residential treatment settings, to be monitored pursuant to the SUD Monitoring Plan as outlined in STC 18 below.

The coverage of SUD treatment services during short term residential and inpatient stays in IMDs will expand Nebraska's current SUD benefit package available to all Nebraska Medicaid beneficiaries ages 21-64 as outlined in Table 1 (see unallowable expenditures not eligible for FFP, detailed in STC 45).

The state attests that the services indicated in Table 1 as being covered under the Medicaid State Plan authority are currently covered in the Nebraska Medicaid State Plan.

Table 1: Nebraska Substance Use Disorder Program SUD Benefits Coverage with Expenditure Authority

Benefit	Type	Medicaid Authority	Expenditure Authority
Outpatient services	SUD	1915(b) (Individual services covered)	N/A
Intensive outpatient services	SUD	1915(b) (Individuals services covered)	N/A
Inpatient services	SUD	1915(b) (Individual services covered)	Services provided to individuals in IMDs
Residential treatment services	SUD	1915(b)(Individual services covered)	Services provided to individuals residing in IMDs
Peer Support Services	SUD	State Plan	N/A
Medically Supervised Withdrawal Management	SUD	State Plan (contingent on anticipated SPA approval)	Services provided to individuals in IMDs
Opioid Treatment Program Services	SUD	State Plan (contingent on anticipated SPA approval)	Services provided to individuals in IMDs
Office Based Opioid Treatment	SUD	State Plan	Services provided to individuals in IMDs

18. **SUD Implementation Plan**. The state must submit the SUD Implementation Plan within 90 calendar days after approval of this demonstration. The state may not claim FFP for services provided in IMDs to beneficiaries with a primary diagnosis of SUD (e.g., OUD) until CMS has approved the SUD Implementation Plan. After approval of the SUD implementation plan required by these STCs, FFP will be available prospectively, not retrospectively. Once approved, the SUD Implementation Plan will be incorporated into the STCs as Attachment C and, once incorporated, may be altered only with CMS approval. Failure to submit a SUD Implementation Plan will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SUD program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral as described in STC 22.

    At a minimum, the SUD Implementation Plan must describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives for the program:

    - **Access to Critical Levels of Care for OUD and other SUDs.** Service delivery for new benefits, including residential treatment and withdrawal management, within 12-24 months of SUD demonstration approval;

    - **Use of Evidence-based SUD-specific Patient Placement Criteria.** Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as ASAM Criteria or other assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of demonstration approval;

    - **Patient Placement.** Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of demonstration approval;

    - **Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities.** Currently, residential treatment service providers must be a licensed organization, pursuant to the residential service provider qualifications described in Nebraska administrative code. The state must establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of

demonstration approval;

- **Standards of Care.** Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;

- **Standards of Care.** Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of demonstration approval;

- **Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for SUD/OUD.** An assessment of the availability of providers in the critical levels of care throughout the state, or in the regions of the state participating under this demonstration, including those that offer MAT within 12 months of demonstration approval;

- **Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and SUD/OUD.** Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;

- **Improved Care Coordination and Transitions between levels of care.** Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of demonstration approval.

- **SUD Health IT Plan.** Implementation of the milestones and metrics as detailed in STC 18(a) or Attachment C.

    a. **SUD Health Information Technology Plan ("Health IT Plan").** The SUD Health IT plan applies to all states where the Health IT functionalities are expected to impact beneficiaries within the demonstration. As outlined in SMDL #18-011 *and #17-003, respectively,* states must submit to CMS the applicable Health IT Plan(s), to be included as a section(s) of the associated Implementation Plan (see STC 18), to develop infrastructure and capabilities consistent with the requirements outlined in the SUD demonstration-type.

    The SUD Health IT Plan must detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The plan(s) will also be used to identify areas of health IT ecosystem improvement. The Plan must include implementation milestones and projected dates for achieving

them (see Attachment C), and must be aligned with the state's broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state's Behavioral Health (BH) IT Health Plan.

The state must include in its Monitoring Protocol (see STC 18.b) an approach to monitoring its SUD Health IT Plan which will include performance metrics to be approved in advance by CMS.

The state must monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines and report on its progress to CMS in in an addendum to its Annual Report (see STC 26).

As applicable, the state should advance the standards identified in the 'Interoperability Standards Advisory – Best Available Standards and Implementation Specifications' (ISA) in developing and implementing the state's SUD Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.

Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state should use the federally-recognized standards, barring another compelling state interest.

Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally-recognized ISA standards, barring no other compelling state interest.

Components of the Health IT Plan include:

i. The SUD Health IT Plan must describe the state's goals, each DY, to enhance the state's prescription drug monitoring program (PDMP).[1]
ii. The SUD Health IT Plan must address how the state's PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[2] This will also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan must describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients' history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.

[1] Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance prescriptions in states. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the "opioid" epidemic and facilitate a nimble and targeted response.

[2] *Ibid.*

iii. The SUD Health IT Plan will, as applicable, describe the state's capabilities to leverage a master patient index (or master data management service, etc.) in support of SUD care delivery. Additionally, the Health IT Plan must describe current and future capabilities regarding PDMP queries—and the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.

iv. The SUD Health IT Plan must describe how the activities described in (i), (ii) and (iii) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.[3]

v. The SUD Health IT Plan must describe the state's current and future capabilities to support providers implementing or expanding Health IT functionality in the following areas: 1) Referrals, 2) Electronic care plans and medical records, 3) Consent, 4) Interoperability, 5) Telehealth, 6) Alerting/analytics, and 7) Identity management.

vi. In developing the SUD Health IT Plan, states should use the following resources.

1. States may use federal resources available on Health IT.Gov (https://www.healthit.gov/topic/behavioral-health) including but not limited to "Behavioral Health and Physical Health Integration" and "Section 34: Opioid Epidemic and Health IT" (https://www.healthit.gov/playbook/health-information-exchange/).
2. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.
3. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to *PDMP interoperability*, electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.

b. **SUD Monitoring Protocol.** The state must submit a Monitoring Protocol for the SUD programs authorized by this demonstration within 150 calendar days after approval of the demonstration. The SUD Monitoring Protocol template must be developed in cooperation with CMS and is subject to CMS approval. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs, as Attachment D. Progress on the performance measures identified in the Monitoring Protocol will be reported via the quarterly and annual monitoring reports. Components of the Monitoring Protocol include:

[3] Shah, Anuj. Corey Hayes and Bradley Martin. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015, MMWR Morb Mortal Wkly Rep 2017;66.

i. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 18, and reporting relevant information to the state's Health IT plan described in STC 18.a;
ii. A description of the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Section VIII of the demonstration; and
iii. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.

19. Evaluation. The SUD Evaluation will be subject to the same requirements as the overall demonstration evaluation, as described in Sections VIII (General Reporting Requirements) and X (Evaluation of the Demonstration) of these STCs.

VI. COST SHARING

20. Cost Sharing. Cost sharing requirements under the demonstration will not differ from the approved Medicaid State Plan.

VII. DELIVERY SYSTEM

21. Delivery System. Nebraska's delivery system will continue to be the Heritage Health Medicaid managed care program that utilizes capitated Medicaid MCOs to provide State Plan and 1915(b) authorized behavioral health services. Heritage Health will continue to operate as approved in DHHS' 1915(b) waiver.

VIII. GENERAL REPORTING REQUIREMENTS

22. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement. The following process will be used: 1) Thirty (30) days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) Thirty days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).

b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state's written extension request.

c. If CMS agrees to an interim corrective plan in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.

d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement with respect to required deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified in these STCs, the deferral(s) will be released.

e. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

23. **Deferral of Federal Financial Participation (FFP) from IMD Claiming for Insufficient Progress Toward Milestones.** Up to $5,000,000 in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones as evidenced by reporting on the milestones in the SUD Implementation Plan and the required performance measures in the Monitoring Protocol agreed upon by the state and CMS. Once CMS determines the state has not made adequate progress, up to $5,000,000 will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made.

24. **Submission of Post-approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.

25. **Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state will work with CMS to:

a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
c. Submit deliverables to the appropriate system as directed by CMS.

IX. MONITORING

26. Monitoring Reports. The state must submit three (3) Quarterly Reports and one (1) Annual Report each DY. The fourth quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual Report. The Quarterly Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The compiled Annual Report is due no later than ninety (90) calendar days following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

a. Operational Updates. The operational updates will focus on progress toward meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

b. Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring

Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately.

d. Evaluation Activities and Interim Findings. Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.
e. SUD Health IT. The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 18.a.

27. SUD Mid-Point Assessment. The state must arrange with an independent assessor to conduct an independent mid-point assessment by January 1, 2022. In the design, planning and conduction of the mid-point assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of managed care organizations (MCO), SUD treatment providers, beneficiaries, and other key partners.

The state must require the assessor to provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than 60 days after the mid-point assessment due date. The state must brief CMS on the report.

For milestones and measure targets at medium to high risk of not being achieved, the state must submit to CMS modifications to the SUD Implementation Plan, and the SUD Monitoring Protocol for ameliorating these risks. Modifications to the applicable Implementation Plan and Monitoring Protocol are subject to CMS approval.

Elements of the mid-point assessment include:

a. An examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plans, and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol;
b. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date;
c. A determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets;
d. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state's SUD Implementation Plan or to pertinent factors that the

state can influence that will support improvement; and

e. An assessment of whether the state is on track to meet the budget neutrality requirements.

28. **Corrective Action.** If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10.

29. **Close-Out Report**. Within 120 calendar days after the expiration of the demonstration, the state must submit a Draft Close-Out Report to CMS for comments.

    a. The draft close-out report must comply with the most current guidance from CMS.
    b. The state will present to and participate in a discussion with CMS on the close-out report.
    c. The state must take into consideration CMS' comments for incorporation into the final close-out report.
    d. The final close-out report is due to CMS no later than 30 calendar days after receipt of CMS' comments.
    e. A delay in submitting the draft or final version of the close-out report may subject the state to penalties described in STC 22.

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

    a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to) any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, enrollment and access, budget neutrality, and progress on evaluation activities.
    b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.
    c. The state and CMS will jointly develop the agenda for the calls.

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

X. EVALUATION OF THE DEMONSTRATION

32. **Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 22.

33. **Independent Evaluator.** Upon approval of the demonstration, the state must begin to arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party to sign an agreement that the independent party will conduct the demonstration evaluation in an independent manner in accord with the CMS-approved draft Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

34. **Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than 180 days after the approval of the demonstration. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable.

    The draft Evaluation Design must be developed in accordance with the following CMS guidance (including but not limited to):

    a. All applicable Evaluation Design guidance, including guidance about SUD. Hypotheses applicable to the demonstration as a whole, and to all key policies referenced above, will include (but will not be limited to): the effects of the demonstration on health outcomes; the financial impact of the demonstration (for example, such as an assessment of medical debt and uncompensated care costs).

    b. Attachment A (Developing the Evaluation Design) of these STCs, technical assistance for developing SUD Evaluation Designs (as applicable, and as provided by CMS), and all applicable technical assistance on how to establish comparison groups to develop a Draft Evaluation Design.

35. **Evaluation Budget.** A budget for the evaluations must be provided with the draft Evaluation Designs. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluations such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the designs are not sufficiently developed, or if the estimates appear to be excessive.

36. **Evaluation Design Approval and Updates.** The state must submit the revised draft Evaluation Designs within 60 calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design(s), the documents will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design to the state's website within thirty (30) calendar days of CMS approval. The state must implement the evaluation designs and submit a description of its evaluation implementation progress in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in theses STCs. Once CMS approves the evaluation designs, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

37. **Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Reports) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

38. **Interim Evaluation Report.** The state must submit an Interim Evaluation Report for each evaluation design, as applicable, and for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Reports should be posted to the state's website with the application for public comment.

    a. The Interim Evaluation Reports will discuss evaluation progress and present findings to date as per the approved evaluation design.
    b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Reports must include an evaluation of the authority as approved by CMS.
    c. If the state is seeking to renew or extend the demonstration, draft Interim Evaluation

Reports is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses and a description of how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, Interim Evaluation reports are due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, draft Interim Evaluation Report*s* are due to CMS on the date that will be specified in the notice of termination or suspension.

d. The state must submit final Interim Evaluation Reports 60 calendar days after receiving CMS comments on the draft Interim Evaluation Reports and post the document to the state's website.
e. The Interim Evaluation Report*s* must comply with Attachment B of these STCs.

39. Summative Evaluation Report. The draft Summative Evaluation Reports must be developed in accordance with Attachment B (Preparing the Evaluation Report) of these STCs. The state must submit draft Summative Evaluation Reports for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Reports must include the information in the approved Evaluation Design.

a. Unless otherwise agreed upon in writing by CMS, the state must submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.
b. The final Summative Evaluation Report must be posted to the state's Medicaid website within 30 calendar days of approval by CMS.

40. Corrective Action Plan Related to Evaluation. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of a renewal process when associated with the state's Interim Evaluation Report. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10.

41. State Presentations for CMS. CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the Interim Evaluation Report, and/or the Summative Evaluation Report.

42. Public Access. The state shall post the final documents (e.g., Monitoring Reports, Close out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 calendar days of approval by CMS.

43. Additional Publications and Presentations. For a period of 12 months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to

release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

XI. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

44. Allowable Expenditures. This demonstration project is approved for expenditures applicable to services rendered during the demonstration approval period designated by CMS.

45. Unallowable Expenditures. In addition to the other unallowable costs and caveats already outlined in these STCs, the state may not receive FFP under any expenditure authority approved under this demonstration for any of the following:

a. Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.
b. Costs for services provided in a nursing facility as defined in section 1919 of the Act that qualifies as an IMD.
c. Costs for services provided to inmates of a public institution, as defined in 42 CFR 435.1010 and clause A after section 1905(a) except if the individual is admitted for at least a 24 hour stay in a medical institution.

46. Standard Medicaid Funding Process. The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this Medicaid section 1115 demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state shall submit form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

47. Extent of Federal Financial Participation for the Demonstration. Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole for the following, subject to the budget neutrality expenditure limits described in section XI:

a. Administrative costs, including those associated with the administration of the demonstration;

b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid State Plan; and

c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.

48. **Sources of Non-Federal Share.** The state certifies that its match for the non-federal share of funds for this section 1115 demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

    a. The state acknowledges that CMS has authority to review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.

    b. The state acknowledges that any amendments that impact the financial status of this section 1115 demonstration must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

49. **State Certification of Funding Conditions.** The state must certify that the following conditions for non-federal share of demonstration expenditures are met:

    a. Units of government, including governmentally operated health care providers, may certify that state or local monies have been expended as the non-federal share of funds under the demonstration.

    b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.

    c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general

revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR §433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR §433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.

d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments.

e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR §447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

50. **Program Integrity.** The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.

51. **Medicaid Expenditure Groups (MEG).** MEGs are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The following table provides a master list of MEGs defined for this demonstration.

Table 2: Master MEG Chart

MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description
ABD	Hypo 1	X		X	Aged, Disabled and Blind
DUAL	Hypo 2	X		X	Dual Eligibles

FAM	Hypo 3	X		X	Families
EXP Non-Medically Frail eff. 10/1/20	Hypo 4	X		X	Expansion population-non-medically frail
EXP Medically Frail eff. 10/1/20	Hypo 5	X		X	Expansion population-medically frail

52. **Reporting Expenditures and Member Months.** The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-10024/7). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

    a. Cost Settlements. The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b, in lieu of lines 9 or 10c. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.

    b. Premiums and Cost Sharing Collected by the State. The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by demonstration year on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.

    c. Pharmacy Rebates. Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.

d. Administrative Costs. The state will separately track and report administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the table below, administrative costs are not counted in the budget neutrality tests.

e. Member Months. As part of the Quarterly and Annual Monitoring Reports described in section IX, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita, and as also indicated in the table below. The term "eligible member months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.

f. Budget Neutrality Specifications Manual. The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state's Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

Table 3: MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 Line(s) To Use	How Expenditures Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date

ABD	All medical assistance expenditures during an IMD stay month for Aged, Blind and Disabled beneficiaries	Refer to STC #45 Unallowable Expenditures	Follow CMS-64.9 Base Category of Service Definitions	Date of service	MAP	Y	July 1, 2019	June 30, 2024
DUAL	All medical assistance expenditures during an IMD stay month for Dual Eligible beneficiaries	Refer to STC #45 Unallowable Expenditures	Follow CMS-64.9 Base Category of Service Definitions	Date of Service	MAP	Y	July 1, 2019	June 30, 2024
FAM	All medical assistance expenditures during an IMD stay month for Families beneficiaries	Refer to STC #45 Unallowable Expenditures	Follow CMS-64.9 Base Category of Service Definitions	Date of Service	MAP	Y	July 1, 2019	June 30, 2024
EXP Non-Medically Frail eff. 10/1/20	All medical assistance expenditures during an IMD stay month for Expansion population-non-medically frail beneficiaries	Refer to STC #45 Unallowable Expenditures	Follow CMS-64.9 Base Category of Service Definitions	Date of Service	MAP	Y	October 1, 2020	June 30, 2024
EXP Medically Frail eff. 10/1/20	All medical assistance expenditures during an IMD stay month for Expansion population-medically frail beneficiaries	Refer to STC #45 Unallowable Expenditures	Follow CMS-64.9 Base Category of Service Definitions	Date of Service	MAP	Y	October 1, 2020	June 30, 2024

53. **Demonstration Years.** Demonstration Years (DY) for this demonstration are defined in the table below.

Table 4: Demonstration Years		
Demonstration Year 1	July 1, 2019 to June 30, 2020	12 months
Demonstration Year 2	July 1, 2020 to June 30, 2021	12 months
Demonstration Year 3	July 1, 2021 to June 30, 2022	12 months
Demonstration Year 4	July 1, 2022 to June 30, 2023	12 months
Demonstration Year 5	July 1, 2023 to June 30, 2024	12 months

54. **Budget Neutrality Monitoring Tool.** The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the performance metrics database and analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing demonstration's actual expenditures to the budget neutrality expenditure limits described in section XI. CMS will provide technical assistance, upon request.[4]

55. **Claiming Period.** The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.

56. **Future Adjustments to Budget Neutrality.** CMS reserves the right to adjust the budget neutrality expenditure limit:

    a. To be consistent with enforcement of laws and policy statements, including

[4] 42 CFR §431.420(a)(2) provides that states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and §431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS's current approach is to include language in STCs requiring, as a condition of demonstration approval, that states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget neutrality limit. CMS has obtained Office of Management and Budget (OMB) approval of the monitoring tool under the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and states agree to use the tool as a condition of demonstration approval.

regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments. CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Social Security Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.

c. The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

XII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

57. **Limit on Title XIX Funding.** The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit may consist of a Main Budget Neutrality Test, and one or more Hypothetical Budget Neutrality Tests, as described below. CMS's assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.

58. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis. If a per capita method is used, the state is at risk for the per capita cost of State Plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the for all demonstration populations, CMS will not place the state at risk for changing economic conditions; however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.

59. **Calculation of the Budget Neutrality Limits and How They Are Applied.** To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which projected fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.

60. **Main Budget Neutrality Test.** This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests. Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS.

61. **Hypothetical Budget Neutrality.** When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid State Plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be "hypothetical;" that is, the expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats

these expenditures as if they were for approved Medicaid State Plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS's current view that states should not have to "pay for," with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid State Plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, during negotiations. If the state's WW hypothetical spending exceeds the supplemental test's expenditure limit, the state agrees (as a condition of CMS approval) to refund the FFP to CMS. The specific Hypothetical Budget Neutrality Test(s) which is/are applicable to this demonstration is/are detailed in STC(s) 62 below.

62. **Hypothetical Budget Neutrality Test 1: SUD Initiative.** This includes expenditures for the costs of all *current State Plan* medical assistance that could be covered, were it not for the Institution for Mental Diseases (IMD) prohibition and provided to otherwise-eligible individuals receiving SUD treatment while residing in an IMD setting**.** The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

Table 6: Hypothetical Budget Neutrality Test

MEG	PC or Agg*	WOW Only, WW Only, or Both	BASE YEAR 2017	TREND	DY 1	DY 2	DY 3	DY 4	DY 5
ABD	PC	Both	$1,838	3.6%	$2,008	$2,080	$2,155	$2,232	$2,313
DUAL	PC	Both	$304	3.6%	$332	$344	$356	$369	$382
FAM	PC	Both	$538	3.7%	$589	$611	$634	$657	$681
EXP Non-Medically Frail eff. 10/1/20	PC	Both		5.7%	$0	$818	$865	$914	$966
EXP Medically Frail eff. 10/1/20	PC	Both		5.7%	$0	$2,062	$2,180	$2,304	$2,436

63. **Composite Federal Share.** The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Main or Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

64. **Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from July 1, 2019 to June 30, 2024. If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

65. **Mid-Course Correction.** If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

Hypothetical Budget Neutrality Test(s)

Table 10: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations		
	Cumulative Target Definition	**Percentage**
DY 1	Cumulative budget neutrality limit plus:	2.0 percent
DY 1 through DY 2	Cumulative budget neutrality limit plus:	1.5 percent
DY 1 through DY 3	Cumulative budget neutrality limit plus:	1.0 percent
DY 1 through DY 4	Cumulative budget neutrality limit plus:	0.5 percent
DY 1 through DY 5	Cumulative budget neutrality limit plus:	0.0 percent

XIII. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION

Date	Deliverable	STC
30 calendar days after approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
90 calendar days after SUD program approval date	SUD Implementation Protocol	#18
150 calendar days after SUD implementation approval date	SUD Monitoring Protocol	#18.b
180 calendar days after approval date	Evaluation Design	#34
30 calendar days after CMS Approval	Approved Evaluation Design published to state's website	#36
June 30, 2023, or with renewal application	Draft Interim Evaluation Report	#38.c
60 days after receipt of CMS comments	Final Interim Evaluation Report	#38
Within 18 months after June 30, 2024	Summative Evaluation Report	#39
60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	#39
Monthly Deliverables	Monitoring Call	#30
Quarterly monitoring reports due 60 calendar days after end of each quarter, except 4th quarter, beginning November 2019.	Quarterly Progress Reports, including implementation updates	#26
	Quarterly Expenditure Reports	#26
Annual Deliverables - Due 90 calendar days after end of each 4th quarter	Annual Reports	#26

ATTACHMENT A

Developing the Evaluation Design

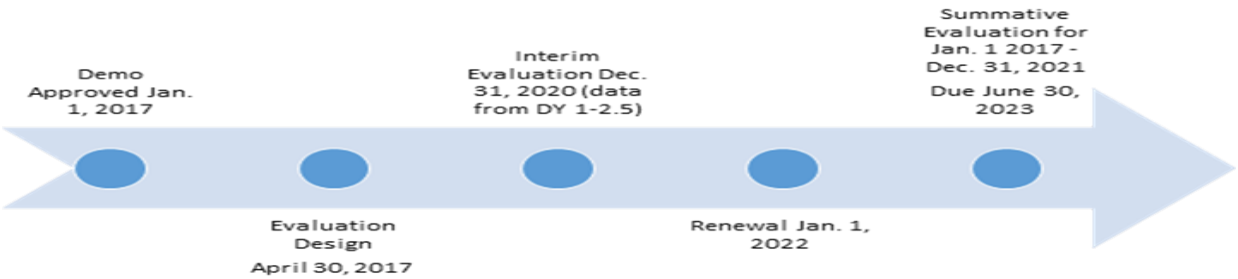
Introduction
For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform both Congress and CMS about Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions. Additional technical assistance is available from CMS, and resources are also available here: https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html

Expectations for Evaluation Designs
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals**.**

The format for the Evaluation Design is as follows:

General Background Information;
Evaluation Questions and Hypotheses;
Methodology;
Methodological Limitations;
Attachments.

Submission Timelines
There is a specified timeline for the state's submission of Evaluation Design and Reports. (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within thirty (30) days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of All Evaluation Designs
The Evaluation Design sets the stage for the Interim and Summative Evaluation Reports. It is important that the Evaluation Design explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology (and limitations) for the evaluation. A copy of the state's Driver Diagram (described in more detail in paragraph B2 below) should be included with an explanation of the depicted information.

A. General Background Information – In this section, the state should include basic information about the demonstration, such as:

1. The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).
2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
3. A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;
4. For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.
5. Describe the population groups impacted by the demonstration.

B. Evaluation Questions and Hypotheses – In this section, the state should:

1. Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.
2. Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The

diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf

3. Identify the state's hypotheses about the outcomes of the demonstration;
4. 4. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
5. 5. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

C. Methodology – In this section, the state is to describe in detail the proposed research methodology.

The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

This section provides the evidence that the demonstration evaluation will use the best available data; reports on, controls for, and makes appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what will be measured and how. Specifically, this section establishes:

1. *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?
2. *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.
3. *Evaluation Period* – Describe the time periods for which data will be included.
4. *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information.

   Additional items to ensure:
   a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
   b. Qualitative analysis methods may be used, and must be described in detail.
   c. Benchmarking and comparisons to national and state standards, should be used,

where appropriate.

d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

5. *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.
   If primary data (data collected specifically for the evaluation) – The methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection. (Copies of any proposed surveys must be reviewed with CMS for approval before implementation).
6. *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:
   a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.
   b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
   c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
   d. The application of sensitivity analyses, as appropriate, should be considered.
7. *Other Additions* – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

Table A. Example Design Table for the Evaluation of the Demonstration

Research Question	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
Hypothesis 1				
Research question 1a	-Measure 1 -Measure 2 -Measure 3	-Sample e.g. All attributed Medicaid beneficiaries -Beneficiaries with diabetes diagnosis	-Medicaid fee-for-service and encounter claims records	-Interrupted time series
Research question 1b	-Measure 1 -Measure 2	-sample, e.g., PPS patients who meet	-Patient survey	Descriptive statistics

	-Measure 3 -Measure 4	survey selection requirements (used services within the last 6 months)		
Hypothesis 2				
Research question 2a	-Measure 1 -Measure 2	-Sample, e.g., PPS administrators	-Key informants	Qualitative analysis of interview material

D. Methodological Limitations – This section provides detailed information on the limitations of the evaluation. This could include the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize the limitations. Additionally, this section should include any information about features of the demonstration that effectively present methodological constraints that the state would like CMS to take into consideration in its review. For example:

1. When the state demonstration is:

    a. Long-standing, non-complex, unchanged, or
    b. Has previously been rigorously evaluated and found to be successful, or
    c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)

2. When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:

    a. Operating smoothly without administrative changes; and
    b. No or minimal appeals and grievances; and
    c. No state issues with CMS-64 reporting or budget neutrality; and
    d. No Corrective Action Plans (CAP) for the demonstration.

E. Attachments

1. **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include "No Conflict of Interest" signed by the independent evaluator.

2. **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey

and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.

3. **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

ATTACHMENT B
Preparing the Interim and Summative Evaluation Reports

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provide important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. As these valid analyses multiply (by a single state or by multiple states with similar demonstrations) and the data sources improve, the reliability of evaluation findings will be able to shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

Intent of this Guidance

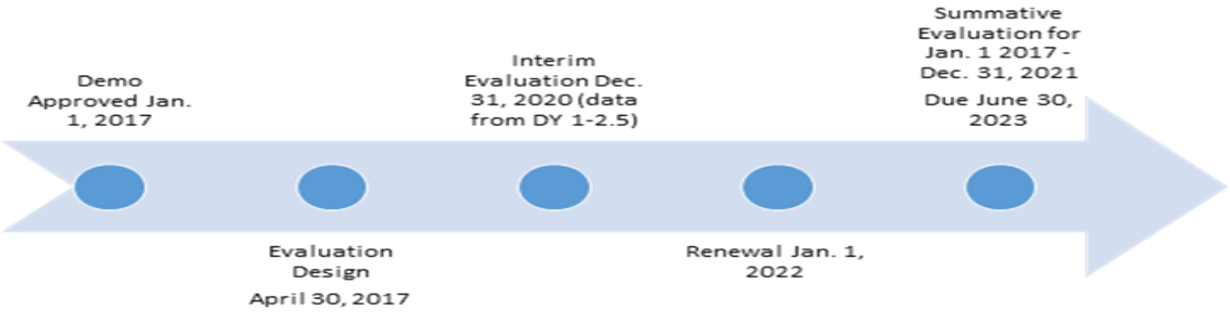
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Guidance is intended to assist states with organizing the required information in a standardized format and understanding the criteria that CMS will use in reviewing the submitted Interim and Summative Evaluation Reports.

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

A. Executive Summary;
B. General Background Information;
C. Evaluation Questions and Hypotheses;
D. Methodology;
E. Methodological Limitations;
F. Results;
G. Conclusions;
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
I. Lessons Learned and Recommendations; and
J. Attachment(s).

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish to the state's website the evaluation design within thirty (30) days of CMS approval, and publish reports within thirty (30) days of submission to CMS , pursuant to 42 CFR 431.424. CMS will also publish a copy to Medicaid.gov.



Required Core Components of Interim and Summative Evaluation Reports
The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. A copy of the state's Driver Diagram (described in the Evaluation Design guidance) must be included with an explanation of the depicted information. The Evaluation Report should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. Therefore, the state's submission must include:

A. **Executive Summary** – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.

B. **General Background Information about the Demonstration** – In this section, the state should include basic information about the demonstration, such as:
   1. The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
   2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
   3. A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
   4. For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
   5. Describe the population groups impacted by the demonstration.

C. **Evaluation Questions and Hypotheses** – In this section, the state should:
   1. Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
   2. Identify the state's hypotheses about the outcomes of the demonstration;

      a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
      b. Explain how this Evaluation Report builds upon and expands earlier

demonstration evaluation findings (if applicable); and

c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

D. Methodology – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design.

The evaluation design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An interim report should provide any available data to date, including both quantitative and qualitative assessments. The Evaluation Design should assure there is appropriate data development and collection in a timely manner to support developing an interim evaluation. This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1. *Evaluation Design* – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?
2. *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.
3. *Evaluation Period* – Describe the time periods for which data will be collected
4. *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?
5. *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data.
6. *Analytic methods* – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
7. *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.

A. Methodological Limitations - This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.

B. Results – In this section, the state presents and uses the quantitative and qualitative data to show to whether and to what degree the evaluation questions and hypotheses of the demonstration were achieved. The findings should visually depict the demonstration results (tables, charts, graphs). This section should include information on the statistical tests conducted.

C. Conclusions – In this section, the state will present the conclusions about the evaluation results.

1. In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
2. Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:
   a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

D. Interpretations, Policy Implications and Interactions with Other State Initiatives – In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long range planning. This should include interrelations of the demonstration with other aspects of the state's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretation of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

E. Lessons Learned and Recommendations – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

1. What lessons were learned as a result of the demonstration?
2. What would you recommend to other states which may be interested in implementing a similar approach?

F. Attachment - Evaluation Design: Provide the CMS-approved Evaluation Design

ATTACHMENT C
SUD Implementation Plan

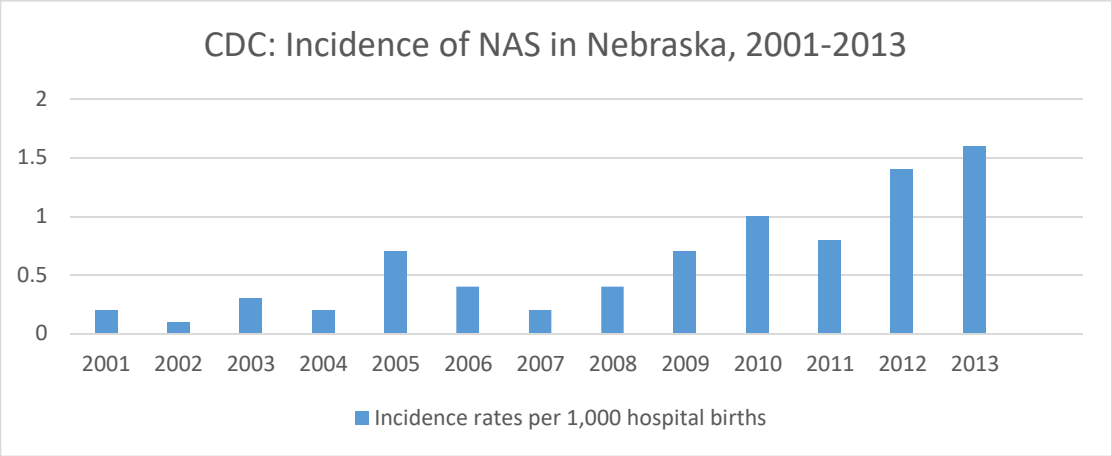
NEBRASKA MEDICAID 1115 SUBSTANCE USE DISORDER DEMONSTRATION IMPLEMENTATION PLAN PROTOCOL

INTRODUCTION

The United States is facing a public health crisis brought on by the abuse of prescription and illicit opioids. According to the National Institutes of Health, more than 130 Americans die from opioid overdoses every day.[1] In 2016, over 63,000 Americans died as a result of drug overdose, 42,200 of which were attributed to opioids.[2] The surge in opioid-related overdose deaths was significant enough to contribute to a decline in overall life expectancy in the U.S. for the second year in a row. This is the first time since the 1960s that U.S. life expectancy has declined over consecutive years.[3]

According to the CDC, Nebraska's drug overdose death rate was 6.9-11 per 100,000 people in 2017.[4] The State is also experiencing an increase in newborns exhibiting drug withdrawal symptoms. Data from the Centers for Disease Control and Prevention (CDC) indicates an increase in Nebraska in the rate of neonatal abstinence syndrome (NAS). As illustrated in Figure 1, incidents of NAS have grown at an annual rate of .1 per 1,000 hospital births from .2 per 1,000 in 2001 to 1.6 per 1,000 in 2013.[5]

Figure 1. Neonatal Abstinence Syndrome (NAS) in Nebraska



[1] National Institutes of Health, Opioid Overdose Crises, January 2019. Available at: https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#one

[2] Centers for Disease Control and Prevention, Drug Overdose Deaths in the United States, 1999–2016, December 2017. Available at: https://www.cdc.gov/nchs/data/databriefs/db294.pdf

[3] Life Expectancy Drops Again As Opioid Deaths Surge In U.S., National Public Radio, December 21, 2017. Available at: https://www.npr.org/sections/health-shots/2017/12/21/572080314/life-expectancy-drops-again-as-opioid-deaths-surge-in-u-s

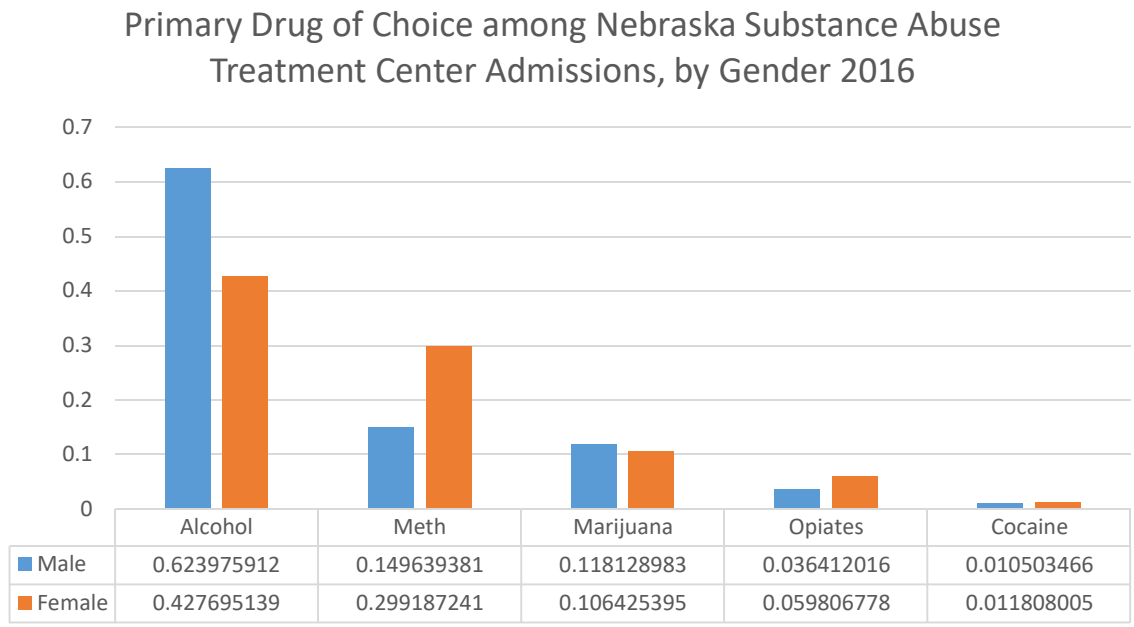
[4] CDC: Drug Overdose Deaths: https://www.cdc.gov/drugoverdose/data/statedeaths.html

[5] Ko JY, Patrick SW, Tong VT, Patel R, Lind JN, Barfield WD. Incidence of Neonatal Abstinence Syndrome — 28 States, 1999–2013. MMWR Morb Mortal Wkly Rep 2016; 65:799–802. DOI: http://dx.doi.org/10.15585/mmwr.mm6531a2.

While Nebraska has not experienced the type of public health crisis afflicting other states as a result of prescription and illicit opioid abuse, the state is still feeling the impact of the national epidemic. Opioid overdoses were responsible for 59 deaths in Nebraska in 2017.[6]

Nebraskans, including those participating in the Medicaid program, continue to struggle with a variety of substance use challenges including opioids. Figure 2 illustrates the drug of choice identified by individuals admitted to Substance Abuse Treatment Centers (SATC) in 2016.

Figure 2. Nebraska Primary Drug of Choice



	Alcohol	Meth	Marijuana	Opiates	Cocaine
Male	0.623975912	0.149639381	0.118128983	0.036412016	0.010503466
Female	0.427695139	0.299187241	0.106425395	0.059806778	0.011808005

Note: Excludes admissions in which the drug of choice information was not reported
Source: Centralized Data System, Nebraska Division of Behavioral Health

The Nebraska Medicaid program's continuum of substance use disorders (SUD) services reflects the experience of the state's population. Consequently, that continuum addresses the areas of highest current need which includes most prominently alcohol and methamphetamine abuse.

Due to Nebraska currently experiencing a lower public health impact related to opioid use disorder (OUD) including fewer overdose deaths when compared to the national trend, the Nebraska Department of Health and Human Services' (DHHS) OUD initiatives focus on the prevention of opioid addiction, through interventions such as the state's Prescription Drug Monitoring Program (PDMP)[7] and

[6] DHHS Receives Additional $10.9 Million for Opioid Prevention and Response. Available at: http://dhhs.ne.gov/News%20Release%20Archive/DHHS%20Receives%20Additional%20$10.9%20Million%20for%20Opioid%20Prevention%20and%20Response.pdf

[7] DHHS Launches Additional Enhancements to Prescription Drug Monitoring Program, January 8, 2018. Available at: http://dhhs.ne.gov/News%20Release%20Archive/DHHS%20Launches%20Additional%20Enhancements%20to%20Prescription%20Drug%20Monitoring%20Program%20%20.pdf

through the State Targeted Response (STR) Grant for Opioid Treatment,[8] the State Opioid Response (SOR) Grant, and targeted interventions implemented by the Medicaid program.

The PDMP in Nebraska, led by the DHHS Division of Public Health (DPH), is a robust initiative with well-defined measurable goals in place in order to address OUD in the state. The strategies in place are intended to increase provider use of the PDMP, provide education to healthcare professions on safe pain management without excessive opioid prescription, and educating the public on Naloxone to save lives. More detail on these strategies and how they impact Medicaid members will be reviewed in Milestone 5.

The STR Grant was awarded to the DHHS Division of Behavioral Health (DBH) in May 2017, and ended April 30, 2019. The grant was utilized to increase Nebraskan's access to clinically appropriate evidence-based practices for the prevention and treatment of OUD with the goal of reducing overdose related deaths for citizens through increasing access to Naloxone and providing additional education and training opportunities for service providers. The SOR Grant, which began October 1, 2018 and extends to September 30, 2020, continues and expands upon the efforts of the STR grant. Further detail on the strategies of these grants and how those strategies impact access to treatment for Medicaid beneficiaries will be reviewed throughout this plan.

PROGRAM OVERVIEW

The Nebraska Medicaid Program provides health coverage to approximately 240,000 residents. In any given month, 10 to 12 percent of the state's population is eligible for Medicaid. Over 98 percent of Medicaid enrollees are served through the State's managed care delivery system.

On January 1, 2017, Nebraska Medicaid launched Heritage Health, a new managed care program that integrates physical health, behavioral health, and pharmacy services into a single, statewide, 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 members. Prior to the launch of Heritage Health, a member 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

[8] State Targeted Response (STR) Opioid Crisis Grant, January 5, 2018. Available at: http://dhhs.ne.gov/Reports/State%20Targeted%20Response%20to%20Opioid%20Crisis%20Fact%20Sheet%20-%202017.pdf

Health removes barriers to addressing all the health needs of each member with a streamlined, person-centered approach.

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 2019. The new DMA platform will have a positive impact on this demonstration, allowing for more detailed data collection and reporting. 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.

The State believes participation in the demonstration program outlined by CMS will allow the state to build on the recent delivery system reforms and DHHS-wide SUD initiatives identified in this Implementation Plan.

MILESTONE 1: ACCESS TO CRITICAL LEVELS OF CARE FOR OUD AND OTHER SUDs

Milestone Criteria:

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 the needs of Medicaid beneficiaries in the state); d) intensive levels of care in residential and inpatient settings; and e) medically supervised withdrawal management. This milestone must be met within 12 to 24 months of demonstration approval or other timeframe in accordance with the special terms and conditions (STC).

Current State:

The Nebraska Medicaid program currently provides a range of SUD services at multiple levels of care identified for this Milestone. Table 1 is a listing of services available at these levels of care. Nebraska recognizes the importance of having services available at critical care levels in order to provide eligible individuals the medically appropriate treatment while also ensuring an efficient and effective use of Medicaid program resources.

In June 2017, the state expanded its continuum of community-focused behavioral health services by adding coverage for Peer Support.[9] Nebraska Medicaid also currently offers non-methadone medication-assisted treatment (MAT) including coverage for naloxone delivered as an injectable or spray, buprenorphine, Suboxone (buprenorphine/naloxone), and Vivitrol (naltrexone).[10]

[9] State Plan Amendment NE-16-0009. Available at: https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/NE/NE-16-0009.pdf

[10] Nebraska Medicaid Preferred Drug List (PDL). March 1, 2018. Available at: https://nebraska.fhsc.com/downloads/PDL/NE_PDL-20180301.pdf

Nebraska Regulations, Nebraska DHHS Title 471 Chapter 20, Psychiatric Services for Individuals Age 21 and Older, requires covered substance use treatment be provided when it is medically necessary[11]. Nebraska contracts with the MCO's to determine their criteria for medical necessity, and requires that criteria be based on valid clinical guidelines and assessments. All guidelines are to be reviewed by Nebraska Medicaid to assure that applicable federal, state, and contractual requirements are met.

Table 1 lists out the SUD specific services and links to the corresponding service definitions. Each of these definitions list out the providers qualified to deliver the service. If the qualifications for any of these provider types require a license to practice this oversight is managed by DPH. The qualifications of each license type are listed in detail in State Regulations, Title 172. The licensing requirements for the provider types providing these services will be reviewed in further detail for Milestone 3.

Table 1: Nebraska Medicaid SUD Services by ASAM Level of Care

ASAM Level	Services	Service Definition	Authority
1	ASA COMMUNITY SUPPORT – LEVEL 1: ADULT SUBSTANCE USE DISORDER	http://dhhs.ne.gov/Behavioral Health Service Definitions/Adult Substance Abuse Community Support.pdf	1915(b)
1	OUTPATIENT GROUP THERAPY - LEVEL 1: ADULT SUBSTANCE USE DISORDER	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Adult%20Substance%20Abuse%20Group%20Therapy-Level%201.pdf	1915(b)
1	ASA OUTPATIENT INDIVIDUAL THERAPY– LEVEL 1: ADULT SUBSTANCE USE DISORDER	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Adult%20Substance%20Abuse%20Individual%20Therapy.pdf	1915(b)
1	ASA OUTPATIENT FAMILY THERAPY - LEVEL 1: SUBSTANCE USE DISORDER	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Adult%20Substance%20Abuse%20Family%20Therapy.pdf	1915(b)
2.1	INTENSIVE OUTPATIENT – LEVEL 2.1: ADULT SUBSTANCE USE DISORDER	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Adult%20Substance%20Abuse%20Intensive%20Outpatient.pdf	1915(b)
2.5	ADULT SUBSTANCE USE DISORDER DAY TREATMENT ADULT ASAM LEVEL 2.5	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Adult%20Substance%20Abuse%20Day%20Treatment%20Level%202.5.pdf	1915(b)
3.1	HALFWAY HOUSE - LEVEL 3.1: ADULT SUBSTANCE USE DISORDER	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Adult%20Substance%20Abuse%20Halfway%20House.pdf	1915(b)
3.2	SOCIAL DETOXIFICATION – LEVEL 3.2 ADULT SUBSTANCE USE DISORDER	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Adult%20Su	1915(b)

[11] 471 NAC 20: http://www.sos.ne.gov/rules-and-regs/regsearch/Rules/Health_and_Human_Services_System/Title-471/Chapter-20.pdf

ASAM Level	Services	Service Definition	Authority
		bstance%20Abuse%20Detoxification-Level%203.2.pdf	
3.3	ASA INTERMEDIATE RESIDENTIAL (CO-OCCURRING DIAGNOSIS CAPABLE) – LEVEL 3.3	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Adult%20Substance%20Abuse%20Intermediate%20Residential.pdf	1915(b)
3.3	THERAPEUTIC COMMUNITY (CO-OCCURRING DIAGNOSIS CAPABLE) ASAM LEVEL 3.3	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Adult%20Substance%20Abuse%20Therapeutic%20Community.pdf	1915(b)
3.5	SHORT TERM RESIDENTIAL (CO-OCCURRING DIAGNOSIS CAPABLE) – LEVEL 3.5 ADULT SUBSTANCE USE DISORDER	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Adult%20Substance%20Abuse%20Short%20Term%20Residential%20(Dual%20Diagnosis).pdf	1915(b)
3.5	DUAL DISORDER RESIDENTIAL (CO-OCCURRING DIAGNOSIS-ENHANCED) – LEVEL 3.5 ADULT SUBSTANCE USE DISORDER	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Adult%20Substance%20Abuse%20Dual%20Disorder%20Residential.pdf	1915(b)
OTHER	ANNUAL SUPERVISION of the MEDICAID ELIGIBLE INDIVIDUAL BY A PSYCHOLOGIST OR AN LIMHP	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Annual%20Supervision%20by%20Licensed%20Independent%20or%20Psychologist.pdf	State Plan Attachment 3.1-A Item 6d Page 1 of 2
OTHER	SUBSTANCE USE DISORDER ADDENDUM – ADULT	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Adult%20Substance%20Abuse%20Addendum.pdf	1915(b)
OTHER	ADULT SUBSTANCE USE DISORDER ASSESSMENT	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Adult%20Substance%20Abuse%20Assessment.pdf	1915(b)
OTHER	FAMILY ASSESSMENT	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Family%20Assessment.pdf	1915(b)
OTHER	OBSERVATION ROOM	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Observation%20Room.pdf	1915(b)
OTHER	PEER SUPPORT	http://dhhs.ne.gov/Behavioral%20Health%20Service%20Definitions/Peer%20Support.pdf	State Plan: Attachment 3.1-A Item 13d, Page 5b

Future State:

Nebraska Medicaid will submit a State Plan Amendment to request authority to cover medically monitored intensive inpatient withdrawal management for adults at ASAM level 3.7-WM in order to meet the service coverage requirements of this milestone.

In order to further align the state's SUD service continuum with CMS's objectives for this program and in recognition of the requirements of Section 1006 of the Support Act[12], Nebraska Medicaid will submit a State Plan Amendment to request authority to cover methadone for MAT.

Nebraska Medicaid will also continue to monitor contracted MCOs for compliance with the existing contract requirements regarding covered services to ensure the full SUD continuum of care is available to members.

Summary of Actions Needed:

Implementation Action Item	Timeline
Submit a State Plan Amendment to request authority to cover medically monitored intensive inpatient withdrawal management for adults at ASAM level 3.7-WM	12- 24 months
Submit a State Plan Amendment to request authority to cover methadone for MAT.	12-24 months

MILESTONE 2: WIDESPREAD USE OF EVIDENCE-BASED, SUD-SPECIFIC PATIENT PLACEMENT CRITERIA

Milestone Criteria:

1. Providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools, or other patient placement assessment tools that reflect evidence-based clinical treatment guidelines; and
2. Contracted MCOs must have 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.

This milestone must be met within 12 to 24 months of demonstration approval or other timeframe in accordance with the STCs.

Current State:

The Nebraska MCO contracts include the expectation that substance abuse treatment services will be appropriate to a member's level of need and that services are available when needed. The service definitions for SUD treatment provided in Table 1 include ASAM criteria and other screening tools used to assess and treat SUD. ASAM standards were utilized in the development of these service definitions. Providers must adhere to the requirements of these service definitions, which will assure the individual meets the diagnostic criteria for a substance use-related disorder as defined in the Diagnostic and Statistical Manual of Mental Disorders (current version) as well as each of the six ASAM dimensional criteria for admission. With the exception of assessment, individual therapy, group therapy, and family therapy, all plans require the services listed in Table 1 be authorized prior to their initiation, which will

[12] SUPPORT for Patients and Communities Act, Section 1006. Available at: https://www.congress.gov/bill/115th-congress/house-bill/6/text#toc-H54D9809005834B7FAEC1764B725A2970

assure medical necessity requirements have been met by the provider. Medicaid SUD services are also required to be recovery-based, and the MCO must ensure that "active treatment" is provided to each member, meaning that a member receiving these services will have an individual plan of care in which the member participates and shows progress.

All contracted MCOs must have a utilization management program in place that complies with Federal utilization control requirements, including the certification of need and recertification of need for continued inpatient settings, including psychiatric residential treatment facilities, and as described in 42 CFR 438. The description of this program must be submitted to MLTC annually, and must include procedures for service authorizations, concurrent review, extensions of lengths of stay, and retrospective reviews for all covered services.

MCOs are required to have procedures in place for concurrent review of inpatient services in order to monitor the medical necessity of the need for a continued stay. The concurrent review system must include provisions for multiple day approvals when the episode of care is reasonably expected to last more than one day, based on the medical necessity determination.

An additional required aspect of the utilization management program is for the MCO to develop and implement retrospective UR functions for examining trends, issues, and problems in utilization, particularly over- and under-utilization that may need to be addressed including retrospective and peer reviews of a sample of network providers to ensure that the services furnished by network providers were provided to members, were appropriate and medically necessary, and were authorized and billed in accordance with the MCO's requirements.

The MCOs have all provided a Utilization Management program plan annually throughout the current contract, as required. All submitted plans have been reviewed and meet these contract requirements.

Each MCO is required to maintain up to date clinical practice guidelines in accordance with 42 CFR 438.236(b) which are maintained on the MCO's public website. Each MCO also submits to Nebraska Medicaid for review and approval the MCO's policies and procedures for treatment guidelines and utilization management approaches. Nebraska does not mandate that the MCOs follow a specific clinical guideline, but it is required that each MCO create and maintain a Clinical Advisory Committee. This committee provides input for the MCO into all policies, procedures, and practices associated with the MCO's utilization management criteria, to ensure that criteria reflect up-to-date standards consistent with research, requirements for evidence-based practices, and community practice standards in the State. It is also required that the MCO's clinical guidelines be based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field. All three of the currently contracted MCOs utilize guidelines published by the American Psychiatric Association in 2006[13] in regard to their treatment for substance abuse disorders. These guidelines stress the importance of using the American Society of Addiction Medicine (ASAM) patient placement criteria when determining the level of care needed for the patient.

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[13] American Psychiatric Association Practice Guideline for the Treatment of Patients with Substance Use Disorders, 2nd edition (2006)
http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/substanceuse.pdf

Future State:

Nebraska Medicaid will continue to monitor contracted MCOs for their compliance with the existing contract requirements regarding access to behavioral health services that are appropriate to the level of need. It is recognized that while each of the MCOs has utilization management policies and procedures that meet this milestone, not all aspects of this milestone are explicitly stated within the contract. Nebraska Medicaid will update contract language to include a requirement that assessment tools used when authorizing or reviewing inpatient stays be based on evidence based clinical treatment guidelines and which assure that requirements of all service definitions, including those found in Table 1, are met. Utilization Management policies and procedures for each of the contracted MCOs will need to specifically address how the requirements of the service definitions are met. Additionally, Nebraska Medicaid will update contract language to require that a concurrent review of care provided to members receiving inpatient residential SUD treatment include an evaluation of each case against established criteria such as national clinical guidelines.

Nebraska Medicaid also proposes to include SUD treatment specific requirements to the existing annual audit tool used to review all contracted MCOs' compliance with this new contract language.

Summary of Actions Needed:

Implementation Action Item	Timeline
Update contract language to reflect specific requirements for utilization management and level of care assessments.	12- 24 months

MILESTONE 3: USE OF NATIONALLY RECOGNIZED, EVIDENCE-BASED, SUD PROGRAM STANDARDS TO SET RESIDENTIAL TREATMENT PROVIDER QUALIFICATIONS

Milestone Criteria:

1. Implementation of residential treatment provider qualifications in licensure requirements, program authorities and 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.
2. Implementation of state process for reviewing residential treatment providers to assure compliance with these standards.
3. Residential treatment facilities offer MAT on-site or facilitate access off-site.

This milestone must be met within 12 to 24 months of demonstration approval or other timeframe in accordance with the STCs.

Current State:

DPH is the entity which assures that residential treatment providers for SUD services meet provider qualifications through the process of licensure. This process assures these providers are practicing in a

setting appropriate to their license. Nebraska DHHS Title 172 -- Professional and Occupational Licensure contains regulations that govern the practitioner licensing requirements, fees, standards of conduct, practice guidelines, and training standards.

DPH is also the entity which assures that facilities for SUD treatment, licensed as a Mental Health and Substance Use (MHSU) Treatment Center, meet facility licensing qualifications. Nebraska DHHS Title 175 Chapter 18, Health Care Facilities and Services Licensure, Substance Abuse Treatment Centers, http://www.sos.ne.gov/rules-and-regs/regsearch/Rules/Health_and_Human_Services_System/Title-175/Chapter-18.pdf, and Title 175 Chapter 19, Mental Health Centers, http://www.sos.ne.gov/rules-and-regs/regsearch/Rules/Health_and_Human_Services_System/Title-175/Chapter-19.pdf, contain regulations that govern the facilities standards of operation, care and treatment. The State statutes relating to substance abuse treatment centers which guide licensing requirements are found here, http://dhhs.ne.gov/licensure/Documents/Facilities-HealthCareFacilities.pdf, and they include the Health Care Facility Licensure Act and Health Care Quality Improvement Act.

Alcohol and Drug Counselors are one type of provider in the State of Nebraska who provide SUD services that are outlined in Milestone 1 of this plan. The DPH Licensing regulations define an Alcohol and Drug Counselor as an individual who provides the 12 core functions of screening, intake, orientation, assessment, treatment planning, counseling (individual, group and significant others), case management, crisis intervention, client education, referral, reports and recordkeeping and consultation with other professionals in regard to client treatment and services. These core functions are in accordance with the International Certification & Reciprocity Consortium (IC&RC) requirements for alcohol and other drug abuse (AODA). The complete definition and licensing requirements for this provider type are explained in Nebraska DHHS Title 172 Chapter 15, Licensure of Alcohol and Drug Counselors, located here: http://www.sos.ne.gov/rules-and-regs/regsearch/Rules/Health_and_Human_Services_System/Title-172/Chapter-015.pdf.

Mental Health Practitioners and Clinical Social Workers who provide SUD related services are licensed by DPH, and their licensing requirements can be found in Nebraska DHHS Title 172 Chapter 94, Licensure of Mental Health Practitioners and the Certification of Marriage and Family Therapists, Professional Counselors and Social Workers: http://www.sos.ne.gov/rules-and-regs/regsearch/Rules/Health_and_Human_Services_System/Title-172/Chapter-094.pdf .

Dispensing Buprenorphine in Nebraska requires certification through the United States Drug Enforcement Administration (DEA). Dispensers must meet state licensing requirements before applying for DEA registration. The DEA will not issue a certification if the state license has been revoked or rescinded. Nebraska has promotions in place to expand the delivery of required training in order to increase the number of waiver qualified Buprenorphine prescribers, see milestone 4 for additional details on activities and goals related to increasing this number.

Nebraska Medicaid has included in the contract for MCOs language specific to their obligation in assuring all Medicaid providers have been appropriately licensed or certified, and are operating within their scope of practice.

In all its contracts with health care professionals, the MCO must comply with the requirements specified in 42 CFR 438.214, 438.610, 455.104, 455.105, 455.106, and 1002.3, which include selection and retention of providers, credentialing and re-credentialing requirements, and nondiscrimination. The MCO must utilize the current NCQA Standards and Guidelines for the Accreditation of MCOs for the credentialing and re-credentialing of licensed independent providers and provider groups with whom/which it contracts or employs and who fall within its scope of authority and action.
The MCO must re-credential each provider a minimum of every three years, taking into consideration various forms of data, including but not limited to grievances, results of quality reviews, results of member satisfaction surveys, and utilization management information. The MCO must communicate with Nebraska Medicaid, DBH, and DPH regarding incidents or audits that potentially affect provider licensure for any applicable provider types.

The Nebraska Medicaid Service Definitions in Table 1 contain information regarding the service expectations, hours of operation, and staffing requirements for the different types of residential treatment facilities in Nebraska. These service definitions were developed utilizing ASAM standards. Through the utilization management procedures detailed in Milestone 2 of this plan, Nebraska Medicaid assures that the standards found within service definitions are met.

Currently, residential providers utilize abstinence-based care models and the State is unaware of any residential providers offering MAT onsite or facilitating offsite access to MAT. One purpose of the DBH Nebraska Opioid STR and SOR Initiatives is to increase Nebraskans' access to clinically appropriate evidence-based practices for treatment of their opioid use disorder, and a method being used to support this goal is increasing the number of practitioners trained on MAT. DBH held a MAT Summit in 2017[14] which had a goal of promoting and expanding use of MAT. An Opioid Summit was held March 2019 in order to continue to provide educational opportunities and increase access to MAT. An additional method supported through the DBH grant efforts to promote provider education for MAT is Project ECHO which is reviewed in detail in Milestone 4.

Future State:

Over the next 24 months, Nebraska will work on promoting a shift in perspective among residential providers to integrate facilitation of MAT into their programmatic requirements and utilization. Residential providers will be required expand their treatment methods by either offering MAT onsite or facilitating access to MAT off-site. This requirement will be built into applicable service definitions listed in Table 1, and rates will be reviewed based on these updates. Because Nebraska's current residential providers practice within abstinence-based care models, this shift will require extensive outreach and additional education opportunities.

Nebraska Medicaid will update contract language to require the MCOs to develop training material to be provided for MHSU Treatment Centers which supports this perspective shift. These educational initiatives will seek to continue to eliminate stereotyping associated with MAT. Educational initiatives

[14] MAT Summit News Release: http://dhhs.ne.gov/News%20Release%20Archive/Medication-Assisted%20Treatment%20(MAT)%20Summit%20in%20August.pdf

will also include state and federal guidance associated with MAT. Substance Abuse and Mental Health Services Administration (SAMHSA) materials will be utilized to provide education to these facilities.

In order to further support the ability of residential providers to offer or facilitate MAT, Nebraska Medicaid is adding coverage of methadone for MAT through a State Plan Amendment as detailed in the future state section of Milestone 1.

Nebraska Medicaid will update 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, not currently reviewed through their current or proposed utilization management procedures detailed in Milestone 2, are met. Nebraska Medicaid will continue to monitor contracted MCOs for their compliance with the existing contract requirements regarding licensure and certification to assure providers meet standards for SUD provider qualifications.

Summary of Actions Needed:

Implementation Action Item	Timeline
Update contract language to require provider education regarding the requirements to facilitate MAT onsite or off site, and on benefits of MAT accessibility, to begin a shift in perspective toward acceptance of MAT as a complementary treatment.	24 months
Update service descriptions to require access to MAT.	24 Months
Update contract language to require reviews of residential treatment providers to assure the types of services, hours of clinical care, and credentials of staff for residential treatment settings are performed according to ASAM Criteria, or other nationally recognized, evidence- based SUD-specific program standards.	24 Months

MILESTONE 4: SUFFICIENT PROVIDER CAPACITY AT EACH LEVEL OF CARE, INCLUDING MAT

Milestone Criteria:

Assess the availability and capacity of providers throughout the state, enrolled in Medicaid, who accept patients in the Milestone 1 critical levels of care: a) outpatient; b) intensive outpatient services; c) medication-assisted treatment (medications as well as counseling and other services); d) intensive levels of care in residential and inpatient settings; and e) medically supervised withdrawal management. This milestone must be met within 12 months of demonstration approval or other timeframe in accordance with the STCs.

Current State:

Care Delivery Infrastructure

Nebraska's publicly funded behavioral health system is anchored by a network of six local regions. The regions contract with local programs to provide public inpatient, outpatient, emergency community mental health, and substance use disorder services. Medicaid managed care plans are required to collaborate with DBH and the local behavioral health regions in the establishment and maintenance of the plans' provider networks.

As of March 2018, Nebraska had just over 20 licensed Mental Health Centers with a capacity of nearly 500 licensed beds and approximately 100 licensed Substance Abuse Treatment Centers with a capacity of over 800 beds.

The state has over 200 Medicaid-enrolled fully licensed Alcohol and Drug Counselors and about 100 Provisionally Licensed Alcohol and Drug Counselors.

There are approximately 1,700 Licensed Mental Health Professionals and Licensed Clinical Social Workers enrolled to serve Medicaid beneficiaries.

Access to Care Monitoring

Nebraska Medicaid currently monitors provider capacity through MCO reporting. MCO's are required to provide quarterly network access reports that assess member access to care.

Current MCO contractual access standards for behavioral health are as follows:

- **Inpatient/Residential Services**: MCOs must, at a minimum, contract with behavioral health inpatient and residential service providers with sufficient locations to allow members to travel by car or other transit provider and return home within a single day in rural and frontier areas. If it is determined by Nebraska Medicaid that no inpatient providers are available within the access requirements, the MCO must develop alternative plans for accessing comparable levels of care, instead of these services, subject to approval by Nebraska Medicaid.

- **Outpatient Services:** MCOs must, at a minimum, contract with an adequate number of behavioral health outpatient assessment and treatment providers to meet the needs of its members and offer a choice of providers. The MCO must provide adequate choice within 30 miles of members' personal residences in urban areas; a minimum of two providers within 45 miles of members' personal residences in rural counties, and a minimum of two providers within 60 miles of members' personal residences in frontier counties. If the rural or frontier requirements cannot be met because of a lack of behavioral health providers in those counties, the MCO must utilize telehealth options.

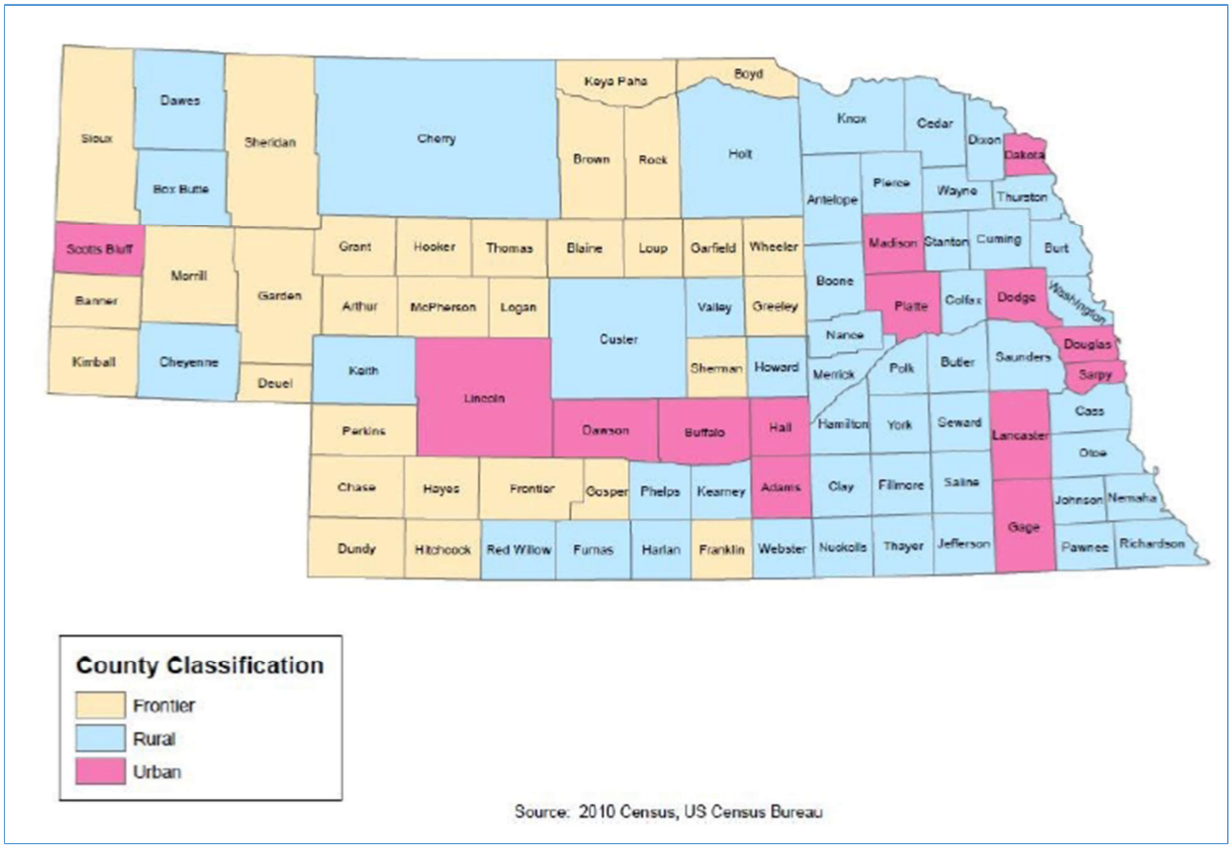
The reporting template for Geographic Access Standards can be found on the Heritage Health Reporting Templates webpage at: http://dhhs.ne.gov/Pages/Heritage-Health-Plan-Reporting-Templates.aspx

As of the submission of this Implementation Plan, the direct link to the current Geographic Access Standards report template can be located at:
http://dhhs.ne.gov/Medicaid%20Health%20Plan%20Reporting%20Templates/Geographic%20Access%20Standards.xls

As illustrated in the template, MCOs are currently required to report county-level behavioral health inpatient and outpatient treatment access on the tabs entitled “BH Inpatient and Residential Service” and “BH Outpatient Assessment and Treatment.”

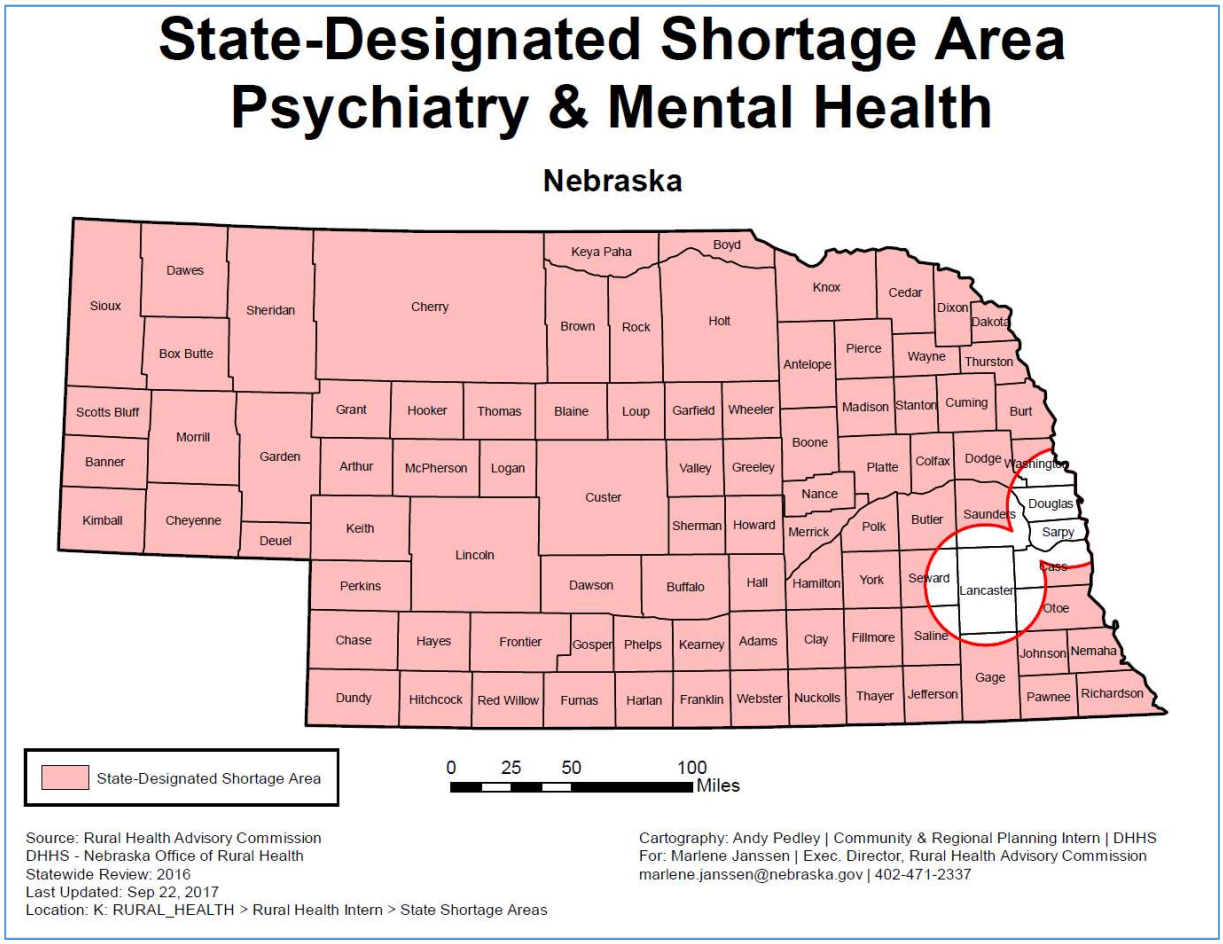
Current Nebraska Medicaid access standards and the Division’s assessment of MCO compliance with those standards must take into account the state’s rural profile. In Nebraska, challenges to accessing care for Medicaid eligible individuals are primarily driven by geographic factors. Nebraska ranks 45th in population density with 23.8 persons per square mile. As illustrated in Figure 3, of the State’s ninety-three (93) counties, forty-eight (48) are considered “rural” and thirty-one (31) are considered “frontier” for purposes of establishing managed care access standards.

Figure 3 - Nebraska Counties Classified by Urban, Rural, or Frontier Status



The geographic challenges impeding access to care for Medicaid-eligible individuals are similar to challenges facing the general Nebraska patient population. As illustrated in Figure 4, access to behavioral health services in all areas other than the state’s two largest metropolitan areas is limited.

Figure 4 - State-Designated Shortage Area – Psychiatry and Mental Health



Nebraska's STR and SOR grants for opioid treatment are being utilized by DBH in part to expand the State's ability to meet the needs of those who are experiencing OUD. To do this, strategies have been implemented to address provider capacity.[15]

In March 2018, Nebraska had 46 providers enrolled in Medicaid who have received a certification to dispense buprenorphine. As of February 2019, the number of dispensers with this certification has grown to 52 providers. One goal of the STR and SOR grants centers on increasing the availability of prescribers certified to prescribe Buprenorphine. The grants provide additional access to the targeted training needed for certification to Nebraska prescribers. At the MAT Summit, mentioned in Milestone 3, DBH provided four of the eight required training hours (for physicians).

With the new SOR grant, these training opportunities will continue with plans being made for Grand Rounds-style mentoring for newly certified prescribers from experts in the field of MAT, along with a "train the trainer" opportunity to expand the number of individuals available to provide live training for

[15] Nebraska DHHS Business Plan July 2018 – June 2019. Pg. 24. Available at: http://dhhs.ne.gov/Documents/BusinessPlan2018-2019.pdf

buprenorphine certification. While this certification is not currently a requirement of Nebraska providers, continued education is available and being promoted through this grant.

Another resource being made available to Nebraska providers through the STR and SOR grants is Project ECHO (Extension for Community Healthcare Outcomes) which connects local providers with specialist mentors at an academic medical center. Project ECHO is a telementoring system which allows educational access for healthcare providers in rural and underserved communities. Scheduled videoconferencing sessions are open to providers, including but not limited to physicians, nurses, physician assistants, behavioral health practitioners, peer support specialists, and pharmacists, and include a 15 minute SUD treatment specific presentation. The remainder of the Project ECHO session is focused on real world consultations, not including protected health information, where the specialist mentors are able to provide recommendations for best practices. Through these sessions the local providers develop their skills and competency to serve individuals with substance use disorders and pain management challenges.[16] The June 2018 through April 2019 schedule with topics of discussion can be found at: https://www.unmc.edu/bhecn/_documents/didactic-schedule-2018-20194-003.pdf. These sessions are continuing to be scheduled, with events planned for 2019 on topics such as wavier certification, methadone, naloxone, and how to assist with locating social support.

An additional DBH STR Grant strategy is the development of an addiction medicine fellowship. This initiative is being developed in partnership with the University of Nebraska Medical Center and will ensure Nebraska providers are equipped to treat substance use disorders and physical health needs of patients. This specialty training program will provide fellows with experience in the prevention, clinical evaluation, treatment, and long-term monitoring of substance-related disorders. The fellowship will engage Nebraska providers and assist in embedding evidenced based practices for SUD treatment into the physical health arena. The SOR grant continues to fund this effort in Nebraska.

Future State:

Going forward, Nebraska Medicaid will implement new reporting requirements focused on SUD provider capacity for critical ASAM levels of care, including the number of participating providers accepting new patients by level of care and those that offer MAT. MCOs will be required to address improving access to SUD services in the MCOs' annual network development plans.

A specific element Nebraska Medicaid will require MCOs to address in network development is increasing incorporation of telehealth in expanding SUD treatment. A recent study in Health Affairs[17] found that while the use of "tele-SUD" increased relatively rapidly over the study years 2010-2017, the overall rates of tele-SUD utilization remained low. The study also noted that regulatory and reimbursement barriers are factors in limiting tele-SUD utilization.

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[16] DHHS, UNMC Team Up to Launch Statewide Education Model for Substance Use Disorder: http://dhhs.ne.gov/News Release Archive/DHHS, UNMC Team Up to Launch Statewide Education Model for Substance Use Disorder.pdf

[17] How is Telemedicine Being Used in Opioid and Other Substance Use Disorder Treatment? Health Affairs, Vol. 37, No. 12 https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2018.05134

Nebraska Medicaid has been proactive in recognizing state-level telehealth barriers and has worked to expand the availability and utilization of telehealth for physical and behavioral health services. On January 1, 2017, Nebraska Medicaid implemented new telehealth regulations that expanded Medicaid-covered telehealth services to include billing for telemonitoring and the originating site fee. With this recent regulatory service expansion, Nebraska Medicaid believes that the state has laid a policy foundation for increased utilization of telehealth services including tele-SUD.

Summary of Actions Needed:

Implementation Action Item	Timeline
Add SUD specific provider capacity reporting requirements which include the number of participating providers accepting new patients by level of care and those that offer MAT	12 Months
Expanded telehealth reporting requirements	12 Months

MILESTONE 5: IMPLEMENTATION OF COMPREHENSIVE TREATMENT AND PREVENTION STRATEGIES TO ADDRESS OPIOID ABUSE AND OUD

Milestone Criteria:

1. Implementation of opioid prescribing guidelines along with other interventions to prevent opioid abuse.
2. Expanded coverage of, and access to, naloxone for overdose reversal.
3. Implementation of strategies to increase utilization and improve functionality, of prescription drug monitoring programs. This includes enhancing the health IT functionality to support PDMP interoperability and enhancing and/or supporting clinicians in their usage of the state's PDMP.

This milestone may be met over the course of the demonstration.

Current State:

Nebraska Medicaid has a Drug Utilization Review (DUR) Program, through the Nebraska Pharmacists Association. In January 2019 the DUR Board announced that in response to the national opioid crisis, Nebraska Medicaid is implementing total daily dose limits of opioids,[18] in alignment with CDC and FDA guidelines. The limit implemented is 300 MME per day, and the board has created a timeline for the continued lowering of this daily limit. By June of 2021, the daily limit will be set at 90 MME per day. There is also in place a restriction for opioid naïve patients that limits those patients to a 7 day prescription at 90 MME per day.

Nebraska Medicaid staff work with all contracted MCOs to ensure the MCOs have policies and procedures in place which follow State guidelines and facilitate the implementation of opioid prescribing guidelines and limits. The MCOs are required to utilize the Nebraska Medicaid Preferred Drug List (https://nebraska.fhsc.com/downloads/PDL/NE_PDL-20190301.pdf in order to determine prescription coverage. Nebraska's PDL includes requirements for prior authorization depending on the class of drugs. The MCOs also utilize Drug Limitations document

[18] Nebraska Medicaid DUR Matters Volume 14, Issue 1, January 2019 https://www.npharm.org//Files/DUR/Newsletters/DUR%20Matters%20Newslettter%20Jan%202019%20Email.pdf

(https://nebraska.fhsc.com/Downloads/neclaimlimitations.pdf) which can be updated by Nebraska Medicaid as CDC and FDA guidelines are modified.

In October 2017, DHHS released the Nebraska Pain Management Guidance Document, a comprehensive opioid prescribing resource for prescribers, to assist in meeting the program objective of ensuring prescription drugs are used for medically appropriate purposes. This resource was created by a diverse task force including practicing clinicians, medical directors, psychiatrists, emergency department providers, pain medicine specialists, anesthesiologists, and public health professionals.
The goal of the document is to provide "real-world tools and advice to practicing clinicians as they seek to comply with national standards." The guidelines outlined in the document align with the CDC Guidelines for Chronic Pain released March 2016 and build off best practices as identified through CDC guidance and similar initiatives in other states.

The Nebraska Medicaid program understands the importance of naloxone for overdose reversal and covers it, with a prescription, as an injectable or spray. Nebraska has legislation in place, Neb. Rev. Stat. §§ 28-470 (https://nebraskalegislature.gov/laws/statutes.php?statute=28-470) and 28-405 (https://nebraskalegislature.gov/laws/statutes.php?statute=28-405) which impacts how naloxone is dispensed in Nebraska. Neb. Rev. Stat. §§ 28-470 allows a health professional who is authorized to prescribe or dispense naloxone to prescribe, administer or dispense naloxone without being subject to administrative action or criminal prosecution. If a prescription is desired, The *Nebraska Naloxone Standing Order* signed by the Chief Medical Officer and Director of the DPH, can be used, pursuant to Neb. Rev. Stat. §§ 38-2840 (https://nebraskalegislature.gov/laws/statutes.php?statute=38-2840).

DBH has initiatives underway, through the STR and SOR grants, to increase access to naloxone. Through DBH regional contracts, funding is available in order to provide naloxone kits to high risk clients. The DPH has a public health campaign, along with a provider education campaign, centered on Naloxone. For providers, education centers on how to identify patients who need naloxone, how to administer the drug, and how to talk with the patient about naloxone. Training is also available to first responders on how to use naloxone to save lives. The SOR grant has also assisted in funding the production of an opioid public education video which addresses how to respond in the event of an opioid overdose so that naloxone can be utilized, along with how to properly dispose of opioid prescriptions when the medication is no longer needed.[19] Through the *Nebraska Naloxone Standing Order*, DBH has been able to supply providers, first responders and those with OUD with 1740 naloxone kits.

The Nebraska Legislature established the state's Prescription Drug Monitoring Program (PDMP) in 2011. The PDMP is overseen by DPH in coordination with the Nebraska Health Information Initiative (NeHII). The primary objectives of the PDMP are to prevent the misuse of prescribed controlled substances, allow prescribers and dispensers to monitor the care and treatment of patients for whom such a prescription drug is prescribed, and to ensure that such prescription drugs are used for medically appropriate purposes.

Nebraska's PDMP was further strengthened in 2016 with the passage of LB 471. Beginning on January 1, 2017, LB 471 required that all dispensed prescriptions for controlled substances must be reported to the

[19] Community Partners Opioid Awareness Video
https://www.youtube.com/watch?v=MC71wrMsQfE#action=share

PDMP. By January 1, 2018, all prescription information must be reported to the prescription drug monitoring system maintained by the PDMP.[20] On January 1, 2018, Nebraska became the first state to require reporting of all dispensed prescription drugs to the PDMP.

As of December 7, 2018, Nebraska's PDMP has 44.6% of licensed Nebraska prescribers and dispensers with addresses in Nebraska, Kansas, Missouri, Iowa, South Dakota, Wyoming, and Colorado registered to access and use the Nebraska PDMP database. DPH continues to focus on increasing PDMP healthcare provider registrations. As of November 30, 2018, 100% of Nebraska licensed community pharmacies and mail-service pharmacies are registered or reporting to the Nebraska PDMP.

The intent of the PDMP tool is to aid providers in making treatment decisions with a more robust medical history of their patient, thus aiding and improving the quality and safety of patient care. Enhancements are continuously being developed with the help of end-users to increase efficiency, decrease impact to workflow, and to provide an effective tool for providers when treating patients. Additional information regarding the Health IT functionality and interoperability of Nebraska's PDMP will be reviewed in Attachment A.

Future State:

The Nebraska Medicaid program will continue to work with internal and external partners to enhance the existing programing and initiatives to ensure that they evolve as the opioid crisis evolves in Nebraska.

Summary of Actions Needed:

There are no anticipated actions needed by Nebraska for fulfillment of this milestone.

MILESTONE 6: IMPROVED CARE COORDINATION AND TRANSITIONS BETWEEN LEVELS OF CARE

Milestone Criteria:

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, and coordination of care for co-occurring physical and mental health conditions. This milestone must be met within 12 to 24 months of demonstration approval or other timeframe in accordance with the STCs.

Current State:

The MCOs are required through contracts with the Nebraska Medicaid program to develop and maintain effective care coordination, continuity of care, and care transition activities to ensure a continuum of care approach to providing health care services to MCO members.

At enrollment, MCO's are required to complete a health assessment on all members to determine if the member could benefit from care management. MCOs must also conduct ongoing predictive modeling to identify members who may need care management evaluation. Member substance use is a component of both the initial assessment and the ongoing predictive evaluation.

[20] LB 471 (2016) PDMP Provisions https://nebraskalegislature.gov/FloorDocs/104/PDF/Final/LB471.pdf

For general care management requirements, the MCOs are to maintain principles of care which are specific to those who have both medical and behavioral health needs. These principles, stated in the MCO contracts, include implementing a system of care which is comprehensive, evidence-informed, and incorporates continuous quality improvement. The requirements specifically address the need to integrate substance use disorders into a member's comprehensive care plan. All providers who serve a member with behavioral and medical health care needs must have access to all relevant clinical information in order to create a holistic and impactful treatment plan.

Additional care management requirements includes discharge planning, assistance in locating community links and social supports to improve outcomes for members, and continuity of care to promote communication between the members providers to assist in transition between levels of care.

The MCOs must submit to Nebraska Medicaid their policies and procedures regarding how the MCO will implement Nebraska's care coordination contract requirements. Any updates to those policies and procedures must also be submitted for approval before the implementation of any changes. In addition, Nebraska Medicaid monitors MCO compliance by reviewing reports such as a quarterly report for members in care management and monthly reports for members with restricted services. Nebraska also performs an annual audit on all MCOs which includes a review of care management files to ensure compliance.

The definitions of the services at the ASAM 3 level of care, found in Table 1, direct that a plan for patient discharge will be included in that individuals treatment plan, to be reviewed every 30 days or more often as needed. Through the utilization management process detailed in Milestone 2 of this plan, along with the facility review process detailed in Milestone 3, assurance of the completion of a discharge plan is completed. The individuals discharge or move to a different level of care is to be assessed based on ASAM criteria. Through utilization management processes, carried out by MCOs and detailed in Milestone 2 of this plan, and facility review processes, detailed in Milestone 3, providers are held accountable to meeting the requirements of this service definition.

DPH Regulations 175 NAC 18, which guide the licensing requirements for the substance use treatment carried out at MHSU Treatment Centers and described with additional detail in Milestone 2 of this Plan, require additional discharge criteria to be established by facility providing services. The facility must establish discharge criteria and use those criteria in developing an appropriate plan for discharge jointly with the client. The discharge plan must include: 1. A relapse prevention plan, which includes triggers and interventions for client to activate; 2. The client's plan for follow up, continuing care, or other post care and treatment services; 3. Documentation of referrals made for the client by the facility; 4. The client's plan to further his/her recovery; 5. The client's signature and the date; and 6. A treatment summary that will be completed no later than 30 days after the client's discharge. The summary must include a description of the client's progress under his or her ISP, the reason for discharge, and any recommendations to the client. DPH requires this documentation for every inpatient stay, and through their survey process this is reviewed to assure compliance.

Future State:

Nebraska Medicaid will continue to monitor contracted MCOs for compliance with the existing care management contract requirements in order to ensure members' health care issues are being

monitored appropriately. Current MCO contract requirements do not detail 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. It is proposed that contract language will be updated to create clear expectations on member follow-up.

Nebraska Medicaid also proposes to include Care Management SUD treatment follow up specific requirements to the existing annual audit tool used to review all contracted MCOs compliance with this new contract language.

Summary of Actions Needed:

Implementation Action Item	Timeline
Update contract language to reflect specific requirements for Care Management follow up after SUD treatment discharge.	12- 24 months

NEBRASKA MEDICAID 1115 SUBSTANCE USE DISORDER DEMONSTRATION

Attachment A – Health IT Plan

Part 1: Implementation of Strategies to Increase Utilization and Improve Functionality of PDMP

Table 1: Strategies to Increase Utilization and Improve Functionality of Nebraska's PDMP

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criterion 1: Enhanced interstate data sharing in order to better track patient specific prescription data	The Nebraska PDMP was established by Neb. Rev. Stat. §§ 71-2454, 71-2455 and 71-2456, which does not allow for Nebraska to participate in interstate data sharing data to other states. However, Nebraska does allow for prescribers or dispensers that have a treatment relationship with a Nebraskan to request access to the Nebraska PDMP. The Nebraska Health Information Initiative (NeHII) includes a Health Information Exchange (HIE), and the Nebraska PDMP is housed on this platform. Nebraska has an enhanced connectivity between the states PDMP and any statewide, regional or local health information exchange. If a prescriber is utilizing the HIE they can query the PDMP directly from the HIE page without the need to exit and research the patient. Additionally, this functionality allows for single sign-on access to EHRs Through Nebraska's HIE, medication history information is available to all payers, including Medicaid. Medication history follows federal rules, regulations, and law around viewing patient information. Nebraska statute requires the reporting of all dispensed prescriptions no matter how they are paid for. Medication history provided to payers does not include cash/self-pay information for federal compliance.	The Nebraska PDMP team is currently developing the infrastructure needed for unidirectional (receiving) data sharing at this time. Preliminary discussions with Nebraska's contiguous states are occurring to prepare for unidirectional sharing. State law currently governs the PDMP's ability to engage in bidirectional interstate data sharing agreements. Future interstate data sharing arrangements will require legislative approval. In January 2019, LB 556 was introduced to amend Neb. Rev.	The Nebraska PDMP team is developing the infrastructure and setting up agreements so that unidirectional sharing can begin within the next calendar year. For bidirectional sharing, if current proposed legislation passes the Nebraska PDMP team is prepared to adjust in order to be able to ensure that bidirectional sharing with other states is also setup within the next calendar year.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
		Stat. §§ 71-2454 to allow for data sharing with other PDMP programs along with entities including State and regional health information exchanges.	
Criterion 2: Enhanced "ease of use" for prescribers and other state and federal stakeholders	State Statute requires all dispensed prescriptions for controlled substances must be reported to the PDMP. Beginning on January 1, 2017, all dispensed controlled substances were required to be reported daily. Additionally, beginning on January 1, 2018, all prescription information must be reported to the PDMP, also on a daily basis. On January 1, 2018, Nebraska became the first state to require reporting of all dispensed prescription drugs to the PDMP. To enhance the PDMP for use by prescribers, the Nebraska PDMP has the Drug Safety Advisory Group that includes key partners and stakeholder involvement. During the development phase for the database this group convened quarterly in order to determine what enhancements will increase the ease of use, increase PDMP utilization, and decrease disruption to daily workflow. Key partners and stakeholders for the PDMP are the Division of Behavioral Health (DBH), Nebraska Hospital Association (NHA), Nebraska Medical Association (NMA), Nebraska Pharmacists Association (NPA), the Nebraska State Patrol, along with the Nebraska Medicaid Program.	The Drug Safety Advisory Group continues to meet quarterly to discuss future enhancements and other ways to increase the utilization of the system by medical providers. The upcoming enhancements that have been requested are interstate data sharing and a designee management system. See criteria 1 for details on interstate sharing. The purpose of the designee management system is to help streamline the registration process and to ensure the integrity of the system.	The interstate sharing system and designee management systems are slated to be implemented within the next calendar year.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criterion 3: Enhanced connectivity between the state's PDMP and any statewide, regional or local health information exchange.	See Criteria 1 response	See Criteria 1 response.	See Criteria 1 response.
Criterion 4: Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns.	In October 2017, DHHS released the Nebraska Pain Management Guidance Document, a comprehensive opioid prescribing resource for prescribers, to assist in meeting the program objective of ensuring prescription drugs are used for medically appropriate purposes. This resource was created by a diverse task force including practicing clinicians, medical directors, psychiatrists, emergency department providers, pain medicine specialists, anesthesiologists, and public health professionals. The goal of the document is to provide "real-world tools and advice to practicing clinicians as they seek to comply with national standards." The guidelines outlined in the document align with the CDC Guidelines for Chronic Pain released March 2016 and build off best practices as identified through CDC guidance and similar initiatives in other states. The development of the prescriber's patient dashboard and its continual enhancements has been central to improving PDMP workflow. Within the functionality of this dashboard, users are allowed to save patients to their physician or prescriber profile, giving them access to easily review their patients regularly. By having high risk patients on a prescriber dashboard, they are quickly aware of any alerts that are associated with one of these patients. The alert types which have been developed for this system are centered on patient actions that could be considered high risk, especially when risks are combined. The current possible alerts are: • overlapping dispensed opioids and benzodiazepines alert;	There are no anticipated actions needed by Nebraska for fulfillment of this criteria.	No actions necessary.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	• multiple prescriber episodes (patients receiving opioid prescriptions from more than one prescriber and having them dispensed at more than one pharmacy) alert; • a risk score alert Thus, this functionality takes multiple alerts combined and brings the situation to the attention of prescribers when patients are at increased risk of an opioid related adverse event. Depending on the situation, as risk thresholds associated with the alert are met or passed, the alert is given a color to give the prescriber additional visual guidance as to the severity of the current situation. When visiting that patient's profile, all of the alerts associated are clear and color coded and can be expanded for detailed information on the events taking place. Within the alert, the prescriber is also given direct links to pertinent sections of the Nebraska Pain Management Guidance document, along with direct links to the CDC's MME calculator, as applicable.		
Criterion 5: Facilitate the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP	The PDMP patient dashboard includes patient matching processes. Because of variations in how names may be maintained in medical records for different medical practices, the dashboard allows patient histories to be combined into a single profile instead of by each variation in patient name, including nick names. When a prescriber searches for a patient only the first 2 letters of the last name and first letter of the first name are required to begin a search. There are options for a cross name search when a patient has, for example, a first name that could be mistakenly identified as a last name. These search features allow for name or date of birth errors to be accounted for. Upon search results, the prescriber is given a selection of patient matches and they are given a "pick list" selection of the names they believe to be the same individual and after confirmation they are able to combine records for individual patients on their dashboard. This search can then be saved and added to the prescriber's patient dashboard to allow for a quick query for that patient in the future.	There are no anticipated actions needed by Nebraska for fulfillment of this criteria.	No actions necessary.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criterion 6: Develop enhanced provider workflow / business processes to better support clinicians in accessing the PDMP prior to prescribing an opioid or other controlled substance to address the issues which follow.	As a part of the DHHS July 2018-July 2019 Business Plan http://dhhs.ne.gov/Documents/BusinessPlan.pdf the following are deliverables in place for Nebraska's PDMP program: Increase the number of new registered healthcare providers to 40% of those licensed (met and exceeded by December 2018), educate healthcare providers on Nebraska pain management guidance education, continue training healthcare providers on access and use of PDMP system in high burden areas and statewide, and continue to convene Drug Safety Advisory Group.	There are no anticipated actions needed by Nebraska for fulfillment of this criteria.	No actions necessary.
Criterion 7: Develop enhanced supports for clinician review of the patients' history of controlled substance prescriptions provided through the PDMP—prior to the issuance of an opioid prescription.	Once the user is reviewing the medication history of their patient they have additional functionality in how they view these medications. Due to the volume of medications possible, there are filters and sorting options in place. In Nebraska, options include • timeframes (3, 6, 9, 12 month periods); • view controlled only; • controlled/non-controlled separated; or all dispensed medication together; • sorting by date; and • roll-up features by drug and strength to quickly view overall medications dispensed to the patient. This control over information allows for the user to easily review the patient's historical use of controlled substances before they choose to prescribe.	There are no anticipated actions needed by Nebraska for fulfillment of this criteria.	No actions necessary.
Criterion 8: Enhance the master patient index (MPI) or master data management service (MDMS) in support of SUD care delivery.	See Criteria 5 response	There are no anticipated actions needed by Nebraska for fulfillment of this criteria.	No actions necessary.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criterion 9: Leverage the above functionalities/capabilities/supports (in concert with any other state health IT, TA or workflow effort) to implement effective controls to minimize the risk of inappropriate opioid overprescribing —and to ensure that Medicaid does not inappropriately pay for opioids.	See Criteria 1, 2, 4, 5 and 7 responses	There are no anticipated actions needed by Nebraska for fulfillment of this criteria.	No actions necessary.

Part 2: Attestation

Statement 1: Indicate whether the state has sufficient health IT infrastructure/"ecosystem" at every appropriate level to achieve the goals of the demonstration.

Nebraska Medicaid is currently working with Deloitte Consulting LLP to build a more advanced data warehouse and decision support system to be utilized at the State level, described in further detail in Statement 2 below. Through its contracts with Medicaid health plans, Nebraska Medicaid is able to leverage the MCO's existing health IT infrastructure to the benefit of members and providers. This existing infrastructure assists in meeting existing and future contract requirements, as detailed in this application's Implementation Plan, so that the demonstration goals can be met.

Nebraska Medicaid and its contracted MCOs have implemented several of the Health IT examples cited by CMS.

In order to assure that Nebraska Medicaid members are accessing care needed for their treatment, contracted MCOs utilize identity management tools. These tools are critical not only to assuring that Medicaid is accessing real-time data for individuals when processing claims, it also assists in monitoring an individual's claim information to track trends in their care. These trends can assist in the establishment of care management plans when a member's health care needs change.

In order to support adherence to and retention in treatment, all contracted MCO's have smartphone apps which are made available to members in order to improve participation in their health care. Capabilities of these apps may include: assistance in locating providers or urgent care centers, options to contact their plan within the app, and checkup alerts. Specific to SUD treatment, one of the health plans utilizes a "recovery app" with trigger alerts and a visual journal, along with a directory of phone numbers to assist in locating an AA meeting near their current location. Through this app they can also add friends, share meetings, and track their progress in recovery.

Nebraska recognizes the importance of provider connectivity to Health Information Systems in the prevention of overdose deaths. As further described in Table 1, Nebraska's PDMP is housed on Nebraska's Health information Exchange (HIE) and can be queried directly from the HIE. Nebraska's PDMP has 44.6% of licensed Nebraska prescribers and dispensers with addresses in Nebraska, Kansas, Missouri, Iowa, South Dakota, Wyoming, and Colorado registered to access and use the Nebraska PDMP database. As of November 30, 2018, 100% of Nebraska licensed community pharmacies and mail-service pharmacies are registered or reporting to the Nebraska PDMP.

Provider capacity for behavioral health services is a challenge in Nebraska due to the state's rural profile. One way that Nebraska Medicaid is addressing this is through the coverage of services provided through telehealth. Nebraska Medicaid has been proactive in recognizing state-level telehealth barriers and has worked to expand the availability and utilization of telehealth for physical and behavioral health services. On January 1, 2017, Nebraska Medicaid implemented new telehealth regulations that expanded Medicaid-covered telehealth services to include billing for telemonitoring and the originating site fee. With this recent regulatory service expansion, Nebraska Medicaid believes that the state has laid a policy foundation for increased utilization of telehealth services including tele-SUD.

As described further in Table 1, Nebraska's PDMP includes tools for providers which are in place to assist in the tracking of high risk individuals. Prescribers can receive alerts for what could be considered high risk behavior, and links within the alert to clinical guidelines that correspond directly to a member's current risk level or need. This functionality can not only prevent the need for a higher level of care due to the early detection of high risk behavior, but it can also be a tool for managing patients through their SUD recovery.

Care management for all contracted health plans is centered on Whole Person Care. In order to meet all of the care needs of members, MCOs utilize predictive modeling technology which can identify risk levels for care management, and by accessing member data can develop individualized risk profiles and identify trends. From there, members can be targeted for specific care management programs which are appropriate for their health conditions and social circumstances. By fully identifying the risks and the individual needs of each member, care management systems assist in the coordination of care through each level of treatment, and can connect members with community resources.

Statement 2: Indicate whether the state's SUD Health IT Plan is "aligned with the state's broader State Medicaid Health IT Plan (SMHP) and if applicable, the state's Behavioral Health (BH) Health IT Plan".

Nebraska Medicaid's SUD Health IT Plan is aligned with the state's broader State Medicaid Health IT Plan.

Nebraska Medicaid is currently replacing its data warehouse and decision support system with an updated data warehouse and business intelligence technology platform. Nebraska Medicaid contracted with Deloitte Consulting LLP to implement their HealthInteractive solution. The DMA project, which successfully began in February 2018, has been on schedule through 2018 and is scheduled for go-live in June 2019.

A key component of the DMA project is the enhancement of the state's encounter acceptance and processing capabilities. Improvements to this process directly impact the implementation of the 1115 SUD waiver and the reporting required over the course of the demonstration. Based on the ongoing discussions between Nebraska and CMS in regards to the state's demonstration application, Nebraska Medicaid believes the implementation calendar for the HealthInteractive solution closely aligns with the timetable for CMS's potential approval of the 1115 SUD demonstration. Therefore, Nebraska Medicaid anticipates that the enhancements made to data collection and analysis through the implementation of HealthInteractive will positively impact waiver implementation and monitoring from the beginning of the demonstration. Furthermore, Nebraska Medicaid believes that future enhancements enabled by the HealthInteractive platform will only further improve Nebraska's ability to meet the milestones established by CMS.

A specific enhancement that will directly impact the state's SUD monitoring and policy development is illustrated by refinements to the Medicaid pharmacy encounter process. 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.

Part 3: Advancing Interoperability using Health IT Standards

Statement 3: Indicate that the state will include appropriate standards reference in the ONC Interoperability Standards Advisory (ISA) and 45 CFR 170 Subpart B in subsequent MCO contract amendments or Medicaid funded MCO/Health Care Plan re-procurements.

Nebraska Medicaid will include appropriate standards, as referenced in the ONC Interoperability Standards Advisory (ISA) and 45 CFR 170 Subpart B, in subsequent MCO contract amendments and MCO re-procurements.

Through contract requirements, implementation of the State's Medicaid Health IT Plan[1], continued participation in other Nebraska health information initiatives, and shared learning with the parent companies and other state affiliates of contracted MCOs, Nebraska Medicaid believes MCOs can achieve implementation of applicable interoperability standards.

All currently contracted Nebraska Medicaid MCOs are participating in coordinated Admission, Discharge, Transfer initiatives either in Nebraska or in other Medicaid markets in which the MCO's parent company operates. For example, the Office of the National Coordinator for Health Information Technology recently highlighted state managed care Health IT initiatives which included references to the utilization of ADT for behavioral health services by the Tennessee affiliate of one of Nebraska's currently contracted health plans.[2]

Parent companies of currently contracted Nebraska Medicaid MCOs have also operationalized other ISA examples cited by CMS in its Attachment A template. For example, the Georgia affiliate of one of Nebraska's currently contracted health plans was instrumental in the eventual implementation of Consolidated-Clinical Document Architecture (C-CDA) transactions by the Georgia Health Information Network.

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[1] State Medicaid Health Information Technology Plan: http://dhhs.ne.gov/medicaid/Documents/State%20Medicaid%20Health%20Information%20Technology%20Plan.pdf

[2] Office of the National Coordinator for Health Information Technology: "Tennessee Empowering MCO Providers: Increasing Health IT Functionality Reducing Reporting Burden." Page 12. Link available at: https://www.healthit.gov/sites/default/files/2018-12/TennesseeEmpoweringMCOProviders.pdf

Attachment E

SUD Evaluation Design

PUBLIC CONSULTING GROUP

Solutions that Matter

Evaluation Design: Nebraska Medicaid SUD Demonstration Program

July 21, 2020

Public Consulting Group
148 State Street.
Boston, MA. 02109

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A. GENERAL BACKGROUND INFORMATION

1. Demonstration Name and Time Period

The Nebraska Substance Use Disorder demonstration is a new 1115 waiver, approved for July 1, 2019 through June 30, 2024.

2. Demonstration Goals

The purpose of this SUD-focused demonstration program is to enable the State to provide a full continuum of care for people struggling with addiction. While Nebraska has not experienced the type of public health crisis afflicting other states as a result of prescription and illicit opioid abuse, the state is still feeling the impact of the national epidemic. Drug overdoses were responsible for 128 deaths in Nebraska in 2016, and of those, 35% involved an opioid.[1] Nebraskans, including those participating in the Medicaid program, continue to struggle with a variety of substance use challenges including opioids. The drug of choice identified by individuals admitted to Substance Abuse Treatment Centers (SATC) in 2016 include alcohol, meth, marijuana, opiates, and cocaine. The State believes the demonstration program approved by CMS will allow the state to build on the recent delivery system reforms and DHHS-wide SUD initiatives.

During the demonstration period, the state seeks to achieve the following goals:

1. Increased rates of identification, initiation, and engagement in treatment for SUD;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. 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;
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 with SUD.

The State seeks to achieve these goals by improving access to evidence-based SUD treatment, and by improving the quality of available SUD treatment. In particular, the demonstration aims to increase access to IMD[2] stays, Medically Managed/Monitored Withdrawal services, and Medication Assisted Treatment for beneficiaries with OUD.

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[1] DHHS Drug Overdose Facts Sheet for 2016. Pg. 1. Available at: http://dhhs.ne.gov/DOP%20document%20library/Special%20Emphasis%20Report%20Prescription%20Drug%20Overdose%202016.pdf

[2] Institution for Mental Diseases (IMD): The term "institution for mental diseases" means a hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services.

3. Description of the Demonstration

Nebraska Medicaid[3] currently offers a range of outpatient and inpatient SUD services, which will be enhanced by the new services added by the demonstration (Table 1). Coverage of IMD stays >15 days had been available previously under "in lieu of service" authority but was authorized under the waiver authority beginning at the launch of the demonstration. The 1115 waiver and State Plan authority were received simultaneously, allowing MLTC to communicate the change to providers and begin waiver-authorized reimbursement immediately. The new service categories offered as part of the SUD waiver demonstration are medically managed/monitored withdrawal management (MMW), and Medication-assisted Treatment/opioid treatment Programs (MAT/OTP). DHHS has applied for State Plan authority for MMW and MAT/OTP, and anticipates receiving approval in July 2020. While the approval is expected to retroactively authorize billing as of Jan 1,2020, reimbursement will be rolled out in the fourth quarter of 2020, due to the preparation required for implementation. Nebraska has low rates of OUD compared to most states, and therefore has not previously developed the infrastructure for comprehensive OUD treatment. Prior to the demonstration, neither MMW or MAT/OTP was widely available in the state, and the few providers offering services did not participate in Medicaid. In order to successfully increase access, DHHS needed to design requirements and rate structures that would be viable for providers, and to support providers in developing capacity for new services. During the first year of the demonstration, MLTC researched other states' policies, and engaged stakeholders including MCOs and current and prospective service providers. Preparations for rollout included development of:

- Service definitions
- Billing guidelines and fees
- IT updates to the billing system
- Updated regulations
- Provider enrollment and certification requirements
- Provider training materials

DHHS anticipates being ready to offer MMW and MAT/OTP services beginning Oct 1, 2020.

[3] The Division of Medicaid and Long-term Care (MLTC) is the agency responsible for the administration of the Medicaid program in Nebraska. MLTC is one of five divisions that make up the Nebraska Department of Health and Humans Services (DHHS).

Table 1. Existing and New Nebraska Medicaid SUD Services by ASAM Level of Care.

ASAM Level of Care	ASAM Service Title	ASAM Brief Definition	Service Start Date	Medicaid Service Authority[4]
1.0	Outpatient Services	Less than nine hours of service/week (adults); less than six hours/week (adolescents) for recovery or motivational enhancement therapies/strategies.	Existing Medicaid Service	1915(b)
2.1	Intensive Outpatient Services	Nine or more hours of service/week (adults); six or more hours/week (adolescents) to treat multidimensional instability.	Existing Medicaid Service	1915(b)
2.5	Partial Hospitalization Services	20 or more hours of service/week for multidimensional instability not requiring 24-hour care	Existing Medicaid Service	1915(b)
3.1	Clinically Managed Low-Intensity Residential Services	24-hour structure with available trained personnel; at least five hours of clinical service/week and prepare for outpatient treatment.	Existing Medicaid Service (Stays >15 days covered under demonstration as of 7/9/2019)	1915(b) and 1115(a)
3.2-WM	Clinically Managed Residential Withdrawal Management	Moderate withdrawal, but needs 24-hour support to complete withdrawal management and increase likelihood of continuing treatment or recovery.	Existing Medicaid Service	1915(b)
3.3	Clinically Managed Population- Specific High- Intensity Residential Services	24-hour care with trained counselors to stabilize multidimensional imminent danger. Less intense milieu and group treatment for those with cognitive or other impairments unable to use full active milieu or therapeutic community and prepare for outpatient treatment.	Existing Medicaid Service (Stays >15 days covered under demonstration as of 7/9/2019)	1915(b) and 1115(a)
3.5	Clinically Managed High-Intensity Residential Services	24-hour care with trained counselors to stabilize multidimensional imminent danger and prepare for outpatient treatment. Able to tolerate and use full milieu or therapeutic community.	Existing Medicaid Service (Stays >15 days covered under demonstration as of 7/9/2019)	1915(b) and 1115(a)
3.7-WM (New)	Medically Monitored Inpatient Withdrawal Management	Severe withdrawal, 24-hour nursing care and physician visits; unlikely to complete withdrawal management without medical monitoring. **	New Service Anticipated 10/1/2020	State Plan (submitted to CMS on March 31, 2020)
Opioid Treatment Program (OTP)	Must meet ASAM criteria for care placement	Community based outpatient addiction treatment for individuals diagnosed with a severe opioid use disorder, as defined in the Diagnostic Statistical Manual (DSM), and meeting American Society of Addiction Medicine (ASAM) criteria for care placement,	New Service Anticipated 10/1/2020	State Plan (submitted to CMS on March 31, 2020)

[4] Services that are impacted by the expenditure authority allowed under this demonstration waiver include a reference to 1115(a) authority in the Medicaid Service Authority column.

		as determined by a practitioner. Opioid treatment programs administer medications approved by the Food and Drug Administration (FDA) to treat opiate addiction and the alleviation of the adverse medical, psychological, or physical effects incident to opioid addiction. Medications are provided in conjunction with rehabilitative and medical services, in accordance with 42 CFR § 8.12. Length of service is based on an individual's medical need, to achieve stabilization and prevent relapse.		
Other	Peer Support	Peer support services are provided by individuals who have lived experience with Mental Health or Substance Use Disorders (SUD). The core element of this service is the development of a relationship based on shared lived experience and mutuality between the provider and individual.	Existing Medicaid Service	State Plan

* Descriptions taken from ASAM Resource Guide
** Includes addition of methadone

4. Description of the population

Currently the Nebraska Medicaid Program provides health coverage to approximately 240,000 residents. In any given month, 10 to 12 percent of the state's population is eligible for Medicaid. DHHS anticipates an increase in the adult beneficiary population beginning Oct 1, 2020 due to Medicaid Expansion. Over 98 percent of Medicaid enrollees are served through the state's managed care delivery system.

While Medicaid beneficiaries receiving long-term services and supports (LTSS) receive their physical health, behavioral health, and pharmacy services through their managed care plan, their LTSS benefits continue to be delivered through the legacy FFS system.

The target population for the demonstration is all Medicaid beneficiaries aged 19-64.

5. Nebraska context

State OUD context

In Nebraska, the prevalence of opioid-related death and hospitalization is lower than national rates but has increased rapidly in recent years. Emergency department visits related to opioid overdoses were 80.8 per 100,000 people in 2017, up from 33.3 per 100,000 in 2007.[4] Inpatient stays similarly grew from 61.4 to 168.5 per 100,000 over the same time period.[5] Nebraska's drug overdose death rate also increased to 8.1 per 100,000 people in 2017, up from 3.6 per 100,000 in 2004.[6] In addition, Nebraska is also experiencing an increase in newborns exhibiting drug withdrawal symptoms. Recent data from the National Institute on Drug Abuse indicates that rates of NAS in Nebraska have not only increased, but more than doubled in a span of only four years, from less than 1 case per 1,000 hospital births in 2010 to 2.1 cases per 1,000 hospital births in 2016.[7]

While Nebraska's rates of SUD are lower than the US average, the frequency of needing but not receiving SUD treatment is similar to the national rate, indicating that Nebraska residents with SUD are underserved.[8] This gap can be attributed in part to a lack of available services. Results from the National Survey of Substance Abuse Treatment Services (N-SSATS) indicated that compared to the US average, Nebraska has fewer facilities providing services for detoxification and for MAT/OTP relative to the size of the adult population[9] (Table 2).

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[5] HCUP Fast Stats. Healthcare Cost and Utilization Project (HCUP). December 2019. Agency for Healthcare Research and Quality, Rockville, MD. www.hcup-us.ahrq.gov/faststats/opioid/opioiduse

[6] National Institute on Drug Abuse, Nebraska Opioid Summary, May 2019. Retrieved from: https://www.drugabuse.gov/opioid-summaries-by-state/nebraska-opioid-summary

[7] HCUP Fast Stats. Healthcare Cost and Utilization Project (HCUP). December 2019. Agency for Healthcare Research and Quality, Rockville, MD. Retrieved from: www.hcup-us.ahrq.gov/faststats/nas/nasquery

[8] 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/

[9] Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, National Survey of Substance Abuse Treatment Services (N–SSATS), 2008–2018.

Table 2 Number of facilities in Nebraska and nationally offering substance use disorder treatment.

	Nebraska		US	
	Number of facilities	**Per 10,000 Adult Residents***	**Number of facilities**	**Per 10,000 Adult Residents***
Total facilities responding to survey	124	0.8502	14,809	0.5803
Facilities offering:				
All detoxification	14	0.0960	3336	0.1307
Outpatient facilities offering detoxification	3	0.0206**	1505	0.0590
Residential non-hospital facilities offering detoxification	8	0.0549	1140	0.0447
Hospital inpatient facilities offering detoxification	3	0.0206	721	0.0283
Opioid specific detoxification	1	0.0069**	861	0.0337
All facilities offering Opioid Treatment Programs (OTPs)	3	0.0206**	1,519	0.0595
Outpatient facilities offering OTPs	3	0.0206**	1411	0.0553
Residential (non-hospital) facilities offering OTPs	0	0**	132	0.0052
Hospital inpatient facilities offering OTPs	0	0**	121	0.0047
Medication-assisted opioid therapy provided at facilities with OTPs	3	0.0206**	1519	0.0595
Any type of medication assisted therapy (MAT)	22	0.1509**	6,259	0.2453
Buprenorphine (includes buprenorphine with and without naloxone, buprenorphine sub-dermal implant, and extended-release injectable buprenorphine)	16	0.1097**	4951	0.1940

Source: Substance Abuse and Mental Health Services Administration, National Survey of Substance Abuse Treatment Services (N-SSATS): 2018. Data on Substance Abuse Treatment Facilities. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2019. Retrieved from: https://www.samhsa.gov/data/data-we-collect/nssats-national-survey-substance-abuse-treatmentservices.

* Number of facilities divided by the number of adult residents in Nebraska (1,458,334) and the US (255,200,373) as reported by U.S. Census Bureau, Population Division, Estimates of the Total Resident Population and Resident Population Age 18 Years and Older for the United States, States, and Puerto Rico: July 1, 2019

History of IMD coverage

A critical element in realizing CMS's goals for this demonstration is the ability for Nebraska Medicaid to allow Medicaid-enrolled individuals requiring inpatient SUD treatment to be allowed to complete their medically appropriate length of stay in facilities that meet the regulatory definition of an Institution for Mental Diseases (IMD) as defined in Section 1905(i) of the Social Security Act.[10]

On July 5, 2016, CMS implemented the Medicaid and CHIP Managed Care Final Rule (Final Rule). 42 CFR 438.6(e) as established by the Final Rule stipulates that a state may make a capitation payment to a managed care organization (MCO) for a Medicaid enrollee age 21-64 receiving inpatient treatment in an IMD for a "short term" stay of no longer than 15 days during the period of the monthly capitation payment.

Prior to the implementation of this provision, Nebraska was among several Medicaid managed care states that included IMD stays (regardless of the length of stay) in rate development for capitation payments utilizing CMS's well established "in lieu of service" authority which allowed states to offer services not covered by the State Plan provided those services met certain criteria including medical appropriateness and cost effectiveness.

Implementing the limitations of the Final Rule had the potential to severely disrupt the treatment plans of some of Nebraska Medicaid's most medically and emotionally fragile adults. The Final Rule limitations incentivize Medicaid health plans and providers to seek treatment for individuals with an SUD in less appropriate and potentially costlier settings as those health plans and providers would anticipate that reimbursement for Medicaid services in IMDs will end after 15 days. In Nebraska, this scenario would almost certainly result in increased utilization of emergency departments as the state's rural profile has historically limited the availability of inpatient behavioral health facilities.

DHHS requested expenditure authority to continue to permit Medicaid MCOs to provide enrolled beneficiaries the appropriate combination of services, in the most appropriate and cost-effective setting, and for the medically appropriate duration without regard to:

1) The 15-day length of stay limit imposed by 42 CFR 438.6(e); and
2) The requirement imposed by 42 CFR 438.6(e) that for purposes of capitation rate setting, that utilization of the substitute services identified in that that section be priced by the state and its contracted actuary at the cost of the same services delivered in state plan settings.

With the waiver approval on Jul 9, 2019, DHHS was granted expenditure authority under Section 1115 to claim as medical assistance the costs of services provided to eligible individuals ages 21-64 residing in facilities meeting the regulatory definition of an IMD.

Upcoming Medicaid Expansion

The demonstration also builds on the state's broad efforts to reform and update the Medicaid program. On January 1, 2017, Nebraska Medicaid launched Heritage Health, a new managed care program that integrates physical health, behavioral health, and pharmacy services into a single, statewide,

[10] Section 1905(i) of the Social Security Act. Available at: https://www.ssa.gov/OP_Home/ssact/title19/1905.htm

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.

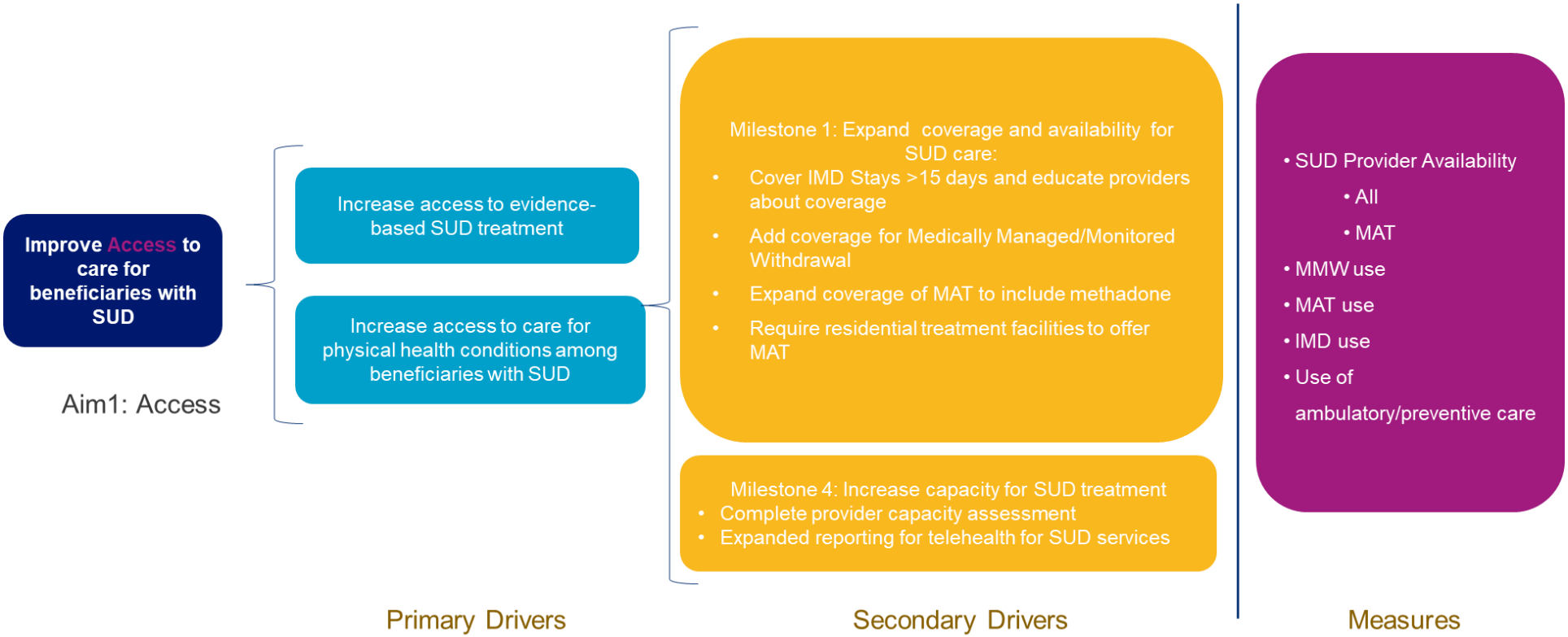

Figure 1 Driver Diagram, Access

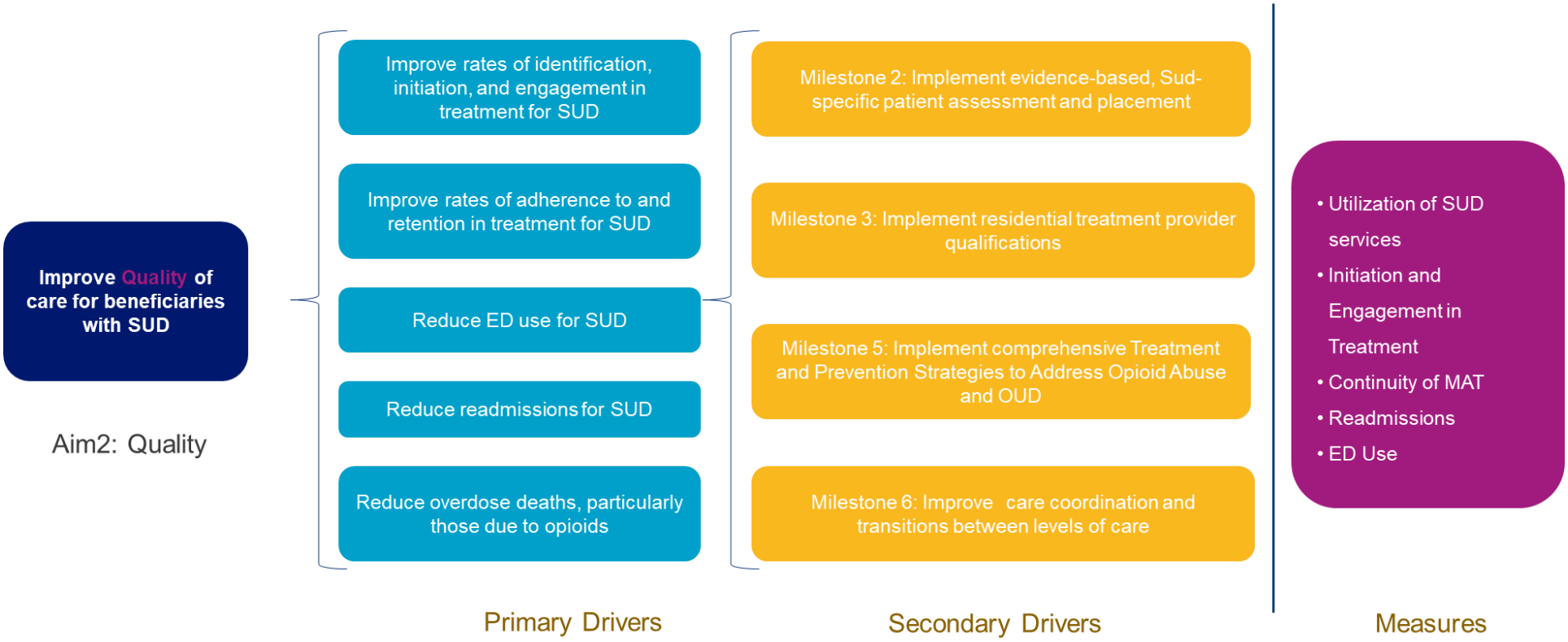

Figure 2 Driver diagram, Quality

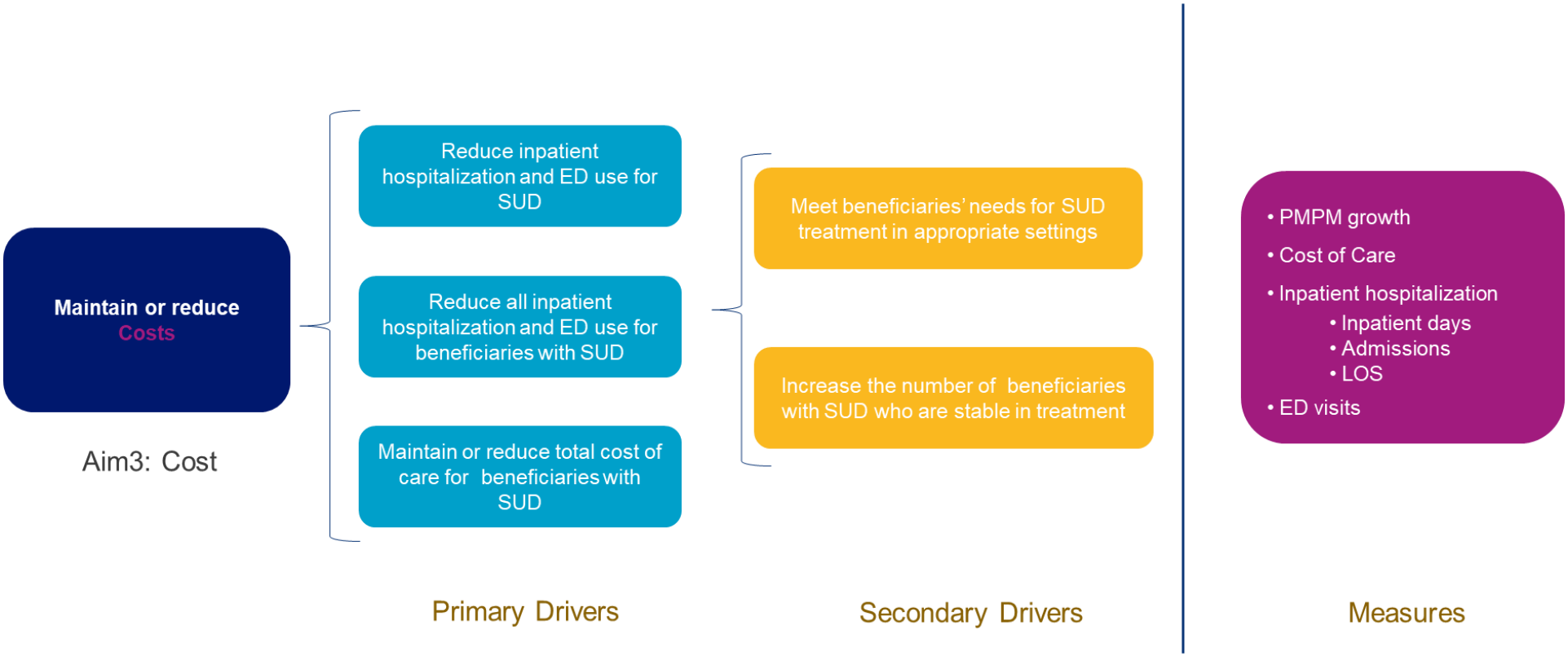

Figure 3 Driver diagram, Cost

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.[15][16] 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