

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop: S2-25-26  
Baltimore, Maryland 21244-1850



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## State Demonstrations Group

March 8, 2024

Christine Osterlund  
Medicaid Director  
Department of Health and Environment  
900 SW Jackson Avenue, Suite 900  
Topeka, KS 66612

Dear Director Osterlund:

The Centers for Medicare & Medicaid Services (CMS) is issuing technical corrections to the Kansas section 1115(a) demonstration, entitled “KanCare” (Project Number 11-W-00283/7). The technical corrections ensure that the special terms and conditions (STCs) accurately reflect CMS’s December 14, 2023 approval of the demonstration extension.

CMS updated the STCs to provide clarification that the state has fulfilled the SUD implementation plan and health IT plan requirements, as documented by CMS’s approval of those deliverables on August 7, 2019. Additionally, CMS modified the STCs pertinent to the performance metrics and evaluation questions and hypotheses to represent more appropriately the scope of the demonstration components in the KanCare extension.

We look forward to our continued partnership on the KanCare section 1115(a) demonstration. If you have any questions, please contact your CMS project officer, Shelby Higgins, at [Shelby.Higgins@cms.hhs.gov](mailto:Shelby.Higgins@cms.hhs.gov).

Sincerely,

Angela D. Garner  
Director  
Division of System Reform Demonstrations

Enclosure

cc: Helenita Augustus, State Monitoring Lead, Medicaid and CHIP Operations Group

## CENTERS FOR MEDICARE & MEDICAID SERVICES

### EXPENDITURE AUTHORITY

**NUMBER:** 11-W-00283/7  
**TITLE:** KanCare Section 1115(a) Demonstration  
**AWARDEE:** Kansas Department of Health and Environment

Under the authority of section 1115(a)(2)(A) of the Social Security Act (the Act), expenditures made by Kansas for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, 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 Kansas to operate the above-identified section 1115 demonstration.

1. **Expenditures for Additional Services for Individuals with Behavioral Health Needs.** Expenditures for the following services furnished to individuals eligible under the approved state plan, pursuant to the limitations and qualifications provided in STC 5.1 to address behavioral health needs:
  - a. Physician Consultation (Case Conferences); and
  - b. Personal Care Services.
2. **Residential and Inpatient Treatment for Individuals with Substance Use Disorder (SUD).** Expenditures for Medicaid state plan services furnished to otherwise eligible individuals who are primarily receiving treatment and/or withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental disease diseases (IMD).
3. **Continuous Eligibility Period for Parents and Other Caretaker Relatives.** Expenditures for health care related costs for individuals who have been determined eligible under the mandatory group for parents and other caretaker relatives using Modified Adjusted Gross Income (MAGI) Eligibility, as described in sections 1902(a)(10)(A)(i)(I) and 1931(b) and (d) of the Act, for continued benefits during any periods within a twelve month eligibility period when these individuals would be found ineligible if subject to redetermination, as described in STC 4.3.
4. **Continuous Coverage for Individuals Aging Out of CHIP.** Expenditures through the end of the COVID-19 public health emergency (PHE) unwinding period, or until all redeterminations are conducted during the unwinding period, to provide continued eligibility for CHIP enrollees who turned 19 during the PHE (and therefore lost eligibility for CHIP due to age).

# CENTERS FOR MEDICARE & MEDICAID SERVICES

## SPECIAL TERMS AND CONDITIONS

**NUMBER:** 11-W-00283/7  
**TITLE:** KanCare  
**AWARDEE:** Kansas Department of Health and Environment

### I. PREFACE

The following are the Special Terms and Conditions (STCs) for the “KanCare” section 1115(a) Medicaid demonstration (hereinafter “demonstration”), to enable the Kansas Department of Health and Environment (hereinafter “state” to operate this demonstration). The Centers for Medicare & Medicaid Services (CMS) has granted waivers of requirements under section 1902(a) of the Social Security Act (Act), and expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on those waivers and 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 this demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted.

The STCs related to the programs for those populations affected by the demonstration are effective from January 1, 2024, through December 31, 2028.

The STCs have been arranged into the following subject areas:

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

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: Monitoring Protocol (Reserved)  
Attachment E: Evaluation Design (Reserved)

## II. PROGRAM DESCRIPTION AND OBJECTIVES

The KanCare demonstration was originally approved on December 27, 2012, for a five-year demonstration period effective from January 1, 2013, through December 31, 2017. CMS then approved a one-year temporary extension of this demonstration on October 13, 2017, and a five-year extension on December 18, 2018, for an approval period of January 1, 2019, through December 31, 2023. On December 28, 2022, the State of Kansas submitted a Medicaid section 1115 demonstration five-year renewal application to extend certain features of the demonstration. This KanCare this demonstration will continue four programs that have been authorized under expenditure authority.

This five-year demonstration will:

- Maintain 12-month continuous eligibility for parents and caretakers;
- Maintain continuous eligibility for the duration of the COVID-19 PHE unwinding period for CHIP enrollees who turned 19 during the COVID-19 PHE unwinding period (and therefore lost eligibility for CHIP due to age) and who are otherwise ineligible for Medicaid;
- Continue federal financial participation for services provided in an IMD for Medicaid beneficiaries with SUD and
- Continue federal financial participation for physician consultation and personal care services for individuals with behavioral health needs.

The KanCare demonstration will assist the state in its goals to:

- Provide better access to services and reduce ineffective disenrollment for certain populations:
  - Reduce churn or inefficient disenrollment with continuous eligibility for parents and caretakers; and
  - Reduce churn or inefficient disenrollment with continuous eligibility for CHIP enrollees who turned 19 during the COVID-19 PHE unwinding period.
- Improve access to appropriate SUD services, including:
  - Increase rates of identification, initiation, and engagement in treatment for SUD;
  - Increase adherence to and retention in SUD treatment;
  - Reduce overdose deaths, particularly those due to opioids;
  - Reduce utilization of EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services;
  - Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; and
  - Improve access to care for physical health conditions among beneficiaries with SUD.

- Improve behavioral health outcomes for serious mental illness (SMI)--diagnosed members, including:
  - Enhance community integration; and
  - Reduce psychiatric hospital admissions.

### III. GENERAL PROGRAM REQUIREMENTS

- 3.1. **Compliance with Federal Non-Discrimination Laws.** 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 Affordable Care Act (Section 1557).
- 3.2. **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.
- 3.3. **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 3.7. 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.
- 3.4. **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. 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 3.7 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.
- 3.5. **State Plan Amendments.** The state will not be required to submit title XIX or title XXI state plan amendments (SPA) 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 may be required, except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP state plans governs.

- 3.6. **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 3.7, except as provided in STC 3.3.
- 3.7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 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 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 3.12. 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 detail 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 neutrality 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.
- 3.8. **Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS from the Governor of the state in accordance with the requirements of 42 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 3.9.

**3.9. 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 3.12, 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 redeterminations 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 redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR 35.916(f)(1). For individuals determined ineligible for Medicaid and CHIP, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e). The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206 through 431.214. 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.

- 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 are 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.
- 3.10. **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 waivers 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's 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.
- 3.11. **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.
- 3.12. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR 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 comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.
- 3.13. **Federal Financial Participation (FFP).** No federal matching funds for expenditures for this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.

- 3.14. **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.
- 3.15. **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

- 4.1. **Individuals Eligible for the OUD/SUD Program Benefit.** Under the demonstration, there is no change to Medicaid eligibility for the SUD benefit Standards for eligibility remain set forth under the state plan. The demonstration will allow Kansas Medicaid recipients to receive substance use disorder treatment services in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD), which are not otherwise matchable expenditures under section 1903 of the Act.
- 4.2. **Individuals Not Otherwise Eligible under the Medicaid State Plan.** Beneficiary eligibility groups who are made eligible for the demonstration by virtue of the expenditure authorities expressly granted in this demonstration are subject to Medicaid laws and regulations, except for those identified as non-applicable in the expenditure authorities for this document. Eligibility criteria are described in STC 4.3 and STC 4.4. Individuals made eligible under this demonstration by virtue of the expenditure authorities expressly granted include:
- a. Individuals in the Parents and Other Caretaker Relatives Group (described in sections 1902(a)(10)(A)(i)(I) and sections 1932(b) and (d) of the Act, and 42 CFR 435.110) who have continued benefits during any part of a twelve-month eligibility period when these individuals would be found ineligible if subject to redetermination.
  - b. Individuals in the Children’s Health Insurance Program (CHIP) who turned 19 during the COVID-19 PHE (and therefore would have lost eligibility for CHIP due to age).
- 4.3. **Continuous Eligibility Period for Parents and Other Caretaker Relatives.**
- a. Duration. The state is authorized to provide a twelve-month continuous eligibility period to Parents and Other Caretaker Relatives specified in STC 4.2(a) regardless of the delivery system through which they receive Medicaid benefits. The twelve-month period shall begin on the effective date of the individual’s eligibility under § 435.915 or most recent redetermination or renewal of eligibility under § 435.916 and extend for twelve months. For individuals already enrolled when the authority to provide twelve months of continuous eligibility goes into effect, the continuous eligibility period begins for each individual on the date the individual was last determined eligible and extends for twelve months.
  - b. Applicability. For Parents and Other Caretaker Relatives described in STC 4.2(a) an individual’s eligibility may not be terminated during a continuous eligibility period, regardless of any changes in circumstances, unless:
    - i. The individual requests voluntary termination of eligibility;
    - ii. The individual ceases to be a resident of the State;
    - iii. The agency determines that eligibility was erroneously granted at the most recent determination, redetermination or renewal of eligibility because of

agency error or fraud, abuse, or perjury attributed to the individual or the individual's representative;

- iv. The individual dies; or
- v. The individual no longer meets the categorical requirements to be a Parent or Caretaker Relative, per 42 CFR §435.4.

**4.4. Continuous Coverage for Individuals Aging Out of CHIP.**

- a. The state is authorized to provide continuous eligibility for CHIP enrollees who turned 19 during the COVID-19 PHE (and therefore lost eligibility for CHIP due to age), specified in STC 4.2(b), through the end of the COVID-19 PHE and subsequent unwinding period, or until all redeterminations are conducted during the unwinding period.

**V. BENEFITS**

5.1. **Additional Services.** KanCare MCOs will provide the following services to certain populations below.

a. Additional services covered by the demonstration:

**Table 1. Additional Services Covered by the Demonstration**

Service	Populations Eligible
<p><b>Physician Consultation (Case Conferences):</b> Communication between licensed mental health practitioners (LMHP), advanced registered nurse practitioner (ARNP) or Psychiatrist for a patient consultation that is medically necessary for the medical management of the psychiatric conditions. These services are prior-authorized and limited to scheduled face to face meetings to discuss problems associated with the member’s treatment.</p>	<p>Severely and Persistently Mentally Ill (SPMI) adults and Seriously Emotionally Disturbed (SED) youth.</p>
<p><b>Personal Care Services:</b> These are services provided a consumer with severe and persistent mental illness or a serious emotional disturbance who would otherwise be placed in a more restrictive setting due to significant functional impairments resulting from an identified mental illness. This service enables the consumer to accomplish tasks or engage in activities that they would normally do themselves if they did not have a mental illness. Assistance is in the form of direct support, supervision and/or cuing so that the consumer performs the task by him/herself. Such assistance most often relates to performance of ADL and IADL and includes assistance with maintaining daily routines and/or engaging in activities critical to residing in their home community. These services are prior-authorized.</p>	<p>SPMI and SED not receiving personal care under the SED waiver.</p>

5.2. **Opioid Use Disorder/Substance Use Disorder (OUD/SUD) Program Benefits.** Under this demonstration component, Kansas Medicaid recipients will continue to have access to high-quality, evidence-based SUD treatment services including services provided in residential and inpatient treatment settings that qualify as an IMD, which are not otherwise matchable expenditures under section 1903 of the Act. The state will continue to be eligible to receive FFP for Medicaid beneficiaries who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance, including SUD services that would otherwise be matchable if the beneficiary were not residing in an IMD. The state will continue to aim for a statewide average length of stay of 30 days or less in residential treatment settings, to be monitored pursuant to the Monitoring Protocol as outlined in STC 8.6, to ensure short-term residential treatment stays.

Under this demonstration, beneficiaries will have access to high quality, evidence-based SUD treatment services across a comprehensive continuum of care, ranging from residential and inpatient treatment to ongoing chronic care for these conditions in cost-effective community-based settings.

5.3. **SUD Implementation Plan and Health IT Plan.**

- a. The state's SUD Implementation Plan, initially approved for the period from August 7, 2019 through December 31, 2023, remains in effect for the approval period from January 1, 2024 through December 31, 2028, and is affixed to the STCs as Attachment C. Any future modifications to the approved Implementation Plan will require CMS approval. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral. The approved SUD Implementation Plan describes the strategic approach and a detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives of this SUD demonstration project:

- i. *Access to Critical Levels of Care for OUD and other SUDs.* Coverage of SUD treatment services across a comprehensive continuum of care including: outpatient; intensive outpatient; medication assisted treatment (MAT) (medication as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state; intensive levels of care in residential and inpatient settings; and medically supervised withdrawal management, within 12-24 months of demonstration approval;
- ii. *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 the American Society of Addiction Medicine (ASAM) Criteria or other assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of demonstration approval;
- iii. *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;
- iv. *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 the Kansas Standards for Licensure/ Certification of Alcohol and/or Other Drug Abuse Programs, rev. 1/1/06. 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;
- v. *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;
- vi. *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;
- vii. *Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for 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;

- viii. *Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and 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;
  - ix. *Improved Care Coordination and Transition 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.
  - x. *SUD Health IT Plan.* Implementation of a Substance Use Disorder Health Information Technology Plan which describes technology that will support the aims of the demonstration. Further information which describes milestones and metrics as detailed in STC 5.3(b) and Attachment C; and
- b. SUD Health Information Technology Plan (“Health IT Plan”). The state has provided CMS with an assurance that it has a sufficient health IT infrastructure/ “ecosystem” at every appropriate level (i.e. state, delivery system, and individual provider) to achieve the goals of the demonstration – or it will submit to CMS a plan to develop the infrastructure/capabilities.

This “SUD Health IT Plan,” or assurance, will be included as a section of the state’s “Implementation Plan” (see STC 5.3), which will remain in effect for the approval period from January 1, 2024 through December 31, 2028, and is affixed to the STCs as Attachment C. The SUD Health IT Plan does detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The plan also is used to identify areas of SUD health IT ecosystem improvement.

- i. The state must include in its Monitoring Protocol (see STC 8.6) an approach to monitoring its SUD Health IT Plan which will include performance metrics to be approved in advance by CMS.
- ii. The state must monitor progress, each demonstration year (DY), on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS within its Annual Reports (see STC 8.7).
- iii. 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.

- iv. 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.
- v. 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.
- vi. Components of the Health IT Plan include:
  1. The Health IT Plan must describe the state’s alignment with Section 5042 of the SUPPORT Act requiring Medicaid providers to query a Qualified Prescription Drug Monitoring Program (PDMP)<sup>1</sup>.
  2. The Health IT Plan must address how the state’s Qualified PDMP will enhance ease of use for prescribers and other state and federal stakeholders.<sup>2</sup> States should favor procurement strategies that incorporate qualified PDMP data into electronic health records as discrete data without added interface costs to Medicaid providers, leveraging existing federal investments in RX Check for Interstate data sharing.
  3. The Health IT Plan will describe how technology will support substance use disorder prevention and treatment outcomes described by the demonstration.
  4. In developing the Health IT Plan, states should use the following resources:
    - 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/>).
    - 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

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<sup>1</sup> 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.

<sup>2</sup> *Ibid.*

<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.

- 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.
- States should review the Office of the National Coordinator’s Interoperability Standards Advisory (<https://www.healthit.gov/isa/>) for information on appropriate standards which may not be required per 45 CFR part 170, subpart B for enhanced funding, but still should be considered industry standards per 42 CFR §433.112(b)(12).

5.4. **Unallowable Expenditures Under the SUD Expenditure Authority.** 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.

## **VI. COST SHARING**

- 6.1. **Cost Sharing.** Cost sharing imposed upon individuals enrolled in the demonstration is consistent with the provisions of the approved state plan.

## **VII. DELIVERY SYSTEM**

- 7.1. **Delivery System.** No modifications to the current Kansas Medicaid delivery system are proposed through this demonstration. Kansas Medicaid beneficiaries will continue to receive services through the current delivery system.

## VIII. MONITORING AND REPORTING REQUIREMENTS

- 8.1. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals 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 singularly or collectively referred to as “deliverable(s)”) are not submitted timely to CMS or found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the 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.
- a. The following process will be used: 1) 30 calendar days after the deliverable(s) were due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (c) below; or 2) 30 calendar days after CMS has notified the state in writing that the deliverable(s) were not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable(s) into alignment with CMS requirements. requirements.
  - b. 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).
  - c. 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, the steps the state has taken to address such issue(s), and the state’s anticipated date of submission. Should CMS agree in writing to the state’s request, a corresponding extension of the deferral process described below can be provided. CMS may agree to a corrective action plan as an interim step before applying the deferral, if the states proposes a corrective action plan in the state’s written extension request.
  - d. If CMS agrees to an interim corrective plan in accordance with subsection (c) above, 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..
  - e. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement with respect to the required deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.
  - f. 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.

- 8.2. **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 and goals as evidenced by reporting on the milestones in the 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.
- 8.3. **Submission of Post-Approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.
- 8.4. **Electronic Submission of Reports.** The state must submit all monitoring and evaluation report deliverables required in these STCs (e.g., quarterly reports, annual reports, evaluation reports) electronically, through CMS' designated electronic system.
- 8.5. **Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional 1115 waiver 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 section 1115 demonstration, Transformed Medicaid Statistical Information System (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.
- 8.6. **Monitoring Protocol.** The state must submit to CMS a draft Monitoring Protocol for the demonstration within 150 calendar days after approval of the demonstration extension. The Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. The state must submit a revised Monitoring Protocol within 60 calendar days after receipt of CMS' comments, if any. Once approved, the Monitoring Protocol will be incorporated into the STCs, as Attachment D. Progress on the performance measures identified in the Monitoring Protocol must be reported via the Quarterly and Annual Monitoring Reports. Components of the Monitoring Protocol include:
  - a. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in Attachment C and information relevant to the state's Health IT Plan described in STC 5.3;
  - b. 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 monitoring and reporting

requirements described in Section VIII (General Reporting Requirements) of the demonstration; and

- c. 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.

8.7. **Monitoring Reports.** The state must submit three Quarterly Monitoring Reports and one Annual Monitoring Report each demonstration year (DY). The fourth-quarter information that would ordinarily be provided in a separate Quarterly Monitoring Report should be reported as distinct information within the Annual Monitoring Report. The Quarterly Monitoring Reports are due no later than 60 calendar days following the end of each demonstration quarter. The Annual Monitoring Report (including the fourth-quarter information) is due no later than 90 calendar days following the end of the DY. The state must submit a revised Monitoring Report within 60 calendar days after receipt of CMS's comments, if any. The reports will include all required elements as per 42 CFR 431.428 and must not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Quarterly and Annual Monitoring Reports must follow the framework to be 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.** 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 operational and other challenges, underlying causes of challenges, and how challenges are being addressed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; updates on the state's financing plan and maintenance of effort described in STC 5.3; legislative updates; and descriptions of any public forums held. In addition, Monitoring Reports should describe key achievements, as well as the conditions and efforts to which these successes can be attributed. The Monitoring Reports 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 toward meeting the goals and milestones – including relative to their projected timelines – of the demonstration's program and policy implementation and infrastructure investments, and transitional non-service expenditures, as applicable and must cover all key policies under this demonstration. Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries, as well as on beneficiaries' outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction or experience of care surveys, if conducted, as well as grievances and appeals.

The state and CMS will work collaboratively to finalize the list of metrics to be reported on in demonstration Monitoring Reports. The demonstration's metrics reporting must cover categories including, but not limited to: enrollment and renewal, including the percent of renewals completed ex-parte (administratively), access to providers, utilization of services, and quality of care and health outcomes. The state must undertake robust reporting of quality of care and health outcomes metrics aligned with the demonstration's policies and objectives to be reported for all demonstration populations. Such reporting must also be stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, primary language, disability status, and geography) and by demonstration component, to the extent feasible. Subpopulation reporting will support identifying any existing shortcomings or disparities in quality of care and health outcomes and help track whether the demonstration's initiatives help improve outcomes for the state's Medicaid population, including the narrowing of any identified disparities. To that end, CMS underscores the importance of the state's reporting of quality of care and health outcomes metrics known to be important for closing key equity gaps in Medicaid/CHIP (e.g., NQF "disparities-sensitive" measures) and prioritizing key outcome measures and their clinical and non-clinical (i.e., social) drivers of health. In coordination with CMS, the state is expected to select such measures for reporting in alignment with a critical set of equity-focused measures CMS is finalizing as part of its upcoming guidance on the Health Equity Measure Slate, as applicable to the demonstration initiatives and populations. If needed, the state may submit an amendment to its monitoring plan no more than 150 days after receiving the final Health Equity Measure Slate from CMS to incorporate these measures.

- i. For the SUD component, the state's monitoring must align with the CMS approved SUD Monitoring Protocol (see STC 8.6), and will cover metrics in alignment with assessment of need and qualification for SUD treatment services and the demonstration's six milestones as outlined in the State Medicaid Director Letter (SMDL) dated November 1, 2017 (SMDL #17- 003).<sup>3</sup>

In addition, if the state, health plans, or health care providers will contract or partner with organizations to implement the demonstration, the state must use monitoring metrics that track the number and characteristics of contracted or participating organizations and corresponding payment-related metrics.

The required monitoring and performance metrics must be included 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

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<sup>3</sup> SMDL #17-003, Strategies to Address the Opioid Epidemic. Available at: <https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf>

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 for this demonstration should be reported separately on the Form CMS-64.

- 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 5.3(b).

8.8. **SUD Mid-Point Assessment.** The state must contract with an independent entity to conduct an independent Mid-Point Assessment by December 31, 2026. This timeline will allow for the Mid-Point Assessment Report to capture approximately the first two-and-a-half years of demonstration program data, accounting for data run-out and data completeness. In addition, if applicable, the state should use the prior approval period experiences as context and conduct the Mid-Point Assessment in light of the data from any such prior approval period(s). In the design, planning and conduct of the Mid- Point Assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of MCOs, health care providers (including SUD treatment providers), beneficiaries, community groups, and other key partners.

- a. The state must require that the assessor provide a Mid-Point Assessment 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 calendar days after December 31, 2026. If requested, the state must brief CMS on the report. The state must submit a revised Mid-Point Assessment Report within 60 calendar days after receipt of CMS's comments, if any.
- b. 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 SUD Monitoring Protocol for ameliorating these risks. Modifications to the Implementation, Financing Plan, and Monitoring Protocol are subject to CMS approval.
- c. Elements of the Mid-Point Assessment must include:
  - i. 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;

- ii. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date;
- iii. 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;
- iv. 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
- v. An assessment of whether the state is on track to meet the SUD budget neutrality requirements in these STCs.

8.9. **Corrective Action Plan Related to Monitoring.** 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. A corrective action plan could include a temporary suspension of implementation of demonstration programs in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS will withdraw an authority, as described in STC 3.10, when metrics indicate substantial and sustained directional change inconsistent with the state's demonstration goals, and the state has not implemented corrective action. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

8.10. **Close-out Report.** Within 120 days after the expiration of the demonstration, the state must submit a draft Close Out Report to CMS for comments.

- a. The Close-Out Report must comply with the most current guidance from CMS.
- b. In consultation with CMS, and per guidance from CMS, the state will include an evaluation of the demonstration (or demonstration components) that are to phase out or expire without extension along with the Close-Out Report. Depending on the timeline of the phase-out during the demonstration approval period, in agreement with CMS, the evaluation requirement may be satisfied through the Interim and/or Summative Evaluation Reports stipulated in STCs 9.7 and 9.8, respectively.
- c. The state will present to and participate in a discussion with CMS on the Close-Out report.
- d. The state must take into consideration CMS' comments for incorporation into the final Close-Out Report.
- e. A revised Close-Out Report is due to CMS no later than 30 calendar days after receipt of CMS's comments.

- f. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 8.1.

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

- a. The purpose of these calls is to discuss ongoing demonstration operation, including (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, budget neutrality, enrollment and access and progress on evaluation activities. 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.

8.12. **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 30 calendar 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 Medicaid website. The state must also post the most recent Annual Monitoring Report on its Medicaid website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the public comments in the Annual Monitoring Report associated with the year in which the forum was held.

## IX. EVALUATION OF THE DEMONSTRATION

- 9.1. **Cooperation with Federal Evaluators and Learning Collaborative.** 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. This may also include the state's participation – including representation from the state's contractors, independent evaluators, and organizations associated with the demonstration operations, as applicable – in a federal learning collaborative aimed at cross-state technical assistance, and identification of lessons learned and best practices for demonstration measurement, data development, implementation, monitoring and 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 8.1.
- 9.2. **Independent Evaluator.** The state must use 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 independent party must sign an agreement to conduct the demonstration evaluation in an independent manner in accordance 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.
- 9.3. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design no later than 180 calendar days after the approval of the demonstration. The Evaluation Design must be drafted in accordance with:
- a. Attachment A (Developing the Evaluation Design) of these STCs,
  - b. CMS's evaluation design guidance for SUD demonstrations, including guidance about SUD and overall demonstration sustainability, and
  - c. Any applicable CMS evaluation guidance and technical assistance for the demonstration's other policy components.

The draft Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, such as quasi-experimental methods like difference-in-differences and interrupted time series, as well as establishing valid comparison groups and assuring causal inferences in demonstration evaluations. In addition to these requirements, if determined culturally appropriate for the communities impacted by the demonstration, the state is encouraged to consider implementation approaches involving randomized control trials and staged rollout (for example, across geographic areas, by service setting, or by beneficiary

characteristic), as these implementation strategies help create strong comparison groups and facilitate robust evaluation. The state is strongly encouraged to use the expertise of the independent party in the development of the draft Evaluation Design. The draft Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STCs 9.7 and 9.8.

For any amendment to the demonstration, the state will be required to update the approved Evaluation Design or submit a new Evaluation Design to accommodate the amendment component. The amended Evaluation Design must be submitted to CMS for review no later than 180 calendar days after CMS's approval of the demonstration amendment. Depending on the scope and timing of the amendment, in consultation with CMS, the state may provide the details on necessary modifications to the approved Evaluation Design via the monitoring reports. The amendment Evaluation Design must also be reflected in the state's Interim and Summative Evaluation Reports, described below.

- 9.4. **Evaluation Budget.** A budget for the evaluation must 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 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 design is not sufficiently developed, or if the estimates appear to be excessive.
- 9.5. **Evaluation Design Approval and Updates.** The state must submit to CMS a revised draft Evaluation Design within 60 calendar days after receipt of CMS' comments, if any. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within 30 calendar days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation progress in each of the Quarterly and Annual Monitoring Reports. Once CMS approves the evaluation design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval if the changes are substantial in scope; otherwise, in consultation with CMS, the state may include updates to the Evaluation Design in Monitoring Reports.
- 9.6. **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 deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS evaluation guidance and technical assistance, the evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact and its effectiveness in achieving the goals.

The hypothesis testing should include, where possible, assessment of both process and outcome measures. The evaluation must study outcomes, such as likelihood of enrollment and enrollment continuity, and various measures of access, utilization, and health outcomes, as appropriate and in alignment with applicable CMS evaluation guidance and technical assistance, for the demonstration policy components. Proposed measures should be selected

from nationally recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) and the Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set), collectively referred to as the CMS Child and Adult Core Measure Sets for Medicaid and CHIP; Consumer Assessment of Health Care Providers and Systems (CAHPS); the Behavioral Risk Factor Surveillance System (BRFSS) survey; and/or measures endorsed by National Quality Forum (NQF). CMS underscores the importance of the state undertaking a well-designed beneficiary survey and/or interviews to assess, for instance, beneficiary understanding of and experience with the various demonstration policy components, including but not limited to the continuous eligibility and coverage, and beneficiary experiences with access to and quality of care.

Specifically, evaluation hypotheses for the SUD component of the demonstration must support an assessment of the demonstration's success in achieving the core goals of the program through addressing, among other outcomes, initiation and compliance with treatment, utilization of health services in appropriate care settings, and reductions in key outcomes such as deaths due to overdose. The state must evaluate how the continuous eligibility policy affects coverage, enrollment, churn (i.e., temporary loss of coverage in which beneficiaries are disenrolled but then re-enroll within 12 months) as well as population-specific appropriate measures of service utilization and health outcomes. In addition, the state may conduct a comprehensive qualitative assessment involving beneficiary focus groups and interviews with key stakeholders to assess the merits of such policies.

As part of its evaluation efforts, the state must also conduct a demonstration cost assessment to include, but not be limited to, administrative costs of demonstration implementation and operation and Medicaid health services expenditures.. In addition, the state must use findings from hypothesis tests aligned with other demonstration goals and cost analyses to assess the demonstration's effects on the fiscal sustainability of the state's Medicaid program.

Finally, the state must accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, English language proficiency, primary language, disability status, and geography). Such stratified data analyses will provide a fuller understanding of existing disparities in access to and quality of care and health outcomes and help inform how the demonstration's various policies might support reducing such disparities.

- 9.7. **Interim Evaluation Report.** The state must submit an Interim Evaluation Report 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 Report should be posted to the state's website with the application for public comment.
- a. The Interim Evaluation Report will discuss evaluation progress and present findings to date as per the approved evaluation design.
  - b. For demonstration authority or any components within the demonstration that expire prior to the overall demonstration's expiration date, and depending on the timeline of

expiration/phase-out, the Interim Evaluation Report must include an evaluation of the authority, to be collaboratively determined by CMS and the state.

- c. If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for the extension is submitted, or one year prior to the end of the demonstration, whichever is sooner. If the state made changes to the demonstration in its application for extension, the research questions and hypotheses and a description of how the design was adapted should be included. If the state is not requesting an extension for a demonstration, an Interim Evaluation Report is due one year prior to the end of the demonstration. For demonstration phase-outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
- d. The state must submit the revised Interim Evaluation Report 60 calendar days after receiving CMS's comments on the draft Interim Evaluation Report, if any.
- e. Once approved by CMS, the state must post the final Interim Evaluation Report to the state's Medicaid website within 30 calendar days.
- f. The Interim Evaluation Report must comply with Attachment B (Preparing the Evaluation Report) of these STCs.

9.8. **Summative Evaluation Report.** The state must draft Summative Evaluation Report for the demonstration's current approval period within eighteen (18) months of the end of the approval period represented by these STCs. The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Interim and Summative Evaluation Reports) of these STCs, and in alignment with the approved Evaluation Design.

- a. Unless otherwise agreed upon in writing by CMS, the state must submit the revised Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft, if any.
- b. Once approved by CMS, the state must post the final Summative Evaluation Report to the state's Medicaid website within 30 calendar days.

9.9. **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 an extension process when associated with the state's Interim Evaluation Report, or as part of the review of the Summative Evaluation Report. A corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

- 9.10. **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, and/or the Summative Evaluation Report.
- 9.11. **Public Access.** The state shall post the final documents (e.g., Implementation Plan, Monitoring Protocol, Monitoring Reports, Mid-Point Assessment, 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.
- 9.12. **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 over which the state has control. 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 30 calendar 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.

## **X. GENERAL FINANCIAL REQUIREMENTS**

- 10.1. **Allowable Expenditures.** This demonstration project is approved for authorized demonstration expenditures applicable to services rendered and for costs incurred during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.
- 10.2. **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 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 thirty (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.
- 10.3. **Sources of Non-Federal Share.** As a condition of demonstration approval, the state certifies that its funds that make up the non-federal share are obtained from permissible state and/or local funds that, unless permitted by law, are not other federal funds. The state further certifies that federal funds provided under this section 1115 demonstration must not be used as the non-federal share required under any other federal grant or contract, except as permitted by law. CMS approval of this demonstration does not constitute direct or indirect approval of any underlying source of non-federal share or associated funding mechanisms and all sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable implementing regulations. CMS reserves the right to deny FFP in expenditures for which it determines that the sources of non-federal share are impermissible.

- a. If requested, the state must submit for CMS review and approval documentation of any sources of non-federal share that would be used to support payments under the demonstration.
- b. If CMS determines that any funding sources are not consistent with applicable federal statutes or regulations, the state must address CMS's concerns within the time frames allotted by CMS.
- c. Without limitation, CMS may request information about the non-federal share sources for any amendments that CMS determines may financially impact the demonstration.

10.4. **State Certification of Funding Conditions.** As a condition of demonstration approval, the state certifies that the following conditions for non-federal share financing of demonstration expenditures have been met:

- a. If units of state or local government, including health care providers that are units of state or local government, supply any funds used as non-federal share for expenditures under the demonstration, the state must certify that state or local monies have been expended as the non-federal share of funds under the demonstration in accordance with section 1903(w) of the Act and applicable implementing regulations.
- b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the non-federal share of expenditures under the demonstration, the state must obtain CMS approval for a cost reimbursement methodology. This methodology must include a detailed explanation of the process, including any necessary cost reporting protocols, by which the state identifies those costs eligible for purposes of certifying public expenditures. The certifying unit of government that incurs costs authorized under the demonstration must certify to the state the amount of public funds allowable under 42 CFR 433.51 it has expended. The federal financial participation paid to match CPEs may not be used as the non-federal share to obtain additional federal funds, except as authorized by federal law, consistent with 42 CFR 433.51(c).
- c. The state may use intergovernmental transfers (IGT) to the extent that the transferred funds are public funds within the meaning of 42 CFR 433.51 and are transferred by units of government within the state. Any transfers from units of government to support the non-federal share of expenditures under the demonstration must be made in an amount not to exceed the non-federal share of the expenditures under the demonstration.
- d. Under all circumstances, health care providers must retain 100 percent of their payments for or in connection with furnishing covered services to beneficiaries. Moreover, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local governments, or third parties to return and/or redirect to the state any portion of the Medicaid payments in a manner inconsistent with the requirements in section 1903(w) of the Act and its

implementing regulations. 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.

- e. The State Medicaid Director or his/her designee certifies that all state and/or local funds used as the state's share of the allowable expenditures reported on the CMS-64 for this demonstration were in accordance with all applicable federal requirements and did not lead to the duplication of any other federal funds.

**10.5. Financial Integrity for Managed Care Delivery Systems.** As a condition of demonstration approval, the state attests to the following, as applicable:

- a. All risk-based managed care organization, prepaid inpatient health plan (PIHP), and prepaid ambulatory health plan (PAHP) payments, comply with the requirements on payments in 42 CFR 438.6(b)(2), 438.6(c), 438.6(d), 438.60, and 438.74.

**10.6. Requirements for Health Care-Related Taxes and Provider Donations.** As a condition of demonstration approval, the state attests to the following, as applicable:

- a. Except as provided in paragraph (c) of this STC, all health care-related taxes as defined by Section 1903(w)(3)(A) of the Act and 42 CFR 433.55 are broad-based as defined by Section 1903(w)(3)(B) of the Act and 42 CFR 433.68(c).
- b. Except as provided in paragraph (c) of this STC, all health care-related taxes are uniform as defined by Section 1903(w)(3)(C) of the Act and 42 CFR 433.68(d).
- c. If the health care-related tax is either not broad-based or not uniform, the state has applied for and received a waiver of the broad-based and/or uniformity requirements as specified by 1903(w)(3)(E)(i) of the Act and 42 CFR 433.72.
- d. The tax does not contain a hold harmless arrangement as described by Section 1903(w)(4) of the Act and 42 CFR 433.68(f).
- e. All provider-related donations as defined by 42 CFR 433.52 are bona fide as defined by Section 1903(w)(2)(B) of the Social Security Act, 42 CFR 433.66, and 42 CFR 433.54.

**10.7. State Monitoring of Non-federal Share.** If any payments under the demonstration are funded in whole or in part by a locality tax, then the state must provide a report to CMS regarding payments under the demonstration no later than sixty (60) days after demonstration approval. This deliverable is subject to the deferral as described in STC 8.1. This report must include:

- a. A detailed description of and a copy of (as applicable) any agreement, written or otherwise agreed upon, regarding any arrangement among the providers including

those with counties, the state, or other entities relating to each locality tax or payments received that are funded by the locality tax;

- b. Number of providers in each locality of the taxing entities for each locality tax;
- c. Whether or not all providers in the locality will be paying the assessment for each locality tax;
- d. The assessment rate that the providers will be paying for each locality tax;
- e. Whether any providers that pay the assessment will not be receiving payments funded by the assessment;
- f. Number of providers that receive at least the total assessment back in the form of Medicaid payments for each locality tax;
- g. The monitoring plan for the taxing arrangement to ensure that the tax complies with section 1903(w)(4) of the Act and 42 CFR 433.68(f); and
- h. Information on whether the state will be reporting the assessment on the CMS form 64.11A as required under section 1903(w) of the Act.

10.8. **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 following demonstration expenditures, subject to the budget neutrality expenditure limits described in the STCs 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.

10.9. **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.

10.10. **Medicaid Expenditure Groups.** Medicaid Expenditure Groups (MEG) 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 Master MEG Chart table provides a master list of MEGs defined for this demonstration.

Table 2: Master MEG Chart					
MEG	Which BN Test Applies?	WOW Per Capita	WOW Aggregate	WW	Brief Description
Personal Care Services/ Physician Consultation	Hypo 1	X		X	All expenditures for providing additional services for individuals with behavioral health needs as described in Expenditure Authority #1
SUD IMD Services	Hypo 2	X		X	All expenditures for services provided to an individual while they are a patient in an IMD for SUD treatment described as described in Expenditure Authority #2
Caretaker Continuous Eligibility	Hypo 3	X		X	All expenditures for providing continuous eligibility for parents and other caretaker relatives as described in Expenditure Authority #3

10.11. **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-00283/7). 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), or line 7. 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 additional 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 MEG Charts and in the STCs in section XI, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.
- e. **Member Months.** As part of the Quarterly and Annual Monitoring Reports described in section VIII, the state must report the actual number of “eligible member months” for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting 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 per person, 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 or 64.10 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
Personal Care Services/ Physician Consultation	All expenditures for providing additional services for individuals with behavioral health needs as described in Expenditure Authority #1		Follow standard CMS-64.9 Category of Service Definitions	Date of service	MAP	Y	1/1/24	12/31/28
SUD IMD Services	All expenditures for services provided to an individual while they are a patient in an IMD for SUD treatment described as described in Expenditure Authority #2		Follow standard CMS-64.9 Category of Service Definitions	Date of service	MAP	Y	1/1/19	12/31/28
Caretaker Continuous Eligibility	All expenditures for providing continuous eligibility for parents and other caretaker relatives as described in Expenditure Authority #3		Follow standard CMS-64.9 Category of Service Definitions	Date of service	MAP	Y	9/29/22	12/31/28
ADM	All additional administrative costs that are directly attributable to the demonstration and not described elsewhere and are not subject to budget neutrality.		Follow standard CMS-64.10 Category of Service Definitions	Date of payment	ADM	N	1/1/19	12/31/28

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

Table 4: Demonstration Years		
Demonstration Year 12	January 1, 2024 to December 31, 2024	12 months
Demonstration Year 13	January 1, 2025 to December 31, 2025	12 months

Demonstration Year 14	January 1, 2026 to December 31, 2026	12 months
Demonstration Year 15	January 1, 2027 to December 31, 2027	12 months
Demonstration Year 16	January 1, 2028 to December 31, 2028	12 months

- 10.13. **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 the demonstration’s actual expenditures to the budget neutrality expenditure limits described in section XI. CMS will provide technical assistance, upon request.<sup>4</sup>
- 10.14. **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.
- 10.15. **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 regulations and guidance, 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 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 FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget

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<sup>4</sup> Per 42 CFR 431.420(a)(2), 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.

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.

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.

**10.16. Budget Neutrality Mid-Course Correction Adjustment Request.** No more than once per demonstration year, the state may request that CMS make an adjustment to its budget neutrality agreement based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

- a. **Contents of Request and Process.** In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 10.16.c. If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. Within 120 days of acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 3.7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.
- b. **Types of Allowable Changes.** Adjustments will be made only for actual costs as reported in expenditure data. CMS will not approve mid-demonstration adjustments for anticipated factors not yet reflected in such expenditure data. Examples of the types of mid-course adjustments that CMS might approve include the following:
  - i. Provider rate increases that are anticipated to further strengthen access to care;
  - ii. CMS or State technical errors in the original budget neutrality formulation applied retrospectively, including, but not limited to the following:

mathematical errors, such as not aging data correctly; or unintended omission of certain applicable costs of services for individual MEGs;

- iii. Changes in federal statute or regulations, not directly associated with Medicaid, which impact expenditures;
- iv. State legislated or regulatory change to Medicaid that significantly affects the costs of medical assistance;
- v. When not already accounted for under Emergency Medicaid 1115 demonstrations, cost impacts from public health emergencies;
- vi. High-cost innovative medical treatments that states are required to cover; or,
- vii. Corrections to coverage/service estimates where there is no prior state experience (e.g., SUD) or small populations where expenditures may vary widely.

c. **Budget Neutrality Update.** The state must submit an updated budget neutrality analysis with its adjustment request, which includes the following elements:

- i. Projected without waiver and with waiver expenditures, estimated member months, and annual limits for each DY through the end of the approval period; and,
- ii. Description of the rationale for the mid-course correction, including an explanation of why the request is based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or is due to a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

## XI. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

- 11.1. **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 consists of two 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.
- 11.2. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 2, Master MEG Chart and Table 3, MEG Detail for Expenditure and Member Month Reporting. 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 demonstration 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.
- 11.3. **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 project 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.
- 11.4. **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), or when a WOW spending baseline for certain WW expenditures is difficult to estimate due to variable and volatile cost data resulting in anomalous trend rates, CMS considers these expenditures to be "hypothetical," such that the expenditures are treated as if the state could have received FFP for them absent the demonstration. 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 expenditures on those services. When evaluating budget neutrality, however, 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 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, as a part of this demonstration approval. If the state’s WW hypothetical spending exceeds the Hypothetical Budget Neutrality Test’s expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending through savings elsewhere in the demonstration or to refund the FFP to CMS.

- 11.5. **Hypothetical Budget Neutrality Test 1: Personal Care Services/Physician Consultation (Expenditure Authority #1).** 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 1 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 5: Hypothetical Budget Neutrality Test 1								
MEG	PC or Ag g	WOW Only, WW Only, or Both	Trend Rate	DY 12	DY 13	DY 14	DY 15	DY 16
Personal Care Services/Physician Consultation	PC	Both	5.1%	\$1.46	\$1.53	\$1.61	\$1.69	\$1.78

- 11.6. **Hypothetical Budget Neutrality Test 1: SUD (Expenditure Authority #2).** The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 2. 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 2 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 6: Hypothetical Budget Neutrality Test 2								
MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 12	DY 13	DY 14	DY 15	DY 16
SUD IMD Services	PC	Both	4.8%	\$1209.55	\$1267.61	\$1328.46	\$1392.23	\$1459.06

11.7. **Hypothetical Budget Neutrality Test 3: Continuous Eligibility (Expenditure Authority #3).** The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 3. 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 3 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 7: Hypothetical Budget Neutrality Test 3								
MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 12	DY 13	DY 14	DY 15	DY 16
Caretaker Continuous Eligibility	PC	Both	4.8%	\$726.30	\$761.16	\$797.69	\$835.98	\$876.11

11.8. **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 Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

- 11.9. **Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the demonstration period, which extends from 1/1/2024 to 12/31/2028. The Main Budget Neutrality Test for this demonstration period may incorporate carry-forward savings, that is, net savings from up to 10 years of the immediately prior demonstration approval period(s) (1/1/2013 to 12/31/2023). If at the end of the demonstration approval period the Main Budget Neutrality Test or a Capped Hypothetical Budget Neutrality Test has been exceeded, the excess federal funds will be returned to CMS. If the Demonstration is terminated prior to the end of the budget neutrality agreement, the budget neutrality test shall be based on the time elapsed through the termination date.
- 11.10. **Budget Neutrality Savings Cap.** The amount of savings available for use by the state during this demonstration period will be limited to the lower of these two amounts: 1) the savings amount the state has available in the current demonstration period, including carry-forward savings as described in STC 11.8, or 2) 15 percent of the state’s projected total Medicaid expenditures in aggregate for this demonstration period. This projection will be determined by taking the state’s total Medicaid spending amount in its most recent year with completed data and trending it forward by the President’s Budget trend rate for this demonstration period. Fifteen percent of the state’s total projected Medicaid expenditures for this demonstration period is \$688,400,929.
- 11.11. **Corrective Action Plan.** 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.

<b>Table 8: Budget Neutrality Test Corrective Action Plan Calculation</b>		
<b>Demonstration Year</b>	<b>Cumulative Target Definition</b>	<b>Percentage</b>
DY 12	Cumulative budget neutrality limit plus:	2.0 percent
DY 12 through DY 13	Cumulative budget neutrality limit plus:	1.5 percent
DY 12 through DY 14	Cumulative budget neutrality limit plus:	1.0 percent
DY 12 through DY 15	Cumulative budget neutrality limit plus:	0.5 percent
DY 12 through DY 16	Cumulative budget neutrality limit plus:	0.0 percent

## XII. SCHEDULE OF STATE DELIVERABLES FOR THE DEMONSTRATION APPROVAL PERIOD

The state is held to all reporting requirements as outlined in the STCs; this schedule of deliverables should serve only as a tool for informational purposes only.

**Table 9. Schedule of Deliverables**

<b>Date - Specific</b>	<b>Deliverable</b>	<b>STC Reference</b>
Within 120 days of expiration	Submit a Draft Close-Out Report	STC 8.10
Within 30 days of receipt of CMS comments	Submit Final Close-Out Report	STC 8.10
30 days after extension approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
150 days after approval date	Monitoring Protocol	STC 8.6
180 days after approval date	Draft Evaluation Design	STC 9.3
60 days after receipt of CMS comments	Revised Draft Evaluation Design	STC 9.5
30 days after CMS Approval	Approved Evaluation Design published to state's website	STC 9.5
One year prior to the end of the demonstration, or with renewal application	Draft Interim Evaluation Report	STC 9.7
60 days after receipt of CMS comments	Revised Interim Evaluation Report	STC 9.7
18 months of the end of the demonstration	Draft Summative Evaluation Report	STC 9.8
60 calendar days after receipt of CMS comments	Revised Summative Evaluation Report	STC 9.8
90 days after middle of DY10	Draft SUD Mid-point Assessment	STC 8.8
60 calendar days after receipt of CMS comments	Revised SUD Mid-point assessment	STC 8.8

Date - Specific	Deliverable	STC Reference
30 calendar days of CMS approval	Approved Final Summative Evaluation Report published to state's website	STC 9.8

**Table 10. Schedule of Annual/Quarterly Deliverables**

	Deliverable	STC Reference
<b>Annually</b>	Annual Monitoring Report	STC 8.7
<b>Quarterly</b>	Quarterly Monitoring Report	STC 8.7
	Budget Neutrality Report	STC 10.13

## **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 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 need rigorous quantitative and qualitative evidence to inform policy decisions.

The evaluation design is the state's plan for how it will accomplish the evaluation. In most cases, states must arrange with an independent evaluator to conduct the evaluation. The state, per the Special Terms and Conditions (STC), is required to submit an evaluation design to CMS for CMS approval after the demonstration is approved. The evaluation design needs to specify the state's hypotheses, evaluation questions, associated measures and analytic methods. To support the development of the evaluation design in accordance with CMS priorities and expectations, CMS is providing the following outline for the evaluation design. It is recommended that states and independent evaluators use this outline to develop the evaluation design for submission to CMS.

The sections in this outline include background, evaluation questions and hypotheses, methodology, methodological limitations, and attachments. It is important to include as much detail as possible when completing this outline, to provide CMS with the best information with which to review the evaluation design.

CMS expects evaluation designs to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. If the state needs technical assistance using this outline or developing the evaluation design, the state should contact its project officer.

## **Developing the Evaluation Design**

### **Recommended Outline**

#### **Expectations for Evaluation Designs**

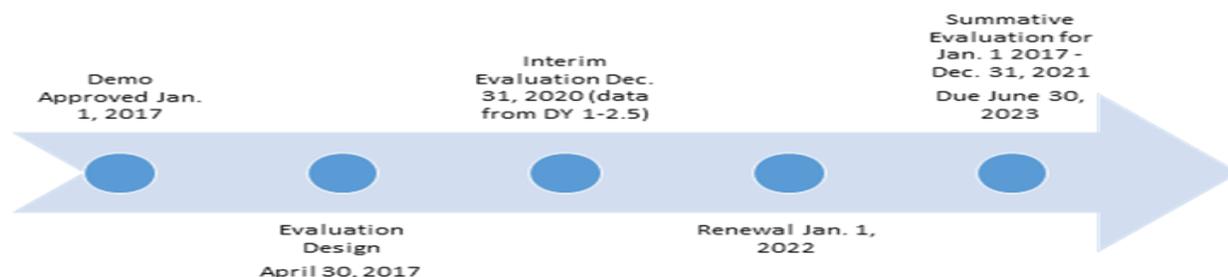
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses,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

The format for the Evaluation Design is as follows:

- A.** General Background Information;
- B.** Evaluation Questions and Hypotheses;
- C.** Methodology;
- D.** Methodological Limitations;
- E.** 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 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:
  - a. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
  - b. 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.

**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.

**E. Special Methodological Considerations-** CMS recognizes that there may be certain instances where a state cannot meet the rigor of an evaluation as expected by CMS. In these instances, the state should document for CMS why it is not able to incorporate key components of a rigorous evaluation, including comparison groups and baseline data analyses. Examples of considerations include:

- 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.

**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
<b>Hypothesis 1</b>				
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 -Measure 3 -Measure 4	-sample, e.g., PPS patients who meet survey selection requirements (used services within the last 6 months)	-Patient survey	Descriptive statistics
<b>Hypothesis 2</b>				
Research question 2a	-Measure 1 -Measure 2	-Sample, e.g., PPS administrators	-Key informants	Qualitative analysis of interview material

## F. 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 Evaluation Report**

#### **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 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 need rigorous quantitative and qualitative evidence to inform policy decisions.

The evaluation report provides the analysis and summary of the hypotheses tested in the evaluation. The hypotheses, evaluation questions, and measures should align with those identified in the CMS approved evaluation design. The state, per the Special Terms and Conditions (STC), is required to submit to CMS an interim evaluation report and a summative evaluation report. To support the development of the interim and summative evaluation reports, CMS is providing the following outline for the evaluation reports. It is recommended that states and independent evaluators use this outline to develop the evaluation reports for submission to CMS.

The sections in this outline include an executive summary, background information, evaluation questions and hypotheses, methodology, methodological limitations, results, conclusions, interpretations, lessons learned and recommendations, and attachments. It is important to provide as much detail as possible when completing this outline, to provide CMS with the best information with which to review the evaluation reports.

If the state needs technical assistance using this outline or preparing the evaluation reports, the state should contact its project officer.

## **Preparing the Evaluation Report Recommended Outline**

### **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. With the following kind of information, states and CMS are best poised to inform and shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. 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. 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 Attachment**

Title XIX of 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 Attachment 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.

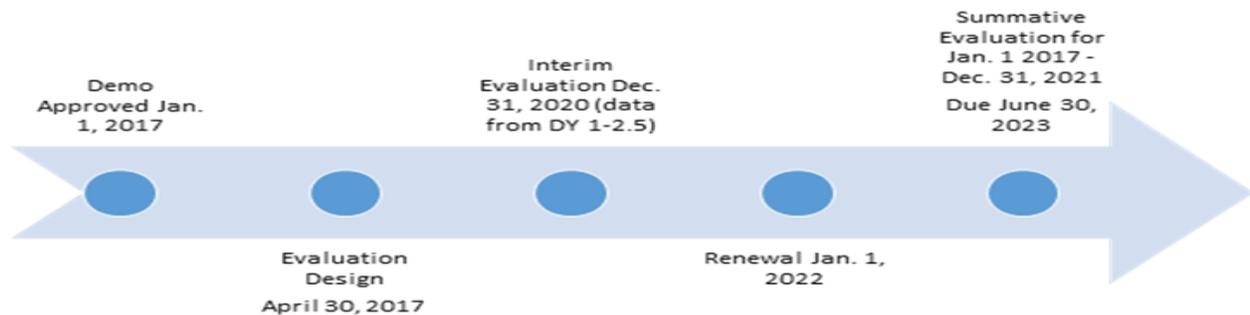
The format for the Interim and Summative Evaluation reports are as follows:

- 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 the evaluation design and reports to the state's website within 30 days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



## 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 Attachment) 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.

**E. Methodological Limitations**

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

**F. 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.

**G. 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?

**H. 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.

**I. 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?

**J. Attachment**

- 1) Evaluation Design: Provide the CMS-approved Evaluation Design

**Attachment C**  
**SUD Implementation Plan and Financing Plan**

## **Section 1115 Substance Use Disorder (SUD) Demonstration: Implementation Plan**

### **Introduction:**

Although Kansas is still below the national average rate for drug overdose mortality, Opioid overdose deaths in Kansas have risen significantly in recent years, and the State is acting strategically to address the crisis as reported in the Kansas State Opioid Response Grant to Substance Abuse and Mental Health Services Administration (SAMSHA) (TI-18-015. P. 1) based on Kansas vital statistics data for age adjusted drug poisoning mortality rates, 2012-2016. Based on this vital statistics data, some key facts include:

- The age adjusted drug poisoning mortality rate was 10.9 deaths per 100,000 Kansans.
- From 2012 to 2016, there were a total of 1,583 drug poisoning deaths in Kansas. From 1999 to 2014, drug poisoning death rates have tripled-placing deaths from poisoning the leading cause of injury related deaths in Kansas.
- Drugs, including prescription, over the counter and illicit drugs, account for more than 80% of all poisoning deaths.
- Seventy-five percent of the drug poisoning deaths in 2014 were unintentional, 17% were due to suicide and 7% were of an undetermined intent.
- Kansans aged 45 years old had the highest rate of drug poisoning deaths involved a prescription pain reliever such as hydrocodone or oxycodone.
- Almost 85% (84.3%) of those deaths involved either a pharmaceutical opioid (e.g., Oxycodone, Hydrocodone), a Methamphetamine/Amphetamine drug (e.g., illicit meth or Adderall), or a Benzodiazepine (e.g. Xanax, Valium). It is of note that, individuals born between 1955 and 1970 experienced a disproportionately higher drug poisoning mortality rate as compared to younger generations.

In addition to prescription opioid death, Kansas has also seen an increase in heroin related and synthetic opioid deaths since 2010. Specifically:

- In 2014, there were 56 drug deaths involving either heroin or a synthetic opioid, such as fentanyl, (age adjusted rate 2.0 deaths per 1000,000 population) representing about 34% of all drug deaths involving an opioid—a 200% increase since 2010 (age adjusted rate: 1.1 deaths per 100,000 population). These rates are likely under estimates of the drug deaths caused by narcotic agents since there are a number of drug deaths where the deaths do not mention a drug specifically.
- Along with an increase in heroin and synthetic opioid deaths is an estimated increase in the number of Kansans 26 years and older who have misused a prescription opioid pain reliever in the past year from 2010 (3.26% to 2014(3.49%).

This Substance Use Disorders (SUD) Demonstration Implementation Plan outlines the State's strategy to provide a full continuum of services for SUD treatment to KanCare members. This waiver request is consistent with Kansas' current strategy to combat the epidemic and builds off

its system of care in Medicaid to provide more complete services, particularly in areas of limited coverage and service gaps such as higher levels of care. The KanCare Section 1115 Waiver Demonstration Renewal Application, submitted to Center for Medicare and Medicaid Services (CMS) on December 20, 2017 (*Attachment #1, KanCare 2.0 Section 1115 Waiver Demonstration Renewal Application, Final Submission, Dec 2017, page 25*) includes this waiver request.

### *Kansas' SUD Crisis*

National studies suggest that patients with a higher dose of opioids, multiple prescribers and several pharmacies are more likely to die from an opioid overdose.<sup>1</sup> Experts have attributed the rise in opioid use disorders (OUD) and the overdose crisis to the increased rate of prescription opioids dispensed since the 1990s.<sup>2</sup> According to the Centers for Disease Control (CDC), the number of prescription opioids dispensed in the U.S. has nearly quadrupled in the past decade. Concurrently, the rate of opioid-related deaths has more than doubled in the United States since 2005. Opioid overdoses accounted for a considerable number of Kansas's drug poisoning deaths from 2012 to 2016. Though the rate of overdose deaths in Kansas remains below the national average, 2016 Kansas vital statistics data indicates that the age-adjusted drug poisoning mortality rate was 10.9 deaths per 100,000 Kansans. From 2012 to 2016, there were a total of 1,583 drug poisoning deaths in Kansas. Almost eighty-five percent (84.3%) of those deaths involved either a pharmaceutical opioid (e.g., Oxycodone, Hydrocodone), a Methamphetamine/Amphetamine drug (e.g., illicit meth or Adderall), or a Benzodiazepine (e.g. Xanax, Valium).

An important factor associated with the increase in drug poisoning deaths in Kansas is the supply of prescription opioids. Kansas's Prescription Drug Monitoring Program, K-TRACS, tracks and monitors Schedule II through IV controlled substances, such as prescription opioids, and other drugs of concern dispensed in Kansas. K-TRACS provides public health and public safety professionals with dispensation data of these drugs statewide. In 2017, there were at least 2,579,058 opioid prescriptions and 189,525,054 opioid units (i.e., pills, patches, films, or vials) dispensed to Kansas patients. This corresponds to a rate of 88.5 prescriptions per 100 Kansans and 65.1 opioid units per Kansan. This is equivalent to dispensing an approximate 14-day supply of an opioid prescription to 8 out of 10 Kansas residents in 2017. Experts estimate that about 100,000 Kansans, or 3 out of every 10, have misused prescription pain medication in a way other than as directed by a doctor or more than the prescribed amount. There was an approximate 9 percent decrease in opioid dispensing statewide from 2016 to 2017 in Kansas, or approximately 249,942 fewer opioid prescriptions. This reduction is consistent with national trends. However, the use of opioids among young adults is a major concern. The Kansas Communities that Care Student Survey (KCTC) assesses prescription drug misuse among Kansas youth in addition to other health risk and protective factors. According to 2017 KCTC data, 3.7 percent of Kansas youth in grades 6, 8, 10 and 12 report using prescription medications not prescribed to them. Of those, more than 75 percent reported that they received, bought or stole them from a friend or relative. The Kansas

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<sup>1</sup> CDC Wonder Online Database, released December 2016. Sourced from: [https://www.kmap-state-ks.us/Documents/Content/Bulletins/18027%20-%20General%20-%20Opioid\\_2.pdf](https://www.kmap-state-ks.us/Documents/Content/Bulletins/18027%20-%20General%20-%20Opioid_2.pdf).

<sup>2</sup> National Institute on Drug Abuse, revised January 2019. Available at: <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis>.

Young Adult Survey also measures prescription and illicit drug use among Kansas young adults ages 18 to 25. In 2017, 6.8 percent of young adults reported using prescription pain medication at least once in the past 30 days, 40 percent did not have a prescription for it. Of the people that report the misuse of prescription pain medications, more than 91 percent reported that they received, purchased or stole them from a friend or relative.

### *Kansas' Strategic Response to the Opioid Overdose Crisis*

Kansas Department for Aging and Disability Services (KDADS) serves as both the State Mental Health Authority (SMHA) and Single State Agency (SSA) for Substance Abuse in Kansas. The Strategic Opioid Response set forth by the SSA with SAMSHA in the State Opioid Response Grant (SOR TI-18-015) will utilize a statewide strategic plan developed through a multidisciplinary statewide process. The strategic plan builds upon existing opioid efforts and tools to combat the opioid epidemic, including the SAMHSA funded State Targeted Response to the Opioid Crisis (STR) Grant, focused on OUD treatment, prevention, and recovery. Kansas was also a recipient of a Partnership For Success 2015 Grant to strategically address prescription drug misuse and abuse in four sites across the State. The Kansas Department of Health and Environment (KDHE) was the recipient of Prescription Drug Overdose (PDO): Data-Driven Prevention Initiative (DDPI) Grant from the Centers for Disease Control (CDC). The Kansas Foundation for Medical Care (KFMC) is the recipient of funds from CMS to coordinate a pain management project at multiple locations across the State. The Statewide Prescription Drug Workgroup serves as a means of coordination and collaboration for these multiple initiatives and will continue to function in this capacity for the SOR grant as well. As part of these federally funded efforts, Kansas will expand access to medication-assisted treatment (MAT) by using a regional approach. The State will require regional grantees to promote primary care provider enrollment in buprenorphine or buprenorphine/ naloxone combination medication prescribing accompanied by education on evidence-based best practices for prescribing opioids and the importance of behavioral health treatment with MAT. The Opioid SOR Grant Access to Care Project Coordinator in each region will be responsible for the development and expansion of MAT services in partnership with clinics, providers, and hospitals. Regional grantees will identify gaps in care specific to their regions and populations with strategies to address these gaps.

In September 2018, the Governor's Task Force on Substance Abuse set strategic priorities to combat the opioid epidemic. These strategies include expanding access to treatment and recovery support, as well as increasing the use of data and health information technology, particularly in reducing opioid prescribing and opioid dependence. These strategies are consistent with this SUD Demonstration request.

### *The Current Delivery System*

KanCare currently integrates medical, behavioral, and long-term care health delivery systems and covers mandatory and optional services under the approved Medicaid State Plan. KanCare provides access to all critical levels of care for opioid use disorder (OUD) and SUD. KanCare contracts with three MCOs statewide to provide access to the American Society of Addiction Medicine (ASAM) levels. The KanCare criteria for treatment is a fidelity-based adaptation of the ASAM Patient Placement Criteria. The Kansas Department for Aging and Disability

Services (KDADS) provide required licenses to KanCare-enrolled SUD treatment providers. Currently State law also requires licenses for any provider who delivers SUD treatment services in a facility setting.

KanCare delivers the outpatient benefits described below pursuant to the service requirements in the Kansas Medicaid State Plan - Attachment 3.1-A, 13.d. The State Plan requires the provision of inpatient and detoxification (withdrawal management) services in State certified facilities. The Kansas Medical Assistance Program Substance Use Disorder Services Provider Manual (KMAP-SUD-PM) details eligibility and service requirements for all KanCare OUD and SUD services by ASAM level. The Manual (*Attachment #2, KMAP-SUD-PM*) provides eligible Medicaid recipients who need SUD or OUD treatment with the full spectrum of care, including outpatient treatment, peer recovery support, intensive outpatient services, medication assisted treatment (MAT), intensive inpatient services, withdrawal management, and residential treatment. MCO network providers include specialty providers such as Women's Treatment Centers for woman and children, which offers prenatal services and services to meet the developmental needs of children. KanCare requires the provision of Person-Centered Case Management as a one-on-one goal-directed service for individuals with a SUD, to assist individuals in obtaining access to needed family, legal, medical, employment, educational, psychiatric, and other services. For individuals served by an MCO, this service must be a part of the treatment plan developed and determined medically necessary by the MCO.

Access to treatment varies by region; western Kansas, a rural, frontier area has very little access to opioid use disorder treatment, including MAT (methadone clinics and buprenorphine prescribers). There are currently nine Methadone Maintenance Treatment clinics in Kansas located primarily in the largest urban areas of the State. These clinics provide non-residential services of long-term methadone maintenance and other medication assistance to support and sustain recovery. Most patients who access these services pay out of pocket for methadone maintenance treatment. Since KanCare does not pay for methadone as a MAT (it covers methadone only for use in pain management), there is currently only one methadone dispensing provider who is in the KanCare network. KanCare will revisit the issue of covering methadone for MAT and make a recommendation of policy within the first half of 2019. This policy will consider the requirement that all inpatient residential treatment centers (including all those currently excluded as IMDs) provide access to MAT through direct provision of the KanCare approved MAT formularies or by coordinated referral and treatment initiation to a KanCare MAT provider.

### *SUD Demonstration Goals*

Kansas will use this 1115 demonstration authority to pursue the following goals:

1. *Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs*: Kansas receives federal funds through SAMSHA, including State Opioid Response and Strategic Targeted Response grants, to run awareness campaigns on the availability of treatment. Kansas continues to support expanding screening, brief intervention, and referral to treatment (SBIRT) as a SUD mitigation practice. Increasing outreach and community education efforts will, in turn, increase need for provider capacity for SUD services, particularly for residential treatment services. Kansas will need to engage facilities of 16 beds

or more (IMDs) to have the appropriate capacity for services at the residential and inpatient level.

2. Reductions in overdose deaths, particularly those due to opioids: Kansas continues its efforts toward reduction of opioid overdose deaths, and the addition of services under this IMD waiver exclusion is a crucial step in assuring access to treatment at all needed levels of care for Medicaid beneficiaries. KDADS currently provides ongoing certification training to SUD providers for Persons Centered Case Management based on the principals and practices of Strength Based Case Management as developed at the University of Kansas. KanCare delivers this service at all levels of care in SUD programs, and training outcomes reflect increased engagement and retention in services. Beginning in 2019, KanCare plans to require inpatient residential treatment facilities to:

- Offer and initiate MAT to all patients who would be clinical candidates for MAT; and
- Improve care coordination and transition of care to the community.

MCOs will report readmission rates and the State will work with KanCare MCOs to develop incentives and/or financial measures to hold residential treatment providers accountable for demonstrating effective engagement of all patients in long term recovery services and reducing readmissions.

3. Reduce utilization of emergency departments and inpatient hospital settings for OUD and other SUD treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services: KDADS contracts with three existing Community Crisis Centers (CCCs) that support and stabilize individuals and engage them in community-based treatment. Services include assessment, sobering, withdrawal management and referral to treatment. Medicaid pays CCCs for crisis intervention and counseling services (but not sobering or withdrawal management) for its beneficiaries. Early data show CCCs have been successful in diverting clients served from incarceration as well as admission to emergency rooms and hospitals. Continued expansion of MAT services, peer supported recovery services, and increased care coordination between community and hospital providers are outlined in the tables below as future actions to be taken in this waiver implementation.
4. Fewer readmissions to the same or higher level of care where readmissions are preventable or medically inappropriate for OUD and other SUDs: The KanCare program has taken measures to promote appropriate admissions for OUD and SUD treatment based on ASAM guidelines (see milestone tables below for more information). Beginning in 2019, KanCare MCOs will have to meet additional care coordination requirements for SUD, OUD and behavioral health conditions that specifically require MCOs to coordinate care with an aim toward reducing readmissions (see table 6 below).
5. Improved access to care for physical health conditions among beneficiaries with OUD or other SUDs: KanCare has made the integration of physical healthcare and behavioral healthcare a focus for the new contracts in effect in 2019. These provisions will improve care coordination and the physical health of beneficiaries with OUD. The State will require MCOs

to work with inpatient and residential facilities to facilitate care transitions and care coordination. The State is also encouraging new payment models to encourage better health outcomes through integration. (*Attachment, #1, KanCare 2.0 Section 1115 Waiver Demonstration Renewal Application, Final Submission, Dec 2017*).

**Milestone 1: Access to Critical Levels of Care for OUD and Other SUDs-** The spectrum of care required in Milestone 1 is summarized in the Table below.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current SUD treatment services covered by the state in each level of care. For services currently covered in the state plan, list the benefit category and page location; for services currently covered in a demonstration, include the program name and Special Term and Condition number.	Provide an overview of planned SUD treatment services to be covered by the state in each level of care: indicate whether planned services will be added to the state plan or authorized through the 1115.	Provide a list of action items needed to be completed to meet milestone requirements, if any. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item.
Coverage of outpatient services	The State covers outpatient non-residential treatment consisting of group, individual, and/or family counseling, community psychiatric support, crisis intervention, and peer support. The State requires an individualized treatment plan, based on ASAM criteria, to be completed within 30 days of admission, updated every 90 days ( <i>Kansas Medicaid State Plan 3.1-A, 13.d. Page 1</i> ).	No changes.	None

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Coverage of intensive outpatient services	Covered based on individualized plan and assessment tool that is based on ASAM criteria. Services delivered in regularly scheduled sessions of structured therapeutic activities that may include SUD educational didactic groups, group counseling, and individual counseling. <i>(Kansas Medicaid State Plan 3.1-A, 13.d. Page 1)</i>	No changes.	None
Coverage of medication assisted treatment (medications as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state)	Coverage includes Buprenorphine products and combo products with naloxone. The State restricts Methadone coverage to pain management. MAT counseling is provided. <i>(Kansas Medicaid State Plan 3.1-A, 13.d. Page 1)</i>	<p>KanCare will require inpatient and residential providers to offer or facilitate MAT initialization and treatment for all who meet the need criteria and choose treatment.</p> <p>KDADS will provide training and work with MCOs to build network capacity for MAT over the course of 2019.</p> <p>KanCare will study the issue of covering methadone for MAT use by September 30, 2019. The State is currently organizing those discussions currently with new agency leadership and will advise CMS as they progress.</p> <p>If the State decides to cover methadone for MAT use, it will issue a draft policy and begin related</p>	<p>Revision of KanCare MCO contracts and/or payment policies to require MAT care/coordination in residential/inpatient settings and education of the provider network.</p> <p>MCO credentialing of plans into the network and Payment live by 12-month mark.</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
		State Plan amendment process by the end of calendar year 2019.	
Coverage of intensive levels of care in residential and inpatient settings	<p>Coverage of 24-hour medically directed evaluation and treatment services for SUD, with the availability of support services for co-occurring medical and mental disorders. (<i>Attachment #2, KMAP-SUD-PM</i>)</p> <p>The State currently covers ASAM levels 1, 2, 3.1, 3.3, 3.5, and 3.7 per the State Plan.</p>	<p>Coverage of SUD treatment includes IMDs with 16 or more beds that: (1) meet KDADS' licensing and certification requirements and (2) participate in MCO provider networks and meet appropriate credentialing requirements. Authorization for services will remain the same as MCOs' current procedure for residential SUD treatment (see Table 2 below).</p>	<p>Revision of Medicaid payment policies, and managed care contracts. Licensing and credentialing of IMDs as SUD residential providers by 12-month mark. Payment live by 12-month mark due to the time needed to license and credential IMDs as SUD providers.</p>
Coverage of medically supervised withdrawal management	<p>Per the Medicaid State Plan, covered for individuals whose withdrawal signs and symptoms are sufficiently severe to require primary medical and nursing care services. Includes 24-hour observation, monitoring, and counseling. (<i>Attachment #2 KMAP-SUD-PM</i>)</p>	No changes.	None

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

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current state use of evidence-based, SUD-specific patient placement criteria and utilization management approach to ensure placement in appropriate level of care and receipt of services recommended for that level of care.	Provide an overview of planned state implementation of requirement that providers use an evidence-based, SUD-specific patient placement criteria and use of utilization management to ensure placement in appropriate level of care and receipt of services recommended for that level of care.	Specify a list of action items needed to be completed to meet milestone requirements. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item.
Implementation of requirement that providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools that reflect evidence-based clinical treatment guidelines	<p>The KanCare criteria for treatment is a fidelity-based adaptation of the ASAM Patient Placement Criteria.</p> <p>Contracted KanCare MCOs require their network providers to use ASAM criteria to assess patient treatment needs. Providers submit a common form to the KanCare MCOs to request authorization for residential treatment services. Each MCO uses its own criteria based on ASAM to make a determination to authorize treatment.</p>	KDADS will work with MCOs and providers to develop one standardized placement criteria that has fidelity to the ASAM placement criteria and uses a multi-dimensional assessment by 2021.	Revise the current Kansas State Approved Placement Criteria (currently not in use at the MCOs) with a new KDADS approved criteria, available online to both MCOs and all providers by 2021. All MCOs and providers will be required to use the revised assessment tool.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Implementation of a utilization management approach such that (a) beneficiaries have access to SUD services at the appropriate level of care	<p>KanCare MCO contracts require the implementation of a utilization management approach that ensures timely access to necessary services at the appropriate level of care. KanCare requires assessment, individual treatment plans and documentation of services. State monitoring of compliance is regular and ongoing.</p> <p><i>(Attachment #3-Current KanCare Contract EVT 0001028, Sections 2.2.40- 2.2.40.14)</i></p>	No changes.	None
Implementation of a utilization management approach such that (b) interventions are appropriate for the diagnosis and level of care	<p>MCOs must have in place and follow, written policies, procedures, and practice guidelines for processing requests for prior authorization and authorization for requests for continuing services. The policies, procedures, and practice guidelines shall include requirements for use of the Kansas medical necessity definition and the ASAM criteria.</p> <p><i>(Attachment #3-Current KanCare Contract EVT 0001028, Sections 2.2.40- 2.2.40.16)</i></p>	No changes.	None
Implementation of a utilization management approach such that (c) there is an	<p>MCOs are responsible for the development of utilization management for residential treatment. The State reviews and</p>	No changes.	None

Milestone Criteria	Current State	Future State	Summary of Actions Needed
independent process for reviewing placement in residential treatment settings	<p>approves MCO utilization management policies. The State also monitors grievances and appeals.</p> <p>The decision or request shall be made by a health care professional who has appropriate clinical expertise in treating the Member's condition or disease.</p> <p><i>(Attachment #3-Current KanCare Contract EVT 0001028, Sections 2.2.40- 2.2.40.16)</i></p>		

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

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current provider qualifications for residential treatment facilities and how these compare to nationally recognized SUD-specific program standards, e.g., the ASAM Criteria	Provide an overview of planned use of nationally recognized SUD-specific program standards in improving provider qualifications for residential treatment facilities.	Specify a list of action items needed to be completed to meet milestone requirements. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item
Implementation of residential treatment provider qualifications in licensure requirements, policy manuals,	KDADS licenses all provider organizations delivering SUD services, including all residential treatment facilities (IMD and others). Licensing regulations include standards for program	KanCare contracts effective in on 1/1/19 and in subsequent years will specify ASAM program compliant (or other national standards i.e. CARF) as the credentialing	<p>Implementation of KanCare contracts effective on January 1, 2019.</p> <p>Development and use of ASAM program criteria compliant</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p>managed care contracts, or other guidance. Qualification should meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding, in particular, the types of services, hours of clinical care, and credentials of staff for residential treatment settings</p>	<p>management, clinical hours, clinical and supportive services, staffing ratios, staff qualifications, facility regulations, medication control, treatment planning, record keeping, client rights, confidentiality, and quality improvement. (<i>Attachment #4 Standards for Licensure/ Certification of Alcohol and/or Other Drug Abuse Programs, rev. 1/1/06</i>). The standards need to be reviewed and revised to meet ASAM program criteria and other national standards (i.e. CARF). See Future State for goals regarding revision.</p> <p>The Kansas Behavioral Sciences Regulatory Board (KSBSRB) licenses individual (non-agency) Addiction Counselors as Licensed Addiction Counselors or Licensed Masters Addiction Counselors. Standards and procedures are set forth in KAS 65-6607-6620 and KSBSRB regulations 102-7-1:12. (<i>see <a href="https://ksbsrb.ks.gov">https://ksbsrb.ks.gov</a></i>)</p> <p>Under KanCare contracts, MCOs are responsible for assuring</p>	<p>standards for MCO provider agreements (<i>Attachment #5, Kansas Medicaid Managed Care (KanCare 2019) RFP EVT0005464 p.66-67</i>).</p> <p>The State will revise licensing standards within 12-24 months. To complete this step, the State will review MCO contract requirements for credentialing and is in the process of comparing current state licensing regulations to ASAM criteria to identify the extent of changes that will be required.</p> <p>Subsequently, the State will need to draft regulations for public comment and follow relevant state requirements before they are effective.</p>	<p>credentialing standards for residential care by all MCOs within 12 months.</p> <p>Revision (as needed) of licensing standards for residential care to comply with ASAM program criteria and other national standards within 12-24 months.</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>the licensure and qualifications of providers according to the above established State licensure standards and Medicaid credentialing policies. (Attachment #6 KanCare 2.0 RFP EVT 0005464- Attachment C- 3.0-SUD Services p. 11-13 and section 4.3.1.1.2-SUD Treatment and MAT p.14)</p>		
<p>Implementation of a state process for reviewing residential treatment providers to ensure compliance with these standards</p>	<p>KDADS completes initial and periodic licensing surveys every 1-3 years, depending on compliance. (Attachment #4 Standards for Licensure/ Certification of Alcohol and/or Other Drug Abuse Programs, rev. 1/1/06 and Attachment #7 KDADS Licensing Surveyor Tool)</p>	<p>KDADS reviews and licenses IMDs in accordance with the Current State column of this row. By the 12-month mark, MCOs will credential them in their networks according to credentialing policies that conform to ASAM program criteria or other national standards for staffing, hours, access, training, and other relevant standards.</p>	<p>Development and use of ASAM program criteria compliant credentialing standards for residential care by all MCOs within 12 months.</p> <p>Update of licensing survey tool to examine provider compliance with any new program standards (e.g., types of services offered, hours of clinical care, staff credentials) within 12-18 months.</p>
<p>Implementation of requirement that residential treatment facilities offer MAT on-site or facilitate access off site</p>	<p>There is currently no requirement that residential treatment facilities offer MAT on-site. The State requires them to assess and refer as appropriate.</p>	<p>KanCare will require residential treatment providers to assess clients and initiate MAT onsite for willing clients.</p> <p>To complete this step, the State will review MCO contract requirements for</p>	<p>The State will update the licensing requirements within 12-24 months to require residential treatment providers to assess clients and initiate MAT onsite for willing clients.</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
		<p>credentialing and is in the process of comparing current state licensing regulations to ASAM criteria to identify the extent of changes that will be required.</p> <p>Subsequently, the State will need to draft regulations for public comment and follow relevant state requirements before they are effective.</p>	MCOs will implement provision by 18-month mark.

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

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

Milestone Criteria	Current State	Future State	Summary of Actions Needed
			each action item.
<p>Completion of assessment of the availability of providers enrolled in Medicaid and accepting new patients in the following critical levels of care throughout the state (or at least in participating regions of the state) including those that offer MAT:</p> <p>Outpatient Services;</p> <p>Intensive Outpatient Services;</p> <p>Medication Assisted Treatment (medications as well as counseling and other services);</p> <p>Intensive Care in Residential and Inpatient Settings;</p> <p>Medically Supervised Withdrawal Management.</p>	<p>The MCOs submit Geo Mapping reports to the State each quarter. The reports include sub-reports by specialty (including SUD providers), provider access and availability reports, including distance to nearest provider, urgent access standards, county breakdowns, and trended access data. KDHE has established processes to monitor and manage the Reports. Provider network access standards require the MCOs to meet requirements for licensed outpatient, inpatient, intensive outpatient, residential treatment, and withdrawal management. <i>(Attachment #8 KanCare Network Adequacy Standards revised 8/6/18, p.9)</i></p> <p>If the State identifies a provider network deficiency, the State will work with the MCO to develop a plan of action to meet the standards and/or if an exception is necessary. The State may also issue a corrective action plan or liquidated damages, as appropriate.</p> <p>KDADS has assessed the needs and gaps in access to treatment, particularly MAT.</p>	<p>The State will require MCOs to expand the existing infrastructure of MAT providers to improve member access to MAT, particularly in rural areas. The State will use Geo Mapping reports to monitor compliance. MCO will provide semi-annual reports outlining the network adequacy of each MCO for all levels of SUD service, by geographic region. These semi-annual reports will also include the number of providers accepting new patients for each level of care. Where Geo mapping does not provide this level of granularity, MCOs will be required to gather data for credentialing and provider network databases and report it to the State.</p>	<p>The State will revise the provider network standards to include MAT by the 12-month mark.</p> <p>KDADS will implement MAT access assessment, training, and network development according to the SOR State plan submitted to SAMSHA for the 2019 project period.</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	Gaps vary by region and are most severe in rural and frontier regions of the State.	<p><i>(Attachment #5 Kansas Medicaid Managed Care (KanCare 2019) RFP EVT0005464 section 5.5.7 and section 5.8.3.2)</i></p> <p>The KDADS SOR coordinator will work closely with KDHE and its contracted MCOs to address MAT service gaps in rural and western regions of the State using its assessment summary for each region. KDADS will provide training to providers for increasing MAT capacity.</p>	

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

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current treatment and prevention strategies to reduce opioid abuse and OUD in the State.	Provide an overview of planned strategies to prevent and treat opioid abuse and OUD.	Specify a list of action items needed to be completed to meet milestone requirements as detailed above. Include persons or entities responsible for

Milestone Criteria	Current State	Future State	Summary of Actions Needed
			completion of each action item. Include timeframe for completion of each action item.
Implementation of opioid prescribing guidelines along with other interventions to prevent opioid abuse	KDHE issued KMAP General Bulletin 18101- effective June 1, 2018, to amend its prescribing guidelines for Opioid Products Indicated for Pain Management to require prior authorization for all patients covered under Kansas Medicaid for any prescription of long acting opioids and any prescription of short acting opioids exceeding a 7-day supply, with exceptions. <i>(Attachment #9 KMAP General Map Bulletin 18101)</i>	Though the Governor’s SUD task force recommends requiring use of the prescription drug monitoring program (PDMP) K-TRACS by all clinicians authorized to prescribe medications subject to abuse and recommends all pharmacists register with K-TRACS, use is currently voluntary. Mandatory Registration with K-TRACS is currently under review by the KS AG as an administrative regulation. Once approved, the Board will implement the regulation. K-TRACS is integrating with the EHRs of large group providers, hospitals and pharmacies (Walmart and Sam’s pharmacies are currently linked). K-TRACS is working to have 100% of all pharmacies in the system.	Final review of mandatory K-TRACS registration (currently before the AG) by 06/19. Implementation of regulation by 12/19.
Expanded coverage of, and access to, naloxone for overdose reversal	Medicaid covers Naloxone in certain forms without prior authorization and it is available at pharmacies without a prescription <i>(K.A.R. 68-7-23)</i>	No changes.	None

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs	<p>Kansas remains a national leader for PDMPs. The Board created and hosted the first PDMP Administrators Roundtable in August 2017. K-TRACS includes all retail and outpatient dispensing records for any controlled substance or drug of concern dispensed in Kansas or to a Kansas resident, regardless of whether the pharmacy is in Kansas. The only exception is for quantities dispensed in the emergency room for 48 hours or less. The software accommodates large chains, independent and small pharmacies, and works seamlessly with the NABP PMP Interconnect® at no charge by NABP. PMPi facilitates the transfer and availability of PDMP data to all 41 participating states. Kansas is currently sharing data with 30 states. Prescriber E-Recap (PERx) is a convenient way for the PDMP to provide prescribers with a snapshot of their prescribing practices regarding controlled substances.</p>	<p>K-TRACS is expanding capabilities to provide interoperability services for all prescribers and pharmacists in Kansas to access K-TRACS through the PDMP Gateway®. This Statewide integration increases availability, ease of access, and use of a patient’s controlled substance prescription history for making critical and informed prescribing and dispensing decisions. This integration creates one-stop-shop making K-TRACS data directly available in the patient’s electronic record.</p> <p>Increase utilization of K-TRACS for surveillance and intervention.</p>	None

**6. Improved Care Coordination and Transitions between Levels of Care**

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current care coordination services and transition services across levels of care.	Provide an overview of planned improvements to care coordination services and transition services across levels of care.	Specify a list of action items needed to be completed to meet milestone requirements. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item.
Implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities.	The State Opioid Response Grant includes activities of a State Opioid Coordinator to work with providers on care coordination and transition services across levels of care. MCOs are responsible to link beneficiaries with community-based services and providers that will coordinate transitions of care.	The current 1115 waiver expands the responsibilities of MCOs to ensure individualized care coordination and links with community-based recovery support for beneficiaries. <i>(Attachment #1 KanCare 2.0 Section 1115 Waiver Demonstration Renewal Application, Final Submission, Dec 2017)</i>	KDHE and KDADS will implement at coordinated approach to increasing service coordination across the spectrum of care, according to activities outlined in the State Opioid Response Grant and the KanCare 1115 waiver. These activities will be completed in a 12-month timeframe.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Additional policies to ensure coordination of care for co-occurring physical and mental health conditions	KanCare requires the provision of Person-Centered Case Management as a one-on-one goal-directed service for individuals with a SUD, to assist individual in obtaining access to needed family, legal, medical, employment, educational, psychiatric, and other services. For individuals served by an MCO, this service must be a part of the treatment plan developed and determined medically necessary by the MCO or by the contracted ASO for all others.	The current 1115 waiver under review at CMS ( <i>Attachment #1 KanCare 2.0 Section 1115 Waiver Demonstration Renewal Application, Final Submission, Dec 2017</i> ) increases support for individuals with behavioral health needs (including SUD) and expands MCO service coordination to assist individuals with accessing housing, food, employment, and other social needs. MCOs will also manage transitions of care between hospital and emergency room admissions to reduce readmission and adverse outcomes. ( <i>Attachment #5 Kansas Medicaid Managed Care (KanCare 2019) RFP EVT0005464 p.11,31-35,56, 59-63</i> )	KDHE will implement Future State activities in accordance with the 1115 waiver implementation timetable within 12 months of waiver approval.

**Section II – Implementation Administration**

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

Name and Title Andy Brown, Commissioner of Behavioral Health Services  
 Telephone Number: 785-291-3359  
 Email Address: Andrew.Brown@ks.gov

**Section III – Relevant Documents**

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

Included under a separate cover are the following attached documents, referenced throughout this text:

1. KanCare Section 2.0 1115 Waiver Demonstration Renewal Application, Final Submission, Dec 2017
2. The Kansas Medical Assistance Program Substance Use Disorder Services Provider Manual (KMAP-SUD-PM)
3. Current KanCare MCO Contract EVT 0001028
4. Standards for Licensure/Certification of Alcohol and/or Other Drug Abuse Programs, rev. 1/1/06
5. Kansas Medicaid Managed Care (KanCare 2019) RFP EVT0005464
6. KanCare 2.0 RFP EVT 0005464 - Attachment C- 3.0-SUD Services
7. KDADS Licensing Surveyor Tool
8. KanCare Network Adequacy Standards revised 8/6/18
9. KMAP General Map Bulletin 18101

## **Attachment A –SUD Health Information Technology (IT) Plan**

The Kansas State Board of Pharmacy is responsible for administration of the Kansas Prescription Drug Monitoring Program (PDMP), known as K-TRACS, which tracks and monitors Schedule II through IV controlled substances and other drugs of concern in Kansas. The goal of the PDMP is to prevent the misuse, abuse, and diversion of controlled substances and drugs of concern, while ensuring continued availability of these medications for legitimate medical use. The Board requires each dispenser (pharmacy) to electronically submit information to the central data collection system for each controlled substance prescription or drug of concern dispensed in an outpatient setting. Prescribers and pharmacists may register for K-TRACS through the Board prior to utilizing the system. K-TRACS is a real-time, web-based system, and users can obtain patient information instantly from any location at any time with the proper login credentials.<sup>3</sup>

The Board employs a Director and a program manager to oversee and administer the PDMP and an epidemiologist in a grant-funded position through August 2019 to analyze K-TRACS data and provide necessary reporting under the federal grants. Additional administrative support is provided by Board of Pharmacy licensing staff.

The Board contracts directly with Appriss for the K-TRACS software. Appriss is the PDMP vendor for 44 other states and provides a strong PDMP solution. The software accommodates large chains, independent and small pharmacies, and works seamlessly with the National Association of Boards of Pharmacy (NABP) - PMP Interconnect® (PMPi) which facilitates the transfer of PDMP data to the 47 participating states. Kansas is currently sharing data with 31 states, including Colorado, Oklahoma, and Texas and recently began sharing with the St. Louis, Missouri PDMP which covers 71 participating jurisdictions. Together these include 84% of the population of Missouri and 85% of the pharmacies.

The Board received a grant in 2012 from the Substance Abuse and Mental Health Services Administration (SAMSHA) through the U.S. Department of Health and Human Services which funded integration of K-TRACS data into the Lewis and Clark Information Exchange (LACIE) and Via Christi Health Systems, enabling a single sign-on for access to a patient's medical record and K-TRACS history. The Board, in conjunction with KDHE, is now expanding that project to provide interoperability services for all prescribers and pharmacists in Kansas to access K-TRACS through the PDMP Gateway®. The project is funded by a grant from the Centers for Disease Control awarded to KDHE. INTEGRx.8 makes K-TRACS data directly available in the patient's electronic record. As of January 2019, 33 hospital corporations (with multiple sites statewide) 130 pharmacy chains and independent pharmacies (with multiple locations statewide) and 11 physicians' offices are integrated with K-TRACS in Kansas.

NarxCare is the newest upgrade to the K-TRACS system beginning January 2019. NarxCare provides patient and clinical decision support beyond the state produced patient's prescription

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<sup>3</sup>January 2018 Report to Legislature: [https://pharmacy.ks.gov/docs/default-source/ktracs/reports/2018-pdmp-legislative-report---final.pdf?sfvrsn=d9caa501\\_2](https://pharmacy.ks.gov/docs/default-source/ktracs/reports/2018-pdmp-legislative-report---final.pdf?sfvrsn=d9caa501_2)

history by: 1) Compiling multiple state reports into one cohesive profile; 2) Analyzing data to provide reports, use scores, predictive scores, red flags, visualizations, and K TRACS data including narcotics, sedatives, and stimulants; 3) Including Medication Assisted Treatment (MAT) locators and CDC printable educational handouts; and finally 4) The Care Team Communications, a powerful tool within NarxCare for the prevention and treatment of substance use disorder provides coordination of care.

K-TRACS was implemented and operated using federal grant funds through June 30, 2016. The Board has now exhausted available grant funding to sustain the program, and the only remaining grant funding is for program enhancements. While the Board continues to pursue grant opportunities, funding presents the largest obstacle to maintaining a PDMP in Kansas. A permanent funding solution will be required prior to July 1, 2019 to ensure program continuation.

**Table 1. State Health IT / PDMP Assessment & Plan**

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p><i>Implementation of comprehensive treatment and prevention strategies to address Opioid Abuse and OUD, that is:</i></p> <ul style="list-style-type: none"> <li><i>--Enhance the state’s health IT functionality to support its PDMP;</i></li> <li><i>and</i></li> <li><i>--Enhance and/or support clinicians in their usage of the state’s PDMP.</i></li> </ul>	<p><i>Provide an overview of current PDMP capabilities, health IT functionalities to support the PDMP, and supports to enhance clinicians’ use of the state’s health IT functionality to achieve the goals of the PDMP.</i></p>	<p><i>Provide an overview of plans for enhancing the state’s PDMP, related enhancements to its health IT functionalities, and related enhancements to support clinicians’ use of the health IT functionality to achieve the goals of the PDMP.</i></p>	<p><i>Specify a list of action items needed to be completed to meet the HIT/PDMP milestones identified in the first column. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item.</i></p>
<b>Prescription Drug Monitoring Program (PDMP) Functionalities</b>			
<p>Enhanced interstate data sharing to better track patient specific prescription data.</p>	<p>K-TRACS accommodates large chains, independent and small pharmacies, and works seamlessly with the NABP PMP Interconnect® (PMPi), provided by the National Association of Boards of Pharmacy at no charge. PMPi is a system which facilitates the transfer and availability of</p>	<p>Since Missouri has not been able to pass statewide legislation establishing a PDMP, Kansas is actively working connect St. Louis county and the other counties that have established a PDMP. St. Louis</p>	<p>Staff at the State Board of Pharmacy is responsible for K-TRACS coordinating with neighboring states. It is in the process of establishing PMPi links with PDMP active counties in</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>PDMP data to all participating states (48 available). Kansas is currently sharing data with 32 states.</p>	<p>County launched its PDMP in April 2017. Fourteen other jurisdictions participate, and more are joining. Currently 84% of Missouri’s population live in county participating the PDMP program. Kansas will be sharing data with those PDMPs by October 2019.</p>	<p>Missouri and will go live with data exchange by October 2019. Kansas will continue to support efforts with the Nebraska legislature to share PDMP data, but no timeframe for completion can be established yet.</p>
<p>Enhanced “ease of use” for prescribers and other state and federal stakeholders.</p>	<p>K-TRACS disseminates materials, created under CDC guidelines, to healthcare providers and students as well as NGOs and academic instructors. MAT and pain management trainings also includes K-TRACS materials. An enhancement generates a “pop-up” in K-TRACS when a prescriber or pharmacist queries a threshold patient. Threshold patients are individuals who received at least five controlled substance prescriptions from prescribers and visited at least five pharmacies to fill those prescriptions in a 90-day period. The Board also maintains a website for K-TRACS at <a href="http://www.ktracs.ks.gov">www.ktracs.ks.gov</a>, with updated forms, frequently asked questions/answers, and other helpful resources for healthcare workers and the public. In addition, the Board publishes articles on best practices and</p>	<p>K-TRACS is in the process of implementing ease of use functionality for specialists. Specialists will be able to see prescribing patterns for other specialists in the same field, which will provide them with decision support on prescribing. and this enhanced feature is going live soon, funded by KDHE.</p> <p>NarxCare went live in January 2019, and provides patient and clinical decision support through reports, use scores, predictive scores, red flags and visualizations and</p>	<p>The Board of Pharmacy staff is responsible for adding functionality to the K-TRACS system, working with the State’s vendor(s). The enhanced features for specialists will be live by August 31, 2019.</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	reminders in a quarterly newsletter available on the Board website.	care coordination tools. It also includes MAT locators and CDC handouts.	
Enhanced connectivity between the state’s PDMP and any statewide, regional, or local health information exchange.	In 2012, K-TRACS integrated with the Lewis and Clark Information Exchange (LACIE) and Via Christi Health Systems, enabling a single sign-on for access to a patient’s medical record and K-TRACS history. The project, known as INTEGRx8, has expanded to provide interoperability services for all prescribers and pharmacists in Kansas to access K-TRACS through the PDMP Gateway®. The Kansas Health Information Network is actively pursuing a K-TRACS connection through the PDMP Gateway®.	K-TRACS is currently integrated with 33 hospital corporations (which have multiple additional locations statewide) 130 pharmacies and pharmacy chains (with multiple additional locations statewide), and 11 physician offices. K-TRACS will continue to work on integrating with more pharmacies (including CVS, which is not currently integrated) and more outpatient practices (including dentists and specialists).	The Board of Pharmacy staff is responsible for adding any new functionality to the K-TRACS system, working with the State’s vendor(s).
Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns <sup>4</sup> (see also “Use of PDMP” #2 below).	In December 2017, the Board announce the first Prescriber E-Recap (PERx). PERx is a quick, convenient way for K-TRACS to provide prescribers with a snapshot of their prescribing practices regarding controlled substances. The PERx covers the previous six-month period and includes: (1) How many patients the prescriber has	The Board recently received additional CDC grant funding through KDHE to add advanced clinical alerts to the K-TRACS system. The system provides clinical alerts directly to K-TRACS users and use indicators	The Board of Pharmacy staff will continue to pursue future funding opportunities with the Federal agencies (in conjunction with KDADS and KDHE as appropriate), but Kansas’ efforts have been limited by

<sup>4</sup> Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015. MMWR Morb Mortal Wkly Rep 2017;66:265–269. DOI: <http://dx.doi.org/10.15585/mmwr.mm6610a1>.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>prescribed opioids to, as well as a comparison to other prescribers within the prescriber’s specialty; (2) Morphine Milligram Equivalent (MME) information is broken out so the prescriber can readily see where their opioid prescribing falls within multiple MME ranges; (3) Opioid treatment duration shows the percentage of their patients who have been prescribed opioids for fewer than 7 days, 7 to 28 days, 29 to 90 days, or more than 90 days; (4) K-TRACS usage shows how much the prescriber and their delegate(s) are using K-TRACS; (5) Multiple Provider Episodes (MPE) provide a look at the number of the prescriber’s patients who have met or exceeded the K-TRACS threshold – five prescribers and five pharmacies within 90 days; and (6) Dangerous Combination Therapy provides the prescriber with details of their patients’ combination therapies that may increase a patient’s risk for overdose.<sup>5</sup></p>	<p>that a patient may have multiple provider episodes, previous overdose history, prescriptions for dangerous drug combinations, or high prescription milligram morphine equivalents. INTEGRx8 delivers a more efficient and patient-oriented program, saves users 4.22 minutes per patient on average, and increases the utilization of K-TRACS by a factor of seven. A supplemental FY2019 CDC grant award will allow the Board to deploy the NARxCARE® enhancement, which provides additional metrics, tools, and risk scores for patients prescribed controlled substances and drugs of concern.</p>	<p>recent requirements of several federal agencies to use RX Check (the Federal PDMP data hub being used by BJA, CDC and other Federal Agencies). The terms and conditions for RX Check are in conflict with Kansas’ data use policy. Until such issues are resolved, (i.e. RX Check conforms its data disclosure policy with law enforcement to conform with the more restrictive policies in most states), Kansas will not seek federal funds for new grant initiatives that require use of RX Check.</p>
<p><b>Current and Future PDMP Query Capabilities</b></p>			

<sup>5</sup> January 2018 Report to Legislature: [https://pharmacy.ks.gov/docs/default-source/ktracs/reports/2018-pdmp-legislative-report---final.pdf?sfvrsn=d9caa501\\_2](https://pharmacy.ks.gov/docs/default-source/ktracs/reports/2018-pdmp-legislative-report---final.pdf?sfvrsn=d9caa501_2)

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p>Facilitate the state’s ability to properly match patients receiving opioid prescriptions with patients in the PDMP (i.e. the state’s master patient index (MPI) strategy regarding the PDMP query).</p>	<p>The use of K-TRACS is not mandatory in Kansas. As the Board launches statewide integration of K-TRACS data into hospital and pharmacy electronic health records systems, use of the Gateway is expected to increase queries substantially. These systems can check a patient’s controlled substance prescription history more than one time per second and counts may represent multiple checks per patient.</p>	<p>The K-TRACS staff will continue to work closely with State partners from other agencies and providers to increase utilization of the system. The Board envisions that expansion of the Gateway is the best way to increase use and allow providers to properly match opioid prescriptions for their patients in the PDMP.</p> <p>The State will explore feasibility and options of developing a shared Master Patient Index.</p>	<p>The Board of Pharmacy staff is responsible for adding any new functionality to the K-TRACS system, working with the State’s vendor(s).</p>
<p><b>Use of PDMP – Supporting Clinicians with Changing Office Workflows / Business Processes</b></p>			
<p>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.</p>	<p>The integration of K-TRACS, LACIE, and Via Christi Health Systems enabling a single sign-on for patient medical record access in conjunction with the PDMP Gateway® gives Kansas an opportunity to deliver a more efficient and patient-oriented program. This integration allows prescribers and pharmacists to log into one program instead of separate system to query patient data which takes valuable time away from patient care and interaction. This integration simplifies the process by</p>	<p>INTEGRx.8 makes K-TRACS data directly available in the patient's electronic record. As of January 2019, 33 hospital corporations (with multiple sites statewide) 130 pharmacy chains and independent pharmacies (with multiple locations statewide) and 11 physicians' offices are integrated with K-TRACS in Kansas.</p>	<p>The Board of Pharmacy staff is responsible for adding any new functionality to the K-TRACS system, working with the State’s vendor(s).</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>creating a one-stop-shop making K-TRACS data directly available in the patient’s electronic record and saving 4.22 minutes per patient, on average and up to 10 minutes per patient in rural areas.</p>		
<p>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.</p>	<p>In December 2017, the Board announce the first Prescriber E-Recap (PERx). PERx is a quick, convenient way for the PDMP to provide prescribers with a snapshot of their prescribing practices regarding controlled substances. The PERx covers the previous six-month period and includes: (1) How many patients the prescriber has prescribed opioids to, as well as a comparison to other prescribers within the prescriber’s specialty. (2) The system provides Morphine Milligram Equivalent (MME) information broken out so the prescriber can readily see where their opioid prescribing falls within multiple MME ranges. (3) Opioid treatment duration shows prescribers the percentage of their patients prescribed opioids for fewer than 7 days, 7 to 28 days, 29 to 90 days, or more than 90 days. (4) K-TRACS usage, which shows how much the prescriber and their delegate(s) are using K-TRACS. (5) Multiple Provider Episodes (MPE) provide a look at the number of the prescriber’s patients who</p>	<p>The Board will continue to expand the use of PERx with clinicians using the PDMP and will establish daily MME guidelines and compliance with those guidelines to providers using the PDMP.</p> <p>INTEGRx.8 makes K-TRACS data directly available in the patient's electronic record. As of January 2019, 33 hospital corporations (with multiple sites statewide) 130 pharmacy chains and independent pharmacies (with multiple locations statewide) and 11 physicians' offices are integrated with K-TRACS in Kansas.</p>	<p>The Board of Pharmacy staff will be responsible for adding functionality to the K-TRACS system, working with the State’s vendor(s).</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>have met or exceeded the K-TRACS threshold of 5/5/90 – five prescribers and five pharmacies within 90 days. (6) Dangerous Combination Therapy provides the prescriber with details of their patients’ combination therapies that may increase a patient’s risk for overdose.<sup>6</sup></p>		
<b>Master Patient Index / Identity Management</b>			
<p>Enhance the master patient index (or master data management service, etc.) in support of SUD care delivery.</p>	<p>The Kansas Eligibility Enforcement System (KEES) system includes a master person index (MPI) for each person that applies for Medicaid. The MPI serves as the system of record for all person-based information throughout KEES. The MPI issues a “client ID number” that identifies a person throughout KEES.</p> <p>The State recognizes limitations in currently supported patient matching in the PDMP and intends to find ways to link this issue to improve data linkage and identity mapping.</p>	<p>The State will explore feasibility and options of developing a shared Master Patient Index.</p>	<p>The Board of Pharmacy staff will be responsible for adding this functionality to the K-TRACS system, working with the State’s vendor(s). The Board will identify: (1) facilitators and barriers, and (2) options to link Patient Identifiers and across different systems.</p>
<b>Overall Objective for Enhancing PDMP Functionality &amp; Interoperability</b>			

<sup>6</sup> January 2018 Report to Legislature: [https://pharmacy.ks.gov/docs/default-source/ktracs/reports/2018-pdmp-legislative-report--final.pdf?sfvrsn=d9caa501\\_2](https://pharmacy.ks.gov/docs/default-source/ktracs/reports/2018-pdmp-legislative-report--final.pdf?sfvrsn=d9caa501_2)

Milestone Criteria	Current State	Future State	Summary of Actions Needed
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.	Through the integration described in milestone objectives above, K-TRACS providers, including those treating Medicaid beneficiaries are using the tools and methods supported in the PDMP to minimize inappropriate opioid prescribing.	Continuation of all initiatives stated in the milestones above.	. The Board of Pharmacy staff will continue to pursue future funding opportunities with the Federal agencies (in conjunction with KDADS and KDHE as appropriate), but Kansas’ efforts have been limited by recent requirements of several federal agencies to use RX Check (the Federal PDMP data hub being used by BJA, CDC and other Federal Agencies).

**Attachment A, Section II – Implementation Administration**

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

Name and Title: Lori K. Haskett, Assistant Director, K-TRACS  
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**Attachment A, Section III – Relevant Documents**

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

1. January 2018 Report to Legislature: [https://pharmacy.ks.gov/docs/default-source/ktracs/reports/2018-pdmp-legislative-report---final.pdf?sfvrsn=d9caa501\\_2](https://pharmacy.ks.gov/docs/default-source/ktracs/reports/2018-pdmp-legislative-report---final.pdf?sfvrsn=d9caa501_2)
2. Presentation by Board of Pharmacy in December 2017 (contains great background on the PDMP): [https://qioprogram.org/sites/default/files/editors/141/KS\\_PDMP\\_Recording\\_508.pdf](https://qioprogram.org/sites/default/files/editors/141/KS_PDMP_Recording_508.pdf)
3. Presentation by Board of Pharmacy in March 2017: [https://www.deadiversion.usdoj.gov/mtgs/pharm\\_awareness/conf\\_2017/march\\_2017/wic\\_hita/kenton.pdf](https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2017/march_2017/wic_hita/kenton.pdf)

4. 2nd Quarter 2018 K-TRACS Quarterly Review: [https://pharmacy.ks.gov/docs/default-source/ktracs/reports/july-20-2018.pdf?sfvrsn=ecba501\\_2](https://pharmacy.ks.gov/docs/default-source/ktracs/reports/july-20-2018.pdf?sfvrsn=ecba501_2)

**Attachment D**  
**Monitoring Protocol (Reserved)**

**Attachment E**  
**Evaluation Design (Reserved)**