CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: **11-W-00306/4 and 21-W-00067/4**

TITLE: **KY HEALTH Section 1115 Demonstration**

AWARDEE: **Kentucky Cabinet for Health and Family Services**

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by the Commonwealth of Kentucky for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act, must, unless otherwise specified, be regarded as matchable expenditures under the state's Title XIX plan but are further limited by the special terms and conditions (STCs) for the KY HEALTH section 1115 demonstration. Expenditures associated with KY HEALTH are approved from January 12, 2018 through September 30, 2023.

As discussed in the Centers for Medicare & Medicaid Services' (CMS) approval letter, the Secretary of Health and Human Services has determined that the KY HEALTH Section 1115 demonstration, including the granting of the waiver and expenditure authorities described below, is likely to assist in promoting the objectives of title XIX of the Social Security Act.

The following expenditure authorities shall enable Kentucky to implement the KY HEALTH demonstration:

1. Expenditures to the extent necessary to enable Kentucky to align a beneficiary's annual redetermination with their employer sponsored insurance (ESI) open enrollment period, including any children enrolled in Medicaid and covered by a parent or caretaker's ESI, in a manner inconsistent with requirements under section 1943 of the Act as implemented in 42 CFR 435.916(a).

2. Expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental disease (IMD).

CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER LIST

NUMBER: **11-W-00306/4 and 21-W-00067/4**

TITLE: **KY HEALTH Section 1115 Demonstration**

AWARDEE: **Kentucky Cabinet for Health and Family Services**

Title XIX Waiver Authority

All requirements of the Medicaid program expressed in law, regulation and policy statement, not expressly waived or identified as not applicable in accompanying expenditure authorities and/or these STCs, shall apply to the demonstration project through September 30, 2023. In addition, these waivers may only be implemented consistent with the approved STCs. Waivers associated with KY HEALTH are approved from January 12, 2018 through September 30, 2023.

Under the authority of section 1115(a)(1) of the Social Security Act (the Act), the following waivers of state plan requirements contained in section 1902 of the Act are granted for the KY HEALTH section 1115 demonstration, subject to these STCs.

1. Methods of Administration — **Section 1902(a)(4) insofar as it incorporates 42 CFR 431.53**

To the extent necessary to relieve Kentucky of the requirement to assure non-emergency medical transportation to and from providers for all Medicaid beneficiaries to the extent the non-emergency medical transportation is for methadone treatment services. The waiver does not apply with respect to pregnant women or former foster care youth, and also does not apply if the service is provided subject to early and periodic screening, diagnostic, and treatment (EPSDT).

2. Provision of Medical Assistance — **Section 1902(a)(8) and 1902(a)(10)**

To the extent necessary to permit Kentucky to limit the provision of medical assistance (and treatment as eligible) for individuals described in the eligibility group under section 1902(a)(10)(A)(ii)(XX) of the Act and the state plan to only former foster care youth who are under 26 years of age, were in foster care under the responsibility of another state or tribe on the date of attaining 18 years of age (or such higher age as the state has elected), and who were enrolled in Medicaid on that date.

CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER LIST

NUMBER: **11-W-00306/4 and 21-W-00067/4**

TITLE: **KY HEALTH Section 1115 Demonstration**

AWARDEE: **Kentucky Cabinet for Health and Family Services**

Title XXI Waiver Authority

All requirements of the Medicaid or Children's Health Insurance Program (CHIP) program expressed in law, regulation and policy statement, not expressly waived or identified as not applicable in accompanying expenditure authorities and/or these STCs, shall apply to the demonstration project beginning January 12, 2018, through September 30, 2023. In addition, these waivers may only be implemented consistent with the approved STCs.

Under the authority of section 1115(a)(1) of the Act, the following waivers of the CHIP state plan requirements contained in title XXI of the Act are granted for the KY HEALTH section 1115 demonstration, subject to these STCs.

1. Continuous Eligibility — Section 2107(e)(1)(R)

To the extent necessary to enable Kentucky to align a beneficiary's annual redetermination with their employer sponsored insurance (ESI) open enrollment period, including any children enrolled in CHIP and covered by a parent or caretaker's ESI, in a manner inconsistent with requirements under section 1943 of the Act as implemented in 42 CFR 457.343 and 42 CFR 435.916(a).

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: **11-W-00306/4 and 21-W-00067/4**

TITLE: **KY HEALTH 1115 Demonstration**

AWARDEE: **Kentucky Cabinet for Health and Family Services**

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the "KY Helping to Engage and Achieve Long Term Health" (KY HEALTH) section 1115(a) Medicaid and CHIP demonstration (hereinafter "demonstration") to enable Kentucky (state) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted the state waivers of requirements under sections 1902(a) and section 2107 of the Social Security Act (the Act), and expenditure authorities authorizing federal matching of demonstration costs that are not otherwise matchable, and which are separately enumerated. These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration, and the state's obligations to CMS related to this demonstration. The KY HEALTH demonstration will be statewide and is approved from January 12, 2018 through September 30, 2023.

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. Delivery System
VII. General Reporting Requirements
VIII. General Financial Requirements
IX. Budget Neutrality
X. Evaluation
XI. Opioid Use Disorder (OUD)/Substance Use Disorder (SUD)

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

- Attachment A: Developing the Evaluation Design
- Attachment B: Preparing the Evaluation Report
- Attachment C: SUD Implementation Protocol
- Attachment D: SUD Monitoring Protocol
- Attachment E: SUD Health Information Technology (Health IT)

- Attachment F: Evaluation Design

II. PROGRAM DESCRIPTION AND OBJECTIVES

The KY HEALTH section 1115(a) demonstration includes a substance use disorder (SUD) treatment program available to all Kentucky Medicaid beneficiaries to ensure that a broad continuum of care is available to Kentuckians with SUD, which will help improve the quality, care, and health outcomes for Kentucky Medicaid beneficiaries. Additionally, the demonstration also enables the Commonwealth to provide Medicaid coverage to former foster care youth under age 26 who were in foster care under the responsibility of another state or tribe when they turned 18 (or such higher age as the state has elected for termination of federal foster care assistance under title IV-E of the Social Security Act), and were enrolled in Medicaid at that time, and are now applying for Medicaid in the Commonwealth.

The KY HEALTH demonstration was originally approved on January 12, 2018. The demonstration previously included the project component known as the Kentucky HEALTH program, which included two consumer-driven incentive tools and various eligibility provisions including a premium obligation, community engagement requirements, and non-eligibility periods for certain beneficiaries for failure to comply with the requirements associated with premiums, redeterminations, and reporting changes in circumstances, and community engagement. On June 29 2018, a district court vacated the approval of the Kentucky HEALTH program, *Stewart v. Azar*, 313 F. Supp. 3d 237, 243 (D.D.C. 2018). After a subsequent approval of the Kentucky HEALTH program on November 20, 2018, a district court vacated the approval of the Kentucky HEALTH program for a second time. On December 16, 2019, Kentucky requested to formally withdraw the Kentucky HEALTH program component which was never implemented. CMS reissued the STCs of the KY HEALTH demonstration on June 16, 2020 to effectuate the state's request.

III. GENERAL PROGRAM REQUIREMENTS

1. Compliance with Federal Non-Discrimination Laws. The state must comply with applicable federal civil rights laws relating to non-discrimination in services and benefits in its programs and activities. 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). Such compliance includes providing reasonable modifications to individuals with disabilities under the ADA, Section 504, and Section 1557 in eligibility and documentation requirements, to ensure they understand program rules and notices, as well as other program requirements necessary to obtain and maintain benefits.

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 written policy, not expressly waived or identified as not

applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid and/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 of an operational nature without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state thirty (30) calendar days in advance of the expected approval date of the amended STCs to allow the state to provide comment.

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 well as a modified allotment neutrality worksheet as necessary to comply with such change. Further, the state may seek an amendment to the demonstration (as per STC 7) 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 day such state legislation becomes effective, or on the last day such legislation was required to be in effect under federal law, whichever is sooner.

5. **State Plan Amendments.** The state will not be required to submit title XIX or title XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan may be required, except as otherwise noted in these STCs. In all such instances, the Medicaid and CHIP state plans govern.

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

been approved through the amendment process set forth in STC 7, except as provided in STC 3.

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

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

b. A data analysis worksheet which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include 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;

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

d. An explanation of the public process used by the state consistent with the requirements of STC 13; and,

e. If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.

8. **Extension of the Demonstration.** States that intend to request a demonstration extension under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in statute. Otherwise, no later than twelve months prior to the expiration date of the demonstration, the Governor or Chief Executive Officer of the state must submit to CMS either a demonstration extension request that meets federal requirements at 42 CFR 431.412(c) or a transition and phase-out plan consistent with the requirements of STC 9.

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

a. <u>Notification of Suspension or Termination.</u> 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 thirty (30) day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 13, if applicable. Once the thirty (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 transition and phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.

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

d. Transition and Phase-out Procedures. The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, 431.211, and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 C.F.R. 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

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

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

g. Federal Financial Participation (FFP). FFP will be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

10. Expiring Demonstration Authority. For demonstration authority that expires prior to the demonstration's expiration date, the state must submit a demonstration authority expiration plan to CMS no later than six months prior to the applicable demonstration authority's expiration date, consistent with the following requirements:

a. Expiration Requirements. The state must include, at a minimum, in its demonstration authority expiration plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration authority for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities.

b. Expiration Procedures. The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, 431.211, and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

c. Federal Public Notice. CMS will conduct a thirty (30) day federal public comment period consistent with the process outlined in 42 CFR 431.416 in order to solicit public input on the state's demonstration authority expiration plan. CMS will consider comments received during the thirty (30) day period during its review of

the state's demonstration authority expiration plan. The state must obtain CMS approval of the demonstration authority expiration plan prior to the implementation of the expiration activities. Implementation of expiration activities must be no sooner than fourteen (14) calendar days after CMS approval of the demonstration authority expiration plan.

d. Federal Financial Participation (FFP). FFP will be limited to normal closeout costs associated with the expiration of the demonstration authority including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

11. 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 must promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

12. Adequacy of Infrastructure. The state must 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.

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

The state must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

14. Federal Financial Participation (FFP). No federal matching for state expenditures under 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.

15. Common Rule Exemption. The state shall 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 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. The Secretary 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

16. Eligibility Groups Affected by the Demonstration. There is no change to Medicaid state plan eligibility. Standards and methodologies for eligibility remain set forth under the state plan and are subject to all applicable Medicaid laws and regulations.

17. Former Foster Care Youth. Beneficiaries made eligible under the demonstration are former foster care youth who are under 26 years of age, were in foster care under the responsibility of another state or tribe on the date of attaining 18 years of age (or such higher age as the state has elected), and who were enrolled in Medicaid on that date.

V. BENEFITS

18. Former Foster Care Youth Benefits. Out-of-state former foster care youth will receive the same Medicaid State Plan benefits and may be subject to the same cost-sharing requirements effectuated by the state for the mandatory title IV-E foster care youth eligibility category enacted by the Adoption Assistance and Child Welfare Act of 1980 (Pub. L. 96-272).

19. Non-Emergency Medical Transportation (NEMT). Offering methadone through the state plan is contingent upon the waiver of NEMT.

VI. DELIVERY SYSTEM

20. Overview. Kentucky HEALTH will utilize the current statewide mandatory managed care delivery system for all covered populations under the authority of the Kentucky Managed Care Organization Program 1915(b) waiver.

VII. GENERAL REPORTING REQUIREMENTS

21. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singularly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the demonstration. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

The following process will be used: 1) Thirty (30) days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) Thirty (30) days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

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

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

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

d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting 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.

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.

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

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

a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;

b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and

c. Submit deliverables to the appropriate system as directed by CMS.

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

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

b. Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing towards meeting the milestones identified in CMS' framework which includes the following key policies under this demonstration. The performance metrics will also reflect all other components of the state's demonstration, including metrics associated with the waiver of NEMT. For example, these metrics will cover enrollment, disenrollment by specific demographics and reason, access to care, and health outcomes.

Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances, and appeals.

The required monitoring and performance metrics must be included in the Monitoring Reports, and will follow the CMS framework provided by CMS to support federal tracking and analysis.

c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on the 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.

25. Corrective Action. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 11.

26. Close Out Report. Within one hundred twenty (120) calendar days after the expiration of the demonstration, the state must submit a draft Close Out Report to CMS for comments.

a. The draft report must comply with the most current guidance from CMS.

b. The state will present to and participate in a discussion with CMS on the Close-Out report.

c. The state must take into consideration CMS' comments for incorporation into the final Close Out Report.

d. The final Close Out Report is due to CMS no later than thirty (30) calendar days after receipt of CMS' comments.

e. A delay in submitting the draft or final version of the Close Out Report may subject the state to penalties described in STC 21.

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

a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to), any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, budget neutrality, and progress on evaluation activities.

b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.

c. The state and CMS will jointly develop the agenda for the calls.

28. Post Award Forum. Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state shall afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least thirty (30) days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state must also post the most recent annual report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Report.

VIII. GENERAL FINANCIAL REQUIREMENTS

This demonstration is approved for Title XIX expenditures applicable to services rendered during the demonstration period. This section describes the general financial requirements for these expenditures.

29. Quarterly Expenditure Reports. The state must report quarterly expenditures associated with the populations affected by this demonstration on the Form CMS-64.

30. Reporting Expenditures under the Demonstration. The following describes the reporting of expenditures subject to the budget neutrality agreement:

a. **Tracking Expenditures.** In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and state Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in sections 2500 and 2115 of the state Medicaid Manual. All demonstration expenditures subject to the budget neutrality limit must be reported each quarter on separate Forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (including the project number extension, which indicates the DY in which services were rendered or for which capitation payments were made).

b. **Cost Settlements.** For monitoring purposes, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (Form CMS-64.9P Waiver) for the Summary Sheet Line 10B, in lieu of Lines 9 or 10C. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual.

c. **Use of Waiver Forms.** For each DY, separate Forms CMS-64.9 Waiver and/or 64.9P Waiver must be submitted reporting expenditures for beneficiaries enrolled in the demonstration, subject to the budget neutrality limit. The state will complete separate waiver forms for the following benefits/ waiver name:

i. "SUD" expenditures

31. Administrative Costs. Administrative costs will not be included in the budget neutrality limit, but the state shall separately track and report additional administrative costs that are directly attributable to the demonstration, using Forms CMS-64.10 Waiver and/or 64.10P Waiver, with waiver name State and Local Administration Costs ("ADM").

32. Claiming Period. All claims for expenditures subject to the budget neutrality limit (including any cost settlements) shall be made within 2 years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including any cost settlements) shall be made within 2 years after the conclusion or termination of the demonstration. During the latter 2-year period, the state shall continue to identify separately net expenditures related to dates of services during the operation of the demonstration on the Form CMS-64 and Form CMS-21 in order to properly account for these expenditures in determining budget neutrality.

33. Reporting of Member Months. The following describes the reporting of member months for the demonstration populations:

a. For the purpose of calculating the budget neutrality expenditure cap and for other purposes, the state will provide to CMS, as part of the quarterly report required under STC 24, the actual number of eligible member months for the demonstration populations. The state will submit a statement accompanying the quarterly report, which certifies the accuracy of this information.

b. To permit full recognition of “in-process” eligibility, reported counts of member months may be subject to revisions after the end of each quarter. Member month counts may be revised retrospectively as needed.

c. The term "eligible member months" refers to the number of months in which persons 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 to the total, for a total of four eligible member months.

34. Standard Medicaid Funding Process. The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure cap 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 will make federal funds available based upon the state's estimate, as approved by CMS. Within thirty (30) calendar days after the end of each quarter, the state must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter that just ended. CMS will reconcile expenditures reported on the Form CMS-64 quarterly with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

35. Extent of FFP for the Demonstration. Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole as outlined below:

a. Administrative costs, including those associated with the administration of the demonstration. With respect to expenditures for items and services covered through the My Rewards account, only those items and services that the Secretary has found to be necessary for the proper and efficient administration of the state plan may be claimed as administrative costs.

b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved state plan.

c. Medical Assistance expenditures made under section 1115 demonstration authority, including those made in conjunction with the demonstration, cost sharing,

pharmacy rebates, and all other types of third party liability or CMS payment adjustments.

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

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

b. Any amendments that impact the financial status of the demonstration shall require the state to provide information to CMS regarding all sources of the non-federal share of funding.

c. The state assures that all health care-related taxes comport with section 1903(w) of the Act and all other applicable federal statutory and regulatory provisions, as well as the approved Medicaid state plan**.**

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

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

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

c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for payments under the demonstration, governmental entities to which general revenue funds are appropriated shall certify to the state the amount of such tax revenue (state or local) used to fund the non-federal share of demonstration expenditures. The entities that incurred the cost shall also provide cost documentation to support the state's claim for federal match.

d. The state may use intergovernmental transfers to the extent that such funds are derived from state or local tax revenues and are transferred by units of government

within the state. Any transfers from governmentally operated health care providers shall be made in an amount not to exceed the non-federal share of Title XIX payments.

e. Under all circumstances, health care providers must retain 100 percent of the reimbursement amounts claimed by the state as demonstration expenditures. Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state and/or local government to return and/or redirect any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business (such as payments related to taxes (including health care provider-related taxes), fees, and 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.

IX. BUDGET NEUTRALITY

38. Limit on Title XIX Funding. The state is subject to a limit on the amount of federal Title XIX funding that the state may receive on selected Medicaid expenditures during the period of approval of the demonstration. The limit is determined by using the per capita cost method described in STC 40. The budget neutrality expenditure limits are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. The data supplied by the state to CMS to set the annual caps is subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit. CMS' assessment of the state's compliance with these annual limits will be done using the Schedule C reports from the CMS-64.

39. Risk. The state will be at risk for exceeding the limits on per capita cost (as determined by the method described below) for the demonstration expenditures, as described in STC 40 and STC 41, and shall not be at risk for costs pertaining to the number of enrollees in the demonstration population. By providing FFP without regard to enrollment in the demonstration populations, CMS will not place the state at risk for changing economic conditions that impact enrollment levels. However, by placing the state at risk for the per capita costs of current eligibles, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration.

40. Calculation of the Budget Neutrality Limit. For the purpose of calculating the overall budget neutrality limit for the demonstration, separate annual budget limits will be calculated for each DY on a total computable basis, as described in this STC 40(b). The annual limits will then be 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 limit by the Composite Federal Share,

which is defined in STC 43. The demonstration expenditures subject to the budget neutrality limit are those reported under the waiver name "SUD Expenditures".

a. The Medicaid Eligibility Group (MEGs) listed in the table below are included in the calculation of the budget neutrality limit for the Kentucky HEALTH demonstration.

b. The budget neutrality cap is calculated by taking the per member per month (PMPM) cost projection for the below groups in each DY, times the number of eligible member months for that group and DY, and adding the products together across DYs. The federal share of the budget neutrality cap is obtained by multiplying total computable budget neutrality cap by the federal share.

c. The state will not be allowed to obtain budget neutrality "savings" from these populations.

41. Substance Use Disorder Expenditures. As part of the SUD initiative, the state may receive FFP for the continuum of services specified in Table 2 to treat OUD and other SUDs that are provided to all Medicaid beneficiaries in an IMD as authorized by this demonstration. These are state plan services that would be eligible for reimbursement if not for the IMD exclusion. Therefore, they are being treated as hypothetical. The state may only claim FFP via demonstration authority for the services listed in Table 2 that will be provided in an IMD. However, the state will not be allowed to obtain budget neutrality "savings" from these services. Therefore, a separate expenditure cap is established for SUD services.

a. The SUD MEG listed in Table 1 below is included in SUD budget neutrality test.

b. SUD expenditures cap are calculated by multiplying the projected PMPM for each SUD MEG, each DY, by the number of actual eligible SUD member months for the same MEG/DY—and summing the products together across all DYs. The federal share of the SUD expenditure cap is obtained by multiplying those caps by the Composite Federal Share (see STC 43).

c. SUD budget neutrality test is a comparison between the federal share of SUD expenditure cap and total FFP reported by the state for the SUD MEG.

Table 1: Hypothetical Budget Neutrality Test

Eligibility group	Trend Rate	DY 1	DY 2	DY 3	DY 4	DY 5	DY 6
SUD PMPM	5.0%	$1,430.18	$1,501.69	$1,576.77	$1,655.61	$1,738.39	$1,759.72

42. Former Foster Care Youth. CMS has determined that the provision of benefits and services to this demonstration population is budget neutral based on CMS' assessment that the waiver authorities granted for this demonstration population are unlikely to result in any

increase in federal Medicaid expenditures, and that no expenditure authorities are associated with this demonstration population. There will be no budget neutrality expenditure limit established for this demonstration population, and no further test of budget neutrality will be required. Accordingly, the state will not be allowed to obtain budget neutrality "savings" from this demonstration population. All expenditures associated with this population will be reported on the CMS-64 base form(s) for Medicaid State Plan populations in accordance with section 2500 of the State Medicaid Manual.

43. **Composite Federal Share Ratio.** 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, as reported through the MBES/CBES and summarized on Schedule C (with consideration of additional allowable demonstration offsets such as, but not limited to, premium collections) by total computable demonstration expenditures for the same period as reported on the same forms. Should the demonstration be terminated prior to the end of the extension approval period (see STC 9 and STC 11), the Composite Federal Share will be determined based on actual expenditures for the period in which the demonstration was active. 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 upon method.

44. **Enforcement of Budget Neutrality.** CMS must enforce budget neutrality over the life of the demonstration rather than on an annual basis. However, if the state's expenditures exceed the calculated cumulative budget neutrality expenditure cap by the percentage identified below for any of the demonstration years, the state shall submit a corrective action plan to CMS for approval. The state will subsequently implement the approved corrective action plan.

DY	Cumulative Target Definition	Percentage
DY 1 {Approval}- June 30 2018	Cumulative budget neutrality expenditure cap plus:	**2.0%**
DY 2 July 1, 2018- June 30, 2019	Cumulative budget neutrality expenditure cap plus:	**1.5%**
DY 3 July 1, 2019- June 30, 2020	Cumulative budget neutrality expenditure cap plus:	**1.0%**
DY4 July 1, 2020- June 30, 2021	Cumulative budget neutrality expenditure cap plus:	**0.5%**
DY5 July 1, 2020- June 30, 2022	Cumulative budget neutrality expenditure cap plus:	**0%**

DY6 July 1, 2022- September 30, 2023	Cumulative budget neutrality expenditure cap plus:	**0%**

45. **Exceeding Budget Neutrality.** If at the end of the demonstration period the cumulative budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the budget neutrality agreement, an evaluation of this provision will be based on the time elapsed through the termination date.

46. **Impermissible DSH, Taxes or Donations.** The CMS reserves the right to adjust the budget neutrality expenditure limit in order to be consistent with enforcement of impermissible provider payments, health care related taxes, new federal statutes, or with policy interpretations implemented through letters, memoranda, or regulations. CMS reserves the right to make adjustments to the budget neutrality expenditure limit if CMS determines that any health care-related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is in violation of the provider donation and health care related tax provisions of Section 1903(w) of the Act. Adjustments to the budget neutrality agreement will reflect the phase-out of impermissible provider payments by law or regulation, where applicable.

X. EVALUATION

47. **Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state shall 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; providing data and analytic files to CMS; 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 shall include in its contracts with entities that collect, produce or maintain data and files for the demonstration, a requirement that they make data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 21.

48. **Independent Evaluator.** Upon approval of the demonstration, the state must begin to arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party to sign an agreement that the independent party will conduct the demonstration evaluation in an independent manner in accord with the CMS-approved 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.

49. Draft Evaluation Design. The state must submit, for CMS comment and approval, a draft Evaluation Design, no later than one hundred eighty (180) calendar days after approval of the demonstration.

Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable.

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

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

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

50. Evaluation Design Approval and Updates. The state must submit a revised draft Evaluation Design within sixty (60) calendar days after receipt of CMS' comments. 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 thirty (30) days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the 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.

51. Evaluation Questions and Hypotheses. Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, CMS's measure sets for eligibility and coverage, 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).

52. **Evaluation Budget.** A budget for 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 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.

53. **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 that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.

c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses, and how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) 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 final Interim Evaluation Report sixty (60) calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.

e. The Interim Evaluation Report must comply with Attachment B (Preparing the Evaluation Report) of these STCs.

54. **Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Evaluation Report) of these STCs. The state must submit a 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 Summative Evaluation Report must include the information in the approved Evaluation Design.

a. Unless otherwise agreed upon in writing by CMS, the state shall submit the final Summative Evaluation Report within sixty (60) calendar days of receiving comments from CMS on the draft.

b. The final Summative Evaluation Report must be posted to the state's Medicaid website within thirty (30) calendar days of approval by CMS.

55. Corrective Action Plan Related to Evaluation. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of a renewal process when associated with the state's interim evaluation report. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 11.

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

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

58. Additional Publications and Presentations. For a period of twelve (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 ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

XI. OPIOID USE DISORDER (OUD)/SUBSTANCE USE DISORDER (SUD)

Effective upon CMS's approval of the SUD Implementation Protocol, as described in STC 60, the demonstration benefit package for all Medicaid beneficiaries as authorized by this demonstration will include OUD/SUD residential treatment, crisis stabilization and withdrawal management services provided in IMDs, which are not otherwise matchable expenditures under section 1903 of the Act. Medicaid beneficiaries residing in IMDs under the terms of this demonstration will have

coverage of all benefits that would otherwise be covered if the beneficiary were not residing in an IMD. Effective upon CMS's approval of this demonstration, methadone treatment services will be a covered service under the state plan for Medicaid beneficiaries.

The coverage of OUD/SUD residential treatment, crisis stabilization, withdrawal management and methadone treatment services will expand Kentucky's current SUD benefit package available to all Medicaid beneficiaries as outlined in Table 2. Note: Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

Table 2: Kentucky SUD Benefits Coverage with Expenditure Authority

SUD Benefit	Medicaid Authority	Costs Not Otherwise Matchable
Early Intervention (Screening, Brief Intervention and Referral to Treatment)	State plan (Individual services covered)	
Outpatient Therapy (Individual; Group; Family; Collateral)	State plan (Individual services covered)	
Intensive Outpatient Program	State plan (Individual services covered)	
Partial Hospitalization Treatment (including Day Treatment for children/youth under the age of 21)	State plan (Individual services covered)	
Residential Treatment	State plan (Individual services covered)	Services provided to individuals in IMDs
Medically Supervised Withdrawal Management	State plan	Services provided to individuals in IMDs
Medication-Assisted Treatment (MAT)	State plan	Services provided to individuals in IMDs
Methadone treatment for opioid dependence	State Plan (contingent on this 1115 demonstration waiver of NEMT)	Services provided to individuals in IMDs

Peer Support (including Parent/Family Peer Support)	State plan	Services provided to individuals in IMDs
Crisis Intervention (including Mobile Crisis)	State plan (Individual services covered)	
Residential Crisis Stabilization	State plan (Individual services covered)	Services provided to individuals in IMDs

59. Methadone Treatment Services. "Methadone Treatment Services" will be covered in the Medicaid state plan. A waiver of the NEMT assurance is granted for Methadone Treatment Services to allow the state not to provide NEMT for methadone services to all Medicaid beneficiaries, except that NEMT for methadone services will be provided for children under age 21 who are subject to EPSDT, former foster care youth, and for pregnant women. (A waiver of the NEMT assurance for all other Medicaid covered services is granted for beneficiaries eligible through the new adult group, as defined in 42 CFR 435.119, except for beneficiaries in that group who are under age 21 and subject to EPSDT, pregnant, medically frail, survivors of domestic violence, or former foster care youth.)

a. The components of Methadone Treatment Services are defined in the Medicaid state plan.

60. SUD Implementation Protocol. The state must submit a SUD Implementation Protocol within one hundred twenty (120) calendar days after approval of this demonstration. The protocol must be approved by CMS. The state may not claim FFP for services provided in IMDs until CMS has approved the SUD Implementation Protocol. Once approved, the SUD Implementation Protocol will be incorporated into these STCs, as Attachment D, and once incorporated, may be altered only with CMS approval. After approval of the SUD Implementation Protocol, FFP will be available prospectively, not retrospectively. Failure to submit a SUD Implementation Protocol or failure to obtain CMS approval will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the IMD expenditure authority. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral or withholding.

At a minimum, the SUD Implementation Protocol will describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones that reflect the key goals and objectives of the SUD component of this demonstration program:

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

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

c. **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 24 months of demonstration approval;

d. **Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities:** Currently, residential treatment service providers must be accredited by the Commission on the Accreditation of Rehabilitation Facilities and must be a licensed organization, pursuant to the residential service provider qualifications described in the Kentucky Medicaid state plan. The state will 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 comparable, 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 24 months of SUD program demonstration approval;

e. **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 SUD program demonstration approval;

f. **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 SUD program demonstration approval;

g. **Sufficient Provider Capacity at Critical Levels of Care including Medication Assisted Treatment for OUD:** An assessment of the availability of providers in the key levels of care throughout the state, or in the regions of the state participating under the demonstration including those that offer MAT, within twelve (12) months of SUD program demonstration approval over the course of the demonstration;

h. **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 access to naloxone;

i. **SUD Health IT Plan:** Implementation of the milestones and metrics as described in Attachment E; and

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

61. **SUD Monitoring Protocol.** The state must submit an SUD Monitoring Protocol within one hundred fifty (150) calendar days after approval of the demonstration. The SUD Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. Upon approval, the SUD Monitoring Protocol will be incorporated into these STCs, as Attachment D. At a minimum, the SUD Monitoring Protocol will include reporting relevant to each of the program implementation areas listed in STC 60. In addition, the SUD Monitoring Protocol will include regular reporting by the state on access to medication assisted therapy (MAT) in each county of the state, availability of MAT providers in each county, the number of individuals accessing MAT including methadone in each county, as well as the estimated cost of providing NEMT for accessing methadone in each county. The protocol will also describe the data collection, reporting and analytic methodologies for performance measures identified by the state and CMS for inclusion in the protocol. The SUD Monitoring Protocol will specify the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in these STCs. In addition, for each performance measure, the SUD Monitoring Protocol will identify a baseline, a target to be achieved by the end of the demonstration and an annual goal for closing the gap between baseline and target expressed as percentage points. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings. CMS will closely monitor demonstration spending on services in IMDs to ensure adherence to budget neutrality requirements.

62. **Mid-Point Assessment.** The state must conduct an independent mid-point assessment within ninety (90) days after the third year after approval of this demonstration. The assessor must collaborate with key stakeholders, including representatives of MCOs, SUD treatment providers, beneficiaries, and other key partners in the design, planning and conducting of the mid-point assessment. The assessment will include an examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Protocol, and toward closing the gap between baseline and target each year in performance measures as approved in the SUD Monitoring Protocol. The assessment will also include a determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date, and a determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and the risk of possibly missing those milestones and performance targets. For each

milestone and measure target at medium to high risk of not being achieved, the assessor will provide for consideration by the state, recommendations for adjustments in the state's implementation plan or to pertinent factors that the state can influence that will support improvement. The assessor will provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. A copy of the report will be provided to CMS. CMS will be briefed on the report.

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

63. Deferral of Federal Financial Participation (FFP) from IMD Claiming for Insufficient Progress Towards Milestones. Up to $5 million 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 Table 2 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 million will be deferred in the next calendar quarter and each calendar quarter thereafter until the CMS has determined sufficient progress has been made.

64. SUD Evaluation. The SUD Evaluation will be subject to the same terms as the overall demonstration evaluation, as listed in Section VII of these STCs.

65. SUD Evaluation Design. The state must submit, for CMS comment and approval, a draft SUD Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after approval of the demonstration. Failure to submit an acceptable and timely evaluation design along with any required monitoring, expenditure, or other evaluation reporting will subject the state to a $5 million deferral. The state must use an independent evaluator to design the evaluation.

a. **Evaluation Design Approval and Updates.** The state must submit a revised draft SUD Evaluation Design within sixty (60) days after receipt of CMS' comments. 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 SUD Evaluation Design within thirty (30) days of CMS approval. The state must implement the SUD Evaluation Design and submit a description of its evaluation implementation progress in each of the Monitoring Reports.

b. **Evaluation Questions and Hypotheses Specific to the SUD Program.** The state must follow the general evaluation questions and hypotheses requirements as specified in STC 51. In addition, hypotheses for the SUD program should include an assessment of the objectives of the SUD component of this demonstration, to include (but is not limited to) initiative and compliance with treatment, utilization of health services (emergency department and inpatient hospital settings), and a

reduction in key outcomes such as deaths due to overdose. The SUD Evaluation Design must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. The hypotheses should include an assessment of the objectives of SUD section 1115 demonstrations, to include (but is not limited to): initiation and compliance with treatment; utilization of health services including emergency department and inpatient hospital settings; effectiveness of MAT; interaction of MAT impact and access to NEMT; impact of the demonstration on key outcomes including deaths due to overdose; and cost effectiveness of the demonstration, particularly services provided in IMDs and the waiver of NEMT.

Proposed measures should be selected from nationally-recognized sources and national measure sets, where possible. Measures set 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). Data to evaluate the NEMT waiver impact on MAT shall include a beneficiary survey to be approved by CMS.

66. SUD Interim Evaluation Report. The state must submit a SUD 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 SUD Interim Evaluation Report should be posted to the state's website with the application for public comment.

a. The SUD Interim Evaluation Report will discuss evaluation progress and present findings to date as per the approved evaluation design.

b. For demonstration authority that expires prior to the overall demonstration's expiration date, the SUD Interim Evaluation Report must include an evaluation of the authority as approved by CMS.

c. If the state is seeking to renew or extend the demonstration, the draft SUD Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses, and how the design will be adapted, should be included. If the state is not requesting a renewal for a demonstration, a SUD Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft SUD 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 final Interim Evaluation Report sixty (60) days after receiving CMS comments on the draft SUD Interim Evaluation Report and post the document to the state's website.

e. The SUD Interim Evaluation Report must comply with Attachment B of these STCs.

67. SUD Summative Evaluation Report. The draft Summative Evaluation Report must be developed in accordance with Attachment B of these STCs. The state must submit a 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 Summative Evaluation Report must include the information in the approved Evaluation Design.

a. Unless otherwise agreed upon in writing by CMS, the state shall submit the final Summative Evaluation Report within sixty (60) days of receiving comments from CMS on the draft.

b. The final Summative Evaluation Report must be posted to the state's Medicaid website within thirty (30) days of approval by CMS.

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.

Expectations for Evaluation Designs

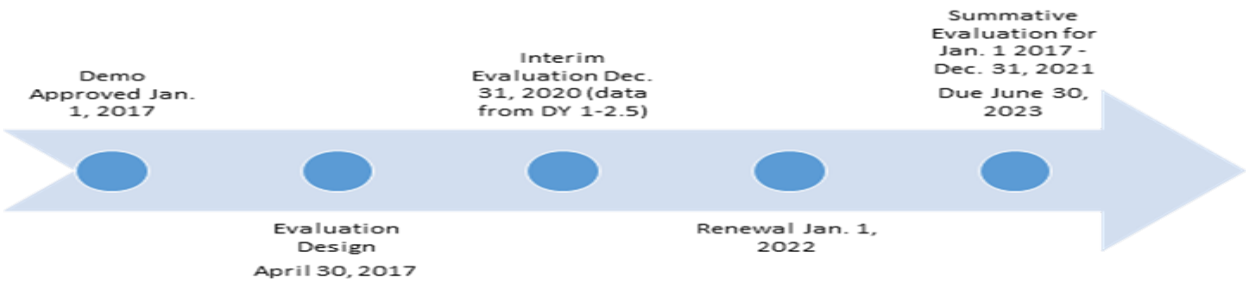
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, 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.

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

Research Question	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
Hypothesis 1				
Research question 1a	-Measure 1 -Measure 2 -Measure 3	-Sample e.g. All attributed Medicaid beneficiaries -Beneficiaries with diabetes diagnosis	-Medicaid fee-for-service and encounter claims records	-Interrupted time series
Research question 1b	-Measure 1 -Measure 2 -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
Hypothesis 2				
Research question 2a	-Measure 1 -Measure 2	-Sample, e.g., PPS administrators	-Key informants	Qualitative analysis of interview material

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

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:

When the demonstration is 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.

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 a "No Conflict of Interest" statement 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 improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. 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.

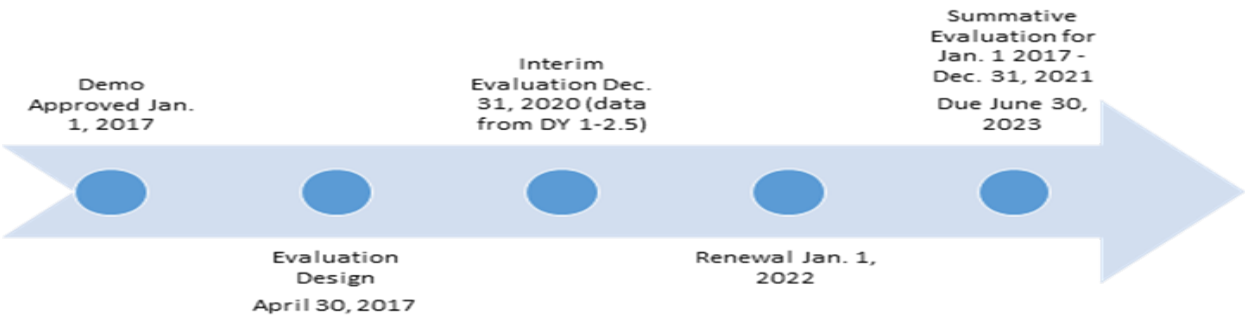
The format for the Interim and Summative Evaluation reports is as follows:

A. Executive Summary;
B. General Background Information;
C. Evaluation Questions and Hypotheses;
D. Methodology;

E. Methodological Limitations;
F. Results;
G. Conclusions;
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
I. Lessons Learned and Recommendations; and
J. Attachment(s).

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish 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 Protocol

Commonwealth of Kentucky
Section 1115 Substance Use Disorder (SUD) Demonstration
Implementation Plan

Date: 10-05-18

Overview

The Commonwealth of Kentucky is facing a substance use crisis of epic proportions. [1] In 2016, the commonwealth lost 1,404 Kentuckians due fatal drug overdoses. Over the past 5 years Kentucky has seen a 38% increase in overdose deaths. Historically among the Substance Use Disorder (SUD) population the number of patients who have one of the common co-morbidities associated with SUD are much greater than patients without an SUD. For example, the state has seen a rapid increase (nearly 115%) in cases of Neonatal Abstinence Syndrome (NAS).[2] Of those cases, Medicaid accounted for over 80%. In 2016 the Center for Disease Control (CDC) identified 220 counties in the United States that are most susceptible for Human Immunodeficiency Virus (HIV) outbreak, of the 220 counties 54 reside in the Commonwealth of Kentucky.

Kentucky has created multiple initiatives to combat the SUD crisis and increase awareness. Below are a number of programs that have either been implemented or are under development:

- In 2012, Kentucky passed sweeping legislation that has become a national model. This statute required; the use of Prescription Drug Monitoring Program (PDMP) for all prescribers of controlled substances, regulated pain clinics by requiring them to be physician or hospital owned, and fostered increased cooperation among the PDMP, Kentucky licensure boards and law enforcement.
- In 2015, Kentucky passed several harm reduction measures including; Syringe Exchange, Naloxone Distribution and the Good Samaritan Law.
- In 2015, the Kentucky Board of Medical Licensure (KBML) promulgated a regulation containing buprenorphine prescribing guidelines to help improve the effectiveness of medication assisted treatment with buprenorphine.

[1] Slide 5 SUD DMS Provider Forums 2017 (using 2011-2016 data)
[2] Produced by the Kentucky Injury Prevention and Research Center, May 2016. Kentucky Inpatient Hospitalization Claims Files, Frankfort, KY, [2000-2015]; Cabinet for Health and Family Services, Office of Health Policy. Data for 2010-2015 are provisional; therefore these results are subject to change.

- In 2017 House Bill 333 – Introduced as the professional standard of a 3-day prescribing limit on Schedule II controlled substances for acute pain.
- Kentucky Opioid Response Effort (KORE) Initiatives:
  - ER Bridge Clinics – Established Bridge Clinics in three (3) major Hospital Systems, where individuals admitted to the Emergency Room as a result of drug overdose will have the option to begin treatment at a "Bridge Clinic", which will then be able to provide Medication Assisted Treatment (MAT). Peer Support Specialists will also meet with individuals in the ED to provide support around accessing treatment and recovery services. Following discharge, Peer Support Specialists as well as other treatment staff (e.g., case managers, certified providers, and licensed evaluator) will contact individuals as part of an assertive, ongoing engagement effort. Individuals accepting services will have rapid access to treatment, including MAT, by being transferred to a Bridge clinic located nearby.
  - Sponsoring opioid stewardship aimed at prescriber education and reducing the dependence on opioids for pain management.
  - Expand prevention programs Sources of Strength in middle, high and post-secondary institutions.
- Department for Behavioral Health Developmental and Intellectual Disabilities (DBHDID) Grant > Behavioral Health & Primary Care Integration.
- State Wide Screening referral service for substance abuse treatment Helpline.
- In 2018 Kentucky will implement –a Web based treatment locator designed for referrals from Primary Care Physicians, Emergency Room and Health Departments.
- Addition of Methadone coverage for SUD treatment via state plan.

KENTUCKY HEALTH

Section I – Milestone Completion

Milestones

1. Access to Critical Levels of Care for OUD and Other SUDs

To improve access to Opioid Use Disorder (OUD) and SUD treatment services for Medicaid beneficiaries, it is important to offer a range of services at varying levels of intensity across a continuum of care since the type of treatment or level of care needed may be more or less effective depending on the individual beneficiary.

- Outpatient Services;
- Intensive Outpatient Services;
- Medication assisted treatment (medications 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

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Coverage of outpatient services	Department for Medicaid Services (DMS) currently provides a comprehensive array of behavioral health services including; Screening, Assessment, Crisis Intervention, Partial Hospitalization, Individual, Group and Family therapies, Peer Support, Targeted Case	Will add treatment plan development for alcohol and/or substance abuse to the array of services allowed in State Plan. Will continue providing coverage of outpatient services through the State Plan.	• Amend State Plan to include service planning for SUD treatment. • Update regulations to reflect added service. DMS Division of Policy and Operations will oversee completion of tasks.

	Management, and residential service for SUD. DMS also provides medication assisted treatment with buprenorphine, and vivitrol. These services will continue under Kentucky's State Plan. Click Here for State Plan Amendment		• DMS Senior Behavioral Health Policy Advisor will oversee completion of tasks. • Estimated completion September 12, 2019.
Coverage of intensive outpatient services	Intensive Outpatient Program (IOP) is currently a covered service through Kentucky's State Plan and is an alternative to or transition from inpatient hospitalization or partial hospitalization for mental health or substance use disorders. IOP must be provided at least three (3) hours per day and at least three (3) days per week. This service will continue under Kentucky's State Plan. Partial Hospitalization is a short-term (average of four (4) to six (6) weeks), less than 24 hour, intensive treatment program for individuals experiencing significant impairment to daily functioning due to substance	Currently Partial Hospitalization may be provided in a hospital or Community Mental Health Center (CMHC). Propose to add Behavioral Health Services Organization (BHSO) as an allowable setting to perform partial hospitalization services. Will continue to cover IOP throughout the demonstration under State Plan.	• Amend regulations adding partial hospitalization to the service array for a BHSO. • DMS Senior Behavioral Health Policy Advisor will oversee completion of tasks. • September 12, 2019 completion time from approval of implementation plan.

	use disorders, mental health disorders or co-occurring mental health and substance use disorders. This service is designed for individuals who cannot effectively be served in community-based therapies or IOP. Click Here for State Plan Amendment		
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)	DMS currently covers MAT for Buprenorphine and Vivitrol.	DMS will expand MAT to cover Methadone for the treatment of Substance Use Disorders.	• DMS will amend the State Plan to include coverage of Methadone for MAT. • Amend behavioral health services organization regulation to include narcotic treatment program. • DMS Senior Behavioral Health Policy Advisor will oversee completion of tasks. • Estimated Time Frame: September 12, 2019.
Coverage of intensive levels of care in residential and inpatient settings	DMS currently provides coverage of residential services for Substance Use Disorders (SUD) in the State Plan. Services must be provided under the medical direction of a physician and provide continuous nursing	Kentucky will perform its own certification program developing forms for on-site visits with a four-person team from Department for Medicaid Services Behavioral Health Policy Team. DMS will certify providers to the	State Plan Amendment and Regulation changes to reflect certification levels • DMS Senior Behavioral Health Policy Advisor will oversee completion of tasks.

	services in which a registered nurse shall be on-site during traditional first shift hours, continuously available by phone after hours' and on-site as needed in follow-up to telephone consultation after hours. Residential coverage have two levels of treatment. Short term services should have twenty-four (24) hour staff and have a duration of less than thirty (30) days. Long term services should have twenty-four (24) hour staff as required by licensing regulations with lengths of stay thirty (30) to ninety (90) days. DMS will not pay for this service in a unit of more than 16 beds or multiple units operating as one unified facility with more than 16 aggregated beds except for services furnished pursuant to the state plan benefit "inpatient psychiatric services for individuals under twenty-one (21)" (section 1905(a)(16) of the Act; 42 CFR 440.160) or pursuant to an exclusion for individuals age 65 or older who reside in institutions that	appropriate ASAM level for residential services in the current edition of The ASAM criteria.	• On-Site certification forms completed by October 15, 2018 • On-Site provider certification completed by 01/15/2019.

	are Institution for Mental Disease (IMDs) (section 1905(a) of the Act; 42 CFR 440.140.). Require BHSO to be licensed as a non-medical and non-hospital based alcohol and other drug treatment program in accordance with state licensing regulations. Click Here for State Plan Amendment		
Coverage of medically supervised withdrawal management(WM)	DMS currently covers medical detox in a hospital setting.	DMS will incorporate all levels of withdrawal management (Level 1 –WM Ambulatory withdrawal management without extended on-site monitoring, Level 2-WM Ambulatory withdrawal management with extended on-site monitoring, Level 3-WM Residential/inpatient withdrawal management and Level 3.2-WM Clinically managed residential withdrawal management, Level 3.7-WM medically monitored inpatient withdrawal management and Level 4- WM Medically managed intensive inpatient	• Amend service definitions to include withdrawal management at appropriate levels of care within State Plan and KY regulations. • DMS Senior Behavioral Health Policy Advisor will oversee completion of tasks. • Completed by September 12, 2019.

		withdrawal management) within the continuum of care offered in Kentucky.	

Kentucky defines the following categories of providers that are able to provide State Plan Services Behavioral Health and Substance Use Disorder services:

- Individual Practitioner: An individual practitioner who is licensed by the respective board in the Commonwealth of Kentucky or who is supervised by a licensed practitioner to render health services and/or bill DMS. The practitioners include: Licensed Professional Art Therapist, Applied Behavior Analyst, Licensed Professional Clinical Counselor, Licensed Clinical Social Worker, Licensed Marriage and Family Therapist, Licensed Psychological Practitioner, Licensed Psychologist, Physician, Advanced Registered Nurse Practitioner with Psychiatry Specialty and Physician Assistant.
- Provider Group: A group of more than one individually licensed practitioner who forms a business entity to render behavioral health services and bill DMS.
- Licensed Organization: A business entity that employs licensed and non-licensed health professionals and is licensed to render behavioral health services and bill DMS. This organization must also meet the following criteria:
    (1) Be enrolled as a Medicaid provider in the Commonwealth of Kentucky;
    (2) Demonstrate experience serving the population of individuals with behavioral health disorders relevant to the particular services provided;
    (3) Have the administrative capacity to provide quality of services in accordance with state and federal requirements;
    (4) Use a financial management system that provides documentation of services and costs; and
    (5) Demonstrate capacity to document and maintain individual case records in accordance with state and federal requirements.

The Licensed Organizations include: Behavioral Health Services Organization and Community Mental Health Centers.

All providers must operate within the scope of their license. Providing services to Medicaid recipients outside a provider's licensure is considered fraud.

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

Implementation of evidence-based, SUD-specific patient placement criteria is identified as a critical milestone that states are to address as part of the demonstration. To meet this milestone, states must ensure that the following criteria are met:

- Providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools, e.g., the ASAM Criteria, or other patient placement assessment tools that reflect evidence-based clinical treatment guidelines; and
- Utilization management approaches are implemented to ensure that (a) beneficiaries have access to SUD services at the appropriate level of care, (b) interventions are appropriate for the diagnosis and level of care, and (c) there is an independent process for reviewing placement in residential treatment settings.

Currently DMS, through Managed Care Contracts require the use of ASAM Criteria for authorization regarding Level of Care (LOC) for SUD treatment. Managed Care Organizations (MCO) apply ASAM to both outpatient and residential services with no predetermined limits of care established for these services. Continued involvement in a level of care is based on individual need determined through medical necessity criteria. DMS will continue to require ASAM Criteria for authorization of treatment and recovery services for individuals with an SUD through the contractual requirement with the MCO's. Below is the language utilized in the MCO contracts to address utilization management.

> [3]The MCO's shall have in place mechanisms to check the consistency of application of review criteria. The written clinical criteria and protocols shall provide for mechanisms to obtain all necessary information, including pertinent clinical information, and consultation with the attending physician or other health care provider as appropriate. The Medical Director and Behavioral Health Director shall supervise the UM program and shall be accessible and available for consultation as needed. Criteria approved under a prior contract must be resubmitted to ensure it meets the requirements of this Contract. Decisions to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, must be made by a physician who has appropriate clinical expertise in treating the Member's condition or disease. The clinical reason for the denial, in whole or in part,

[3] Language from MCO SFY 18 Contracts

specific to the Member shall be cited. Physician consultants from appropriate medical, surgical and psychiatric specialties shall be accessible and available for consultation as needed. The Medical Necessity review process shall be completed within two (2) business days of receiving the request and shall include a provision for expedited reviews in urgent decisions. Post-service review requests shall be completed within fourteen (14) days or, if the Member or the Provider requests an extension or the Contractor justifies a need for additional information and how the extension is in the Member's interest, may extend up to an additional fourteen (14) days.

A. The MCO's shall submit its request to change any prior authorization requirement to Department for Medicaid Services (DMS) for review.

B. For the processing of requests for initial and continuing authorization of services, the Contractor shall require that its subcontractors have in place written policies and procedures and have in effect a mechanism to ensure consistent application of review criteria for authorization decisions.

C. In the event that a Member or Provider requests written confirmation of an approval, the Contractor shall provide written confirmation of its decision within three working days of providing notification of a decision if the initial decision was not in writing. The written confirmation shall be written in accordance with Member Rights and Responsibilities.

D. The Contractor shall have written policies and procedures that show how the Contractor will monitor to ensure clinically appropriate overall continuity of care.

E. The Contractor shall have written policies to ensure the coordination of services:

1. Between settings of care, including appropriate discharge planning for short term and long-term hospital and institutional stays;
2. With the services the Member receives from any other MCO;
3. With the services the member receives in Fee for Service (FFS); and
4. With the services the Member receives from community and social support providers.

F. The MCO shall have written policies and procedures that explain how prior authorization data will be incorporated into the MCO's overall Quality Improvement Plan.

DMS providers perform an assessment and collect other relevant information that will assist in determining the most appropriate level of care. DMS does not require the provider to utilize one specific multi-dimensional tool. In regulation, DMS defines assessment to include gathering information and engaging in a process with the individual that enables the provider to:

  - Establish the presence or absence of a mental health disorder, substance use disorder, or co-occurring disorders;
  - Determine the individual's readiness for change;
  - Identify the individual's strengths or problem areas that may affect the treatment and recovery processes; and
  - Engage the individual in developing an appropriate treatment relationship;
- Establish or rule out the existence of a clinical disorder or service need;
- Include working with the individual to develop a treatment and service plan; and
- Does not include psychological or psychiatric evaluations or assessments.

As part of the new waiver benefit, Kentucky will require utilization of ASAM's six dimensions of multidimensional assessment to ensure consistency in the assessment and treatment planning process for treatment of substance use disorders. The dimensions will assist the provider to create a holistic, biopsychosocial assessment of the recipient that will assist the provider with development of the treatment planning for any person seeking SUD services. The dimensions include acute intoxication and/or withdrawal potential; biomedical conditions and complications; emotional, behavioral or cognitive conditions and complications; readiness to change; relapse, continued use, or continued problem potential and recovery/living environment.

DMS will ensure that providers are utilizing the appropriate clinician to perform the assessment which include a credentialed counselor or clinician, a certified addiction registered nurse, a psychologist or a physician. DMS will require all SUD providers to incorporate these dimensions as part of their assessment by September 12, 2019. DMS will outline requirements within regulations and ensure all providers will be trained on ASAM criteria. The estimated timeline for completion of changes in regulations related to assessment criteria is September 12, 2019. DMS Division of Policy and Operations will oversee completion of task.

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

Through the new Section 1115 initiative, states will have an opportunity to receive federal financial participation (FFP) for a continuum of SUD services, including services provided to Medicaid enrollees residing in residential treatment facilities that qualify as institutions for mental diseases. To meet this milestone, states must ensure that the following criteria are met:

- Implementation of residential treatment provider qualifications (in licensure requirements, policy manuals, managed care contracts, or other guidance) that meet the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding the types of services, hours of clinical care and credentials of staff for residential treatment settings;

- Implementation of a state process for reviewing residential treatment providers to assure compliance with these standards; and

- Implementation of a requirement that residential treatment facilities offer MAT on-site or facilitate access off site.

Currently DMS only reimburses residential SUD treatment with providers who have less than sixteen (16) bed facilities or for recipients who are under the age of twenty-one (21) or over the age of sixty-four (64). CMHC's, BHSO's and hospitals are DMS provider types licensed through Office of Inspector General (OIG) and provide residential SUD services. These services are based on individual need and may include screening, assessment, service planning, peer support, individual, group and family outpatient therapy. DMS requires residential services be provided under the medical direction of a physician and provide continuous nursing services on site during traditional first shift hours Monday through Friday and continuously available for telephone consultation afterhours and onsite as needed.

The Commonwealth of Kentucky will conduct a statewide survey to assess the current landscape of behavioral health providers. We began with a survey sent out to all Medicaid enrolled residential substance use disorder providers. One component of this survey was for the residential providers to self-attest to their level of ASAM residential care. This survey is currently underway for our residential SUD treatment providers, with an expected completion date of October 15, 2018. This will align with the DMS led certification process. Based on the self-attestation Kentucky would allow for reimbursement of residential services up to 96 beds in an IMD pending certification by the State conducted certification process. DMS is internally considering payment adjustment based on residential level of care.

In order for a SUD residential provider to be eligible for the Institution of Mental Disease (IMD) exclusion, Kentucky will require the provider to be certified to the ASAM residential levels of care which are; 3.1 Clinically Managed Low-Intensity Residential Services, 3.3 Clinically Managed Population Specific High Intensity Residential Services, 3.5 Clinically Managed High-Intensity Residential Services, 3.7 Medically Monitored Intensive Inpatient Services. Kentucky Revised Statutes (KRS) 216B.015 defines the Office of Inspector General, Division of Health Care responsible for inspecting, monitoring, licensing and certifying all health care facilities. This includes acute care hospitals, which DMS designate as Medically Managed Intensive Inpatient Services. Kentucky feels the licensure requirement is sufficient and does not require this level of care to be certified. The SUD residential providers that are ASAM certified will then be able to receive the IMD exclusion for up to 192 beds for short-term residential treatment. Short-term residential treatment is defined as a statewide average length of stay of thirty (30) days.

Kentucky will perform its own certification program of residential levels: 3.1 Clinically Managed Low-Intensity Residential Services, 3.3 Clinically Managed Population Specific High Intensity Residential Services, 3.5 Clinically Managed High-Intensity Residential Services, and 3.7 Medically Monitored Intensive Inpatient Services. Kentucky is developing forms for on-site visits with a four-person team from Department for Medicaid Services Behavioral Health Policy team. Beginning October 15, 2018 this team will

begin to conduct onsite visits of all Medicaid enrolled SUD residential providers to review settings, staff requirements, co-occurring capacity, and programming utilizing state created forms. Certification of all Medicaid enrolled residential SUD providers will be completed by January 15, 2019. Moving forward DMS will continue to explore engaging with ASAM to participate in the pilot for level of care certification.

DMS currently offers all the service components of MAT within the State Plan. Methadone is currently payable for pain not for SUD treatment. DMS is adding the coverage of Methadone to our State Plan services for the treatment of SUD and will ensure residential providers are providing MAT on-site or facilitating access off site, by conducting a provider survey. The offsite facilitation of MAT for residential providers that do not provide medication as part of their treatment continuum will allow individuals who opt for medication as a part of their plan of care to receive the medication services outside of the residential provider. As part of the care coordination in a residential setting, the care coordinator will assist in the logistics of locating, scheduling and transporting an individual for their offsite medication services.

Kentucky has legislation to require the Cabinet of Health and Family Services (CHFS) to develop enhanced licensure and quality standards. These will be based on nationally recognized and evidence-based standards for substance use disorder treatment and recovery that include residential, outpatient and medication-assisted treatment (MAT) services. This legislation requires enhanced and streamline licensure requirements for SUD treatment providers as well as create statewide standards and outcome measures to ensure quality. DMS Division of Policy and Operations Senior Behavior Health Policy Advisor will oversee completion. Estimated for completion by September 12, 2019.

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

To meet this milestone, states must complete an assessment of the availability of providers enrolled in Medicaid and accepting new patients in the critical levels of care listed in Milestone 1. This assessment must determine availability of treatment for Medicaid beneficiaries in each of these levels of care, as well as availability of MAT and medically supervised withdrawal management, throughout the state. This assessment should help to identify gaps in availability of services for beneficiaries in the critical levels of care.

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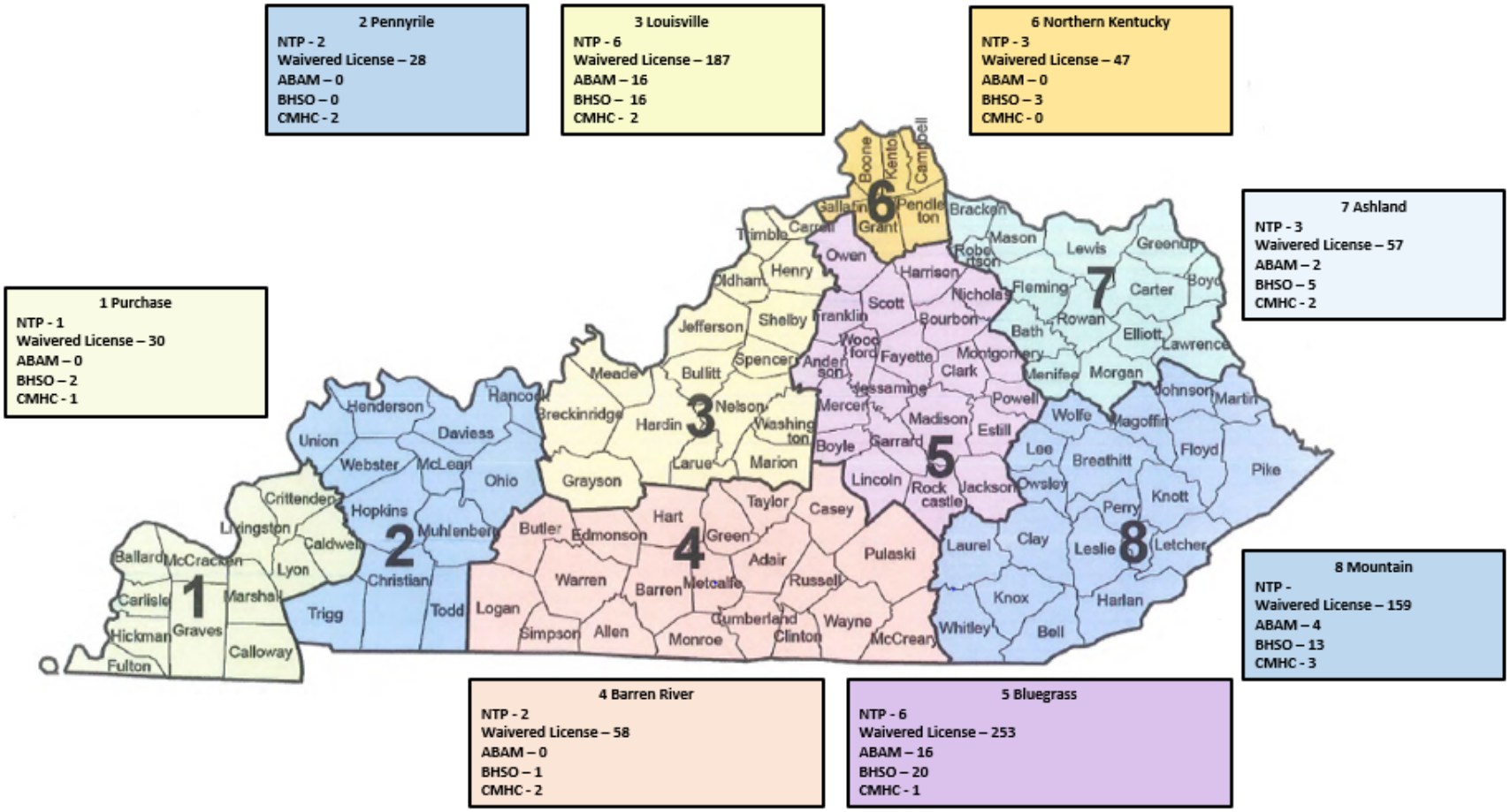

DMS to develop and conduct a survey for Medicaid and Non-Medicaid providers to determine what services they provide related to SUD levels of care and potential for Medicaid enrollment. As part of the survey, Kentucky will be looking at medication assisted treatment (MAT) service capability. Through onsite visits we will verify MAT is offered on-site or facilitated offsite. Completion of provider survey will be within twelve (12) months of Implementation Plan approval. DMS Division of Policy and Operations is responsible for completion of task.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
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: Outpatient Services; Intensive Outpatient Services; Medication Assisted Treatment (medications as well as counseling and other services); Intensive Care in Residential and Inpatient Settings; Medically Supervised Withdrawal Management.		Kentucky Medicaid is conducting a statewide survey of treatment providers that currently offer outpatient, Intensive Outpatient services, MAT and Residential services. With pending changes to licensure requirements for SUD treatment and recovery providers, Kentucky Medicaid will create a Preferred prescriber program that incorporates DMS Pharmacy prescribing program. Participation in the preferred provider program will reduce the administrative burden on the provider. The following are the requirements for participation: • Providing treatment under the license of a buprenorphine waivered practitioner and co-located credentialed addiction treatment practitioners, • Can distribute buprenorphine products during induction • Provide prescriptions for buprenorphine products	• Develop preferred prescriber program in alignment with Pharmacy prescribing program. • DSM Senior Behavioral Health Policy Advisor and DMS Pharmacy Director will oversee completion of task. • Completion by September 12, 2019

		• Provide psychosocial treatment for opioid use disorder that include assessment of psychosocial needs, individual and/or group counseling, linkage and referral to community based services and support systems, care coordination of on-site and off-site treatment services, medical/prescription monitoring.	

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

To meet this milestone, states must ensure that the following criteria are met:

- Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse;
- Expanded coverage of and access to naloxone for overdose reversal; and
- Implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Implementation of opioid prescribing guidelines along with other interventions to prevent opioid abuse	Prescribers are required to; obtain a report on beneficiaries from the prescription drug monitoring program (PDMP), obtain drug screens and encourage the patient's active participation	Revised buprenorphine criteria to increase response access and treatment. Streamlined administrative burden for quality care and qualified providers.	Develop program draft including revised clinical criteria and prior authorization forms -DMS Pharmacy Director is responsible for completion of this task

	in a behavioral modification program. DMS has implemented a 3 day supply limitation for controlled substances. (See statute link below) Click Here for KRS 218A.205	The Department for Medicaid Services (DMS) will align the Prior Authorization requirements (PA) for prescribing or dispensing buprenorphine –mono-product or buprenorphine combined with naloxone, with the professional standards from the KBML. (See regulation link below) Click Here for 201 KAR 9:270 Opioid Utilization Program that will include revised criteria to apply varying utilization controls to long acting opiates and short acting opiates; plus, the implementation of a Morphine Milligram Equivalent (MME) dosing limitations program, including treatment plan agreements and opiate PA requirements.	-Expected on or before 11/1/18 Develop two (2) prior authorization forms. The first form aligning with KBML standards, the second form for the buprenorphine program. -DMS Pharmacy Director is responsible for completion of this task - Following alignment of requirements there will be a 90 day provider notice and education period before changes can Go-Live. Expected on or before 11/1/18. In-Progress -DMS Pharmacy Director is responsible for completion of this task -Approved by KY P&T Committee on 5/01/18; Go-Live 09/04/18

		A brief summary of the utilization controls being reviewed include: limitations on Short Acting (SA) opioids for the treatment of acute pain, limitations on the treatment of chronic, non-cancer pain in non-hospice patients, other class limitations such as age limits, daily dose limits, limits on cough and cold opioid containing products, limits on codeine and tramadol products, and required review of overlapping claims for opioids and benzodiazepines. The MME dosing limitations involve a claim by claim analysis of current member utilization of both Long Acting (LA) and SA opioids. Once complete we will have a better understanding of how members may be utilizing multiple prescriptions to achieve higher cumulative MME and their per day dosing. A simplified conversion factor of 4 MME/unit for methadone will	

		be used to resolve the IT systems limitations surrounding sliding scale as recommended by CMS, until there is a new software release. Analysis will reveal the most common products contributing to the MME per day over 180 and over 300 both for FFS and the MCO populations. The program will allow exceptions for certain disease states such as cancer, sickle cell, and hospice. Additional considerations will apply for others like Long Term Care (LTC), acute surgical procedures, and Narcotic Treatment Program (NTP). We will establish MME thresholds for SA, LA, and combo use of opioids. And employ a step down methodology to reduce overall MME. Prior Authorizations will be revised to allow for new initial limits of opioids without PA up to a certain threshold MME (eg.. 90MME/day), while higher quantities require post limit	

		PA, with an overall max MME threshold (e.g.. 200MME/day). Post limit PA approvals will be limited in duration for acute pain treatment (30 days) but one year for chronic pain care. This will include some required patient reassessment interval (eg.3 mo.) which exceptions for those actively battling cancer.	
Expanded coverage of, and access to, naloxone for overdose reversal	All Kentucky Health Plans currently cover naloxone Nasal Spray and syringes without a co-pay or prior authorization. Although a prescription is required, under a collaborative care agreement pharmacists throughout the Commonwealth are permitted to initiate protocol driven orders for naloxone products. As part Kentucky's Opioid Response Effort, Narcan kits (set of 2 doses) are distributed in the highest-risk regions of the Commonwealth through the Department for Public Health's mobile pharmacy as well as individual pharmacies who enter into an agreement	Increase access to Medication Assisted Treatment (MAT) providers to connect services between emergency room discharge for overdose or high risk to primary provider care and treatment. Resources and connectivity to those for beneficiaries in treatment or within a high risk populations will also be increased.	This effort to educate; beneficiaries, prescribers, dispensers, families and schools will be on-going.

	with KPhA to dispense KORE-funded kits. KPhA is also helping to establish partnerships between community pharmacies and residential treatment programs to ensure individuals have free take-home Narcan upon discharge. A pharmacist comes to the treatment centers to provide the kits as well as training on their use. People Advocating Recovery (PAR) is distributing Narcan kits in community settings targeting eastern Kentucky, other underserved counties, and Oxford Houses. In addition to training on use, education is provided on signs and symptoms, stigma, and Good Samaritan law. In addition 1,000 Narcan kits are being distributed across four Emergency Departments (UK, UL, St. Elizabeth, and St. Claire) to individuals having experienced or at risk for opioid overdose.		

6. Improved Care Coordination and Transitions between Levels of Care

To meet this milestone, states must implement policies to ensure residential and inpatient facilities link beneficiaries, especially those with OUD, with community-based services and supports following stays in these facilities.

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	Kentucky currently offers targeted case management for individuals with a SUD and for individuals with SUD and a chronic/complex physical health issue. This level of case management is individuals with a moderate to severe SUD.	Kentucky Medicaid will implement care coordination services for all individuals within residential treatment to ensure services are coordinated for co-occurring conditions as well as link the recipient to appropriate community services by facilitating medical and behavioral health follow-ups and linking to appropriate level of substance use treatment within the continuum in order to provide ongoing support for recipients.	Amend State Plan to include care coordination within the SUD residential treatment definition outlining the duties of care coordination. Amend State Regulations to include care coordination duties to the SUD residential treatment definition. • DMS Senior Behavioral Health Policy Advisor will oversee completion of tasks. • Completed by September 12, 2019.

DMS is in the early stages of a learning opportunity with other states related to integration of primary and behavioral health care. This learning lab will assist Kentucky with development of a strategic plan to implement policy for integration of physical and behavioral health. Kentucky's vision is to improve outcomes and reduce cost for; adults with serious mental illness and/or substance use disorder, criminal justice, children and youth with social-emotional disturbance, children in state custody who may have juvenile justice involvement.

Through the Learning Lab opportunity Kentucky intends to improve linkages among health, behavioral health and criminal justice data.

Section II – Implementation Administration

Please provide the contact information for the state's point of contact for the Implementation plan.

Name and Title: Ann Hollen, Senior Behavior Health Policy Advisor
Telephone Number: (502) 564-6890
Email Address: ann.hollen@ky.gov

Section III – Relevant Documents

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

Attachment A – Template for SUD Health Information Technology (IT) Plan

Section I.

As a component of Milestone 5, Implementation of Strategies to Increase Utilization and Improve Functionality of Prescription Drug Monitoring Programs (PDMP), in the SMD #17-003, states with approved Section 1115 SUD demonstrations are generally required to submit an SUD Health IT Plan as described in the STCs for these demonstrations within 90 days of demonstration approval.

The SUD Health IT Plan will be a section within the state's SUD Implementation Plan Protocol and, as such, the state may not claim FFP for services provided in IMDs until this Plan has been approved by CMS.

In completing this plan, the following resources are available to the state:

a. Health IT.Gov in "Section 4: Opioid Epidemic and Health IT."[4]
b. CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" and, specifically, the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.[5]

As the state develops its SUD Health IT Plan, it may also request technical assistance to conduct an assessment and develop its plan to ensure it has the specific health IT infrastructure with regards to the state's PDMP plan and, more generally, to meet the goals of the demonstration. Contacts for technical assistance can be found in the guidance documents.

In the event that the state believes it has already made sufficient progress with regards to the health IT programmatic goals described in the STCs (i.e. PDMP functionalities, PDMP query capabilities, supporting prescribing clinicians with using and checking the PDMPs, and master patient index and identity management), it must provide an assurance to that effect via the assessment and plan below (see Table 1, "Current State").

[4] Available at https://www.healthit.gov/playbook/opioid-epidemic-and-health-it.
[5] Available at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html.

SUD Demonstration Milestone 5.0, Specification 3: Implementation of Strategies to Increase Utilization and Improve Functionality of PDMP

The specific milestones to be achieved by developing and implementing an SUD Health IT Plan include:

- Enhancing the health IT functionality to support PDMP interoperability; and
- Enhancing and/or supporting clinicians in their usage of the state's PDMP.

The state should provide CMS with an analysis of the current status of its health IT infrastructure/"ecosystem" to assess its readiness to support PDMP interoperability. Once completed, the analysis will serve as the basis for the health IT functionalities to be addressed over the course of the demonstration—or the assurance described above.

The SUD Health IT Plan should detail the current and planned future state for each functionality/capability/support—and specific actions and a timeline to be completed over the course of the demonstration—to address needed enhancements. In addition to completing the summary table below, the state may provide additional information for each Health IT/PDMP milestone criteria to further describe its plan.

Table 1. State Health IT / PDMP Assessment & Plan

Milestone Criteria	Current State	Future State	Summary of Actions Needed	Measurements
5. Implementation of comprehensive treatment and prevention strategies to address Opioid Abuse and OUD, that is: --Enhance the state's health IT functionality to support its PDMP; and --Enhance and/or support clinicians in their usage of the state's PDMP.	*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.*	*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.*	*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	
Prescription Drug Monitoring Program (PDMP) Functionalities				
Enhanced interstate data sharing in order to better track patient specific prescription data	1.1 The Kentucky PDMP (KASPER) is housed in the Cabinet for Health and Family Services (CHFS) Office of Inspector General (OIG). KASPER is currently able to share data with 12 states including our six border states that have PDMPs. 1.2 Interstate data is available for prescriber and pharmacist PDMP users. KASPER users currently have no tools or analytics available to assist them with identifying other state PDMPs for which a data request may be appropriate for a specific patient (informed data sharing.)	1.1 CHFS plans to enhance KASPER to support more efficient onboarding of additional states. 1.2 CHFS is beginning to work with the Bureau of Justice Assistance and PDMP Training and Technical Assistance Center to investigate the use of data analytics to inform end users of high probability patient data matching states to select when performing an interstate request	1.1 Onboard additional interstate data sharing states. Responsibility: KASPER Integration Project Manager (OATS). Target completion: July 2021. 1.2 Develop data analytic functionality to allow prescriber/pharmacist users to make a more informed decision on other states from which to request data based on their practice location and patient demographic information. Responsibility: KASPER Project Manager. Target completion: April 2020.	1.1 New States will be added at a rate of approximately 1 per month beginning in July, 2018. Monthly meetings are held. Currently we are sharing data with 12 states. The plan is to be connected to the remaining states and D.C. by July of 2021. 1.2 This "Informed Data Sharing" is to be completed by April of 2020. The plan begins with KASPER data only, but will spread to the regional and national level after proper

				analysis and testing. Monthly meetings will be held.
Enhanced "ease of use" for prescribers and other state and federal stakeholders	KASPER provides real-time access to Schedule II through V controlled substance prescription data for authorized health care providers, state and federal law enforcement officers and prosecutors, the Kentucky Medicaid program and other stakeholders. It allows for delegates to request reports on behalf of prescribers and dispensers, and allows for institutional accounts to simplify access for providers in hospitals and long term care facilities. The available controlled substance information includes opioid morphine milligram equivalent (MME) information, basic Prescriber Report Card data, and the ability to review the prescriber	1.1 The KASPER code was developed in 2005, and is in need of modernization. CHFS is planning development of a new KASPER system using a modular design. Included in the modular design will be integrating with Electronic Health Record (EHR) system's and the statewide Kentucky Health Information Exchange (KHIE). 1.2 To increase KASPER effectiveness, the modernization project will include development of an enhanced Prescriber Report Card that will	1.1 Develop a new modular KASPER system designed to provide improved ease of use and operational efficiency. The new system modules will include 1.1.1 User management module, 1.1.2 PDMP System Application Module, 1.1.3 PDMP Sharing Module. Responsibility: KASPER Project Manager. Target completion: September 2020. 1.2 Implement phase 2 of the enhanced KASPER Prescriber Report Card. Responsibility: KASPER Project Manager.	1.1.1 User management module, 4/2019. 1.1.2 PDMP System Application Module, 12/2019 1.1.3 PDMP Sharing Module, 9/2020. Weekly Meetings will be held thru-out the entire project. 1.2 This drill down option is expected by early 2020. This phase 2 option will have monthly meetings between KASPER IT team and OIG.

	controlled substance prescribing history to detect errors or fraud.	include patient level data allowing prescribers easier identification of at-risk patients.	Target: completion date: 4/2020.	
Enhanced connectivity between the state's PDMP and any statewide, regional or local health information exchange	There is currently limited connectivity between KASPER and the statewide health information exchange, KHIE.	Planned projects to integrate KASPER with KHIE include the following: 1.1 Prescriber and pharmacist users can request medical information based on a suspected drug overdose in an Emergency Department (ED). 1.2 Integration with KHIE, so prescriber and pharmacist KHIE users will be able to access KASPER patient data via KHIE without leaving the KHIE process workflow.	1.1 Drug toxicity screen results are being reported by the EDs to KHIE. The technical interface between KASPER and KHIE to obtain information regarding the presence of those results is under development. Responsibility: KASPER Project Manager. Target completion: 12/2018 1.2 Develop and implement technology to allow integrated data requests and responses between KASPER and KHIE. Responsibility: KASPER Project Manager. Target completion: 12/2020.	1.1 This interface is nearly complete. Will be ready by 12/2018. Weekly meetings are currently held. 1.2 This second phase of KASPER to KHIE integration will begin in 2019. Monthly meetings will be held. Should be completed by 12/2020.

Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns[6] (see also "Use of PDMP" #2 below)	1. KASPER currently identifies and flags patients who are receiving a current daily morphine milligram equivalent dose level of 100 or more. This includes a warning that these patients may be at a higher risk of drug overdose, and that increased clinical vigilance may be appropriate.	1.1 KASPER reports are going to be updated to include warning flags for overlapping opioid prescriptions and overlapping opioid and benzodiazepine prescriptions. 1.2 OIG will utilize an epidemiologist to study the correlation between initial opioid use and ongoing use and abuse.	1.1 Modify KASPER reports to reflect overlapping controlled substance prescriptions. Responsibility: KASPER Project Manager. Target completion: 12/2019. 1.2 Study correlations between initial opioid use and patient misuse and abuse patterns, as well as potentially problematic controlled substance prescribing practices. Responsibility: OIG Epidemiologist. Target completion: ongoing.	1.1 This modification will take BA and Development work. Weekly meetings will be held. 12/2019. 1.2 This is an ongoing study that the Epidemiologist will lead.
Current and Future PDMP Query Capabilities				
Facilitate the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP (i.e.	1.1 KASPER currently utilizes advanced data analytics to match controlled	1.1 In March 2017 CHFS implemented a new KASPER Data Collection	1.1 Continue KASPER data quality improvement efforts. This is needed to ensure	1.1 This includes Business Analysts and Resource Management Analysts. This is an

[6] 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.

the state's master patient index (MPI) strategy with regard to PDMP query)	substance prescription records to patients.	System. Via this system, CHFS is implementing new data reporting edits that are helping to improve the quality of data collected. The improved data quality results in increased probability of accurate patient data matching. 1.2 CHFS is planning to implement an Enterprise Data Warehouse (EDW) that will house KASPER data.	and improve data quality. Responsibility: KASPER Project Manager and Project Administrator. Target completion: ongoing. 1.2 Coordinate KASPER patient data matching processes and analytics to be consistent and support a Master Patient Indexing (MPI) within the EDW. Responsibility: KASPER Project Manager. Target completion: 6/2020.	ongoing, daily happening. 1.2 This will be done in conjunction with the Data Analytics group within the Commonwealth. Weekly meetings will be held. Target completion of 6/2020.
Use of PDMP – Supporting Clinicians with Changing Office Workflows / Business Processes				
Develop enhanced provider workflow / business processes to better support clinicians in accessing the PDMP prior to prescribing an opioid or other controlled	The KASPER system is currently fully integrated with a major pharmacy chain, and CHFS has received requests from additional health systems to integrate with their	Integrate with additional EHR and pharmacy systems using solutions that present KASPER data directly in the physician workflow. Capitalize on	1.1 To support additional KASPER/EHR integration and KASPER/KHIE integration, OATS is conducting capacity	1.1 This process may be included in the KASPER Modernization project. Weekly meetings will be

substance to address the issues which follow	EHR systems. The existing pharmacy integration allows the pharmacists to access KASPER data in one simple step without leaving their pharmacy management system workflow.	the integration work done by EHR/Pharmacy system vendors in other states.	planning reviews to ensure sufficient resources to support new integration projects. CHFS is supporting federal efforts to develop an API/Web service for PDMP/EHR integration and may also develop an in-house API/Web service to support integration projects. Responsibility: KASPER Project Manager. Target completion: 9/2020.	held during this process.
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	KASPER currently provides detailed prescription history and opioid MME data to health care provider users. Additional functionality is needed to improve the level of care.	1.1 Implement the ability for all KASPER users to obtain class A misdemeanor and felony drug conviction data for the patient. 1.2 Implement a patient dashboard capability to make it easier for healthcare provider KASPER users to identify overlapping	1.1 Implement a link to the Administrative Office of the Courts (AOC) CourtNet system to allow KASPER users to see drug conviction data for the previous five years. Responsibility: KASPER and AOC Project Managers. Target completion: 07/2018.	1.1 This link is currently in the testing phase and will be completed by 7/2018. Weekly meetings are currently being held. 1.2 This evaluation will need to done prior to the modernization project.

		prescriptions, early refills, multiple provider episodes, potential drug interactions and other indicators that may indicate overdose risk, or controlled substance abuse or diversion.	1.2 Evaluate existing patient dashboard tools and capabilities, and determine whether they can be implemented into the current KASPER system or as part of the KASPER modernization project. Responsibility: OIG and OATS. Target completion: 12/2019	
Master Patient Index / Identity Management				
Enhance the master patient index (or master data management service, etc.) in support of SUD care delivery.	While KASPER and KHIE are not currently integrated, KHIE has a defined algorithm MPI that provides match, merge and search capability.	1.1 As noted above, a KASPER/KHIE integration project is in the planning stage. As part of this project KHIE will utilize the enterprise MPI solution for querying KASPER.	1.1 Procurement of a new KHIE vendor solution was just completed. The KASPER/KHIE integration project will be undertaken after implementation of the new KHIE system. Responsibility: KASPER and KHIE Project Managers. Target completion: 11/2019.	1.1 This MPI will be part of the KHIE system. This will require weekly meetings to properly identify the appropriate matching parameters.
Overall Objective for Enhancing PDMP Functionality & Interoperability				

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	1.1 KASPER currently includes a Prescriber Report Card that provides aggregated controlled substance prescribing data and allows prescribers to compare their controlled substance prescribing with all Kentucky prescribers and with prescribers in their specialty area.	1.1 Phase 2 of the Prescriber Report Card will include patient level data allowing prescribers easier identification of at-risk patients (drill down options) These Prescriber Report Cards are available to the Kentucky prescriber licensure boards to assist with reviewing for inappropriate or illegal controlled substance prescribing.	1.1 Implement phase 2: the enhanced KASPER Prescriber Report Card. Responsibility: KASPER Project Manager. Target: completion date: 4/2020.	1.1 This drill down option is expected by early 2020. This phase 2 option will have monthly meetings between KASPER IT team and OIG.

The Commonwealth of Kentucky has assessed the current infrastructure/"ecosystem" that will be necessary to achieve the goals of the demonstration. The necessary changes have been identified and captured in the Kentucky HEALTH High Level Requirements (HLR) document which will be used to help determine cost and timeline as well as to monitor the overall status throughout development and implementation.

We have reviewed our last submission of the State Medicaid Health IT Plan (SMHP), Health Information Technology Plan to verify that SUD is aligned with the plan, it is. This has been addressed in the plan with integration to eKASPER and KHIE which also includes behavioral health data. It will become more tightly integrated and aligned as the Kentucky HEALTH demonstration project moves forward.

As applicable the Commonwealth of Kentucky will advance the standards referenced in the ISA and 45 CFR Subpart B, and the Manage Care Contractor (MCO) contracts will be updated to comply with the requirements.

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: David Vick/KASPER Program Manager
Telephone Number: 502.564.0105 x2479
Email Address: david.vick@ky.gov

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.

Attachment D: SUD Monitoring Protocol
[To be incorporated after CMS approval.]

ATTACHMENT E: SUD Health Information Technology (Health IT)

Health Information Technology ("Health IT"). The state will provide CMS with an assurance that it has a sufficient health IT infrastructure/"ecosystem" at every appropriate level (i.e. state, delivery system, health plan/MCO 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 60) to be approved by CMS. The SUD Health IT Plan will detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The plan will also be used to identify areas of SUD health IT ecosystem improvement.

a. The SUD Health IT section of the Implementation plan will include implementation milestones and dates for achieving them (see Attachment C).
b. The SUD Health IT Plan must be aligned with the state's broader State Medicaid Health IT Plan (SMHP) and, if applicable, the State's Behavioral Health (BH) and/or BH "Health IT" Plan.
c. The SUD Health IT Plan will describe the state's goals, each DY, to enhance the state's prescription drug monitoring program's (PDMP)[1] ability to engage in interstate data sharing among other state-based PDMPs in order to better track patient-specific prescription data—and support regional law enforcement in cases of controlled substance diversion.[2]
d. The SUD Health IT Plan will address how the state's PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[3] This will also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan will describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients' history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.
e. The SUD Health IT Plan will, as applicable, describe the state's capabilities to leverage a master patient index (or master data management service, etc.) in support of SUD care delivery. Additionally, the SUD Health IT Plan must describe current and future capabilities regarding PDMP queries—and the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.
f. The SUD Health IT Plan will describe how the activities described in (a) through (e) above will: a) support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns; and b) ensure Medicaid does

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

[3] *Ibid*.

not inappropriately pay for opioids and that states implement effective controls to minimize the risk.[4]

g. In developing the Health IT Plan, states shall use the following resources.
   1. States may use resources at Health IT.Gov (https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/) in "Section 4: Opioid Epidemic and Health IT."
   2. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.
   3. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP plans and, more generally, to meet the goals of the demonstration

h. The state will include in its Monitoring Plan (see STC 61) an approach to monitoring its SUD Health IT Plan which will include performance metrics provided by CMS or State defined metrics to be approved in advance by CMS.

i. The state will monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in in an addendum to its Annual Reports (see STC 24).

j. 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.
   1. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state should use the federally-recognized standards, barring no other compelling state interest.
   2. Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally-recognized ISA standards, barring no other compelling State interest.

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

Attachment F: Evaluation Design

Evaluation Plan

Commonwealth of Kentucky
Section 1115 Substance Use Disorder Demonstration

February 18, 2020

The UPenn Kentucky HEALTH Study Group, based at the University of Pennsylvania, is the independent evaluator of the Kentucky Section 1115 Substance Use Disorder (SUD) Demonstration.

Principal Investigators: Kristen Underhill, Atheendar Venkataramani, Kevin Volpp.
Co-Investigators: Genevieve Kanter (SUD), Kristin Linn (Statistician)
Project Staff: Erica Dixon, Elizabeth Bair, William Ferrell

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A. GENERAL BACKGROUND INFORMATION

A.1. Purpose

Although the opioid crisis is national in scope, the Commonwealth of Kentucky has been particularly acutely affected, ranking among the top 10 states in opioid-related overdose deaths [1]. Furthermore, about 40% of adults with opioid addiction are within the Medicaid-insured population [2], and 80% of hospitalizations for neonatal abstinence syndrome in Kentucky are reimbursed by Medicaid [3].

Kentucky Medicaid proposed a Substance Use Disorder (SUD) demonstration project as part of its larger application for a Section 1115 demonstration project, "Kentucky Helping to Engage and Achieve Long Term Health" (KY HEALTH), to buttress its ongoing efforts to address the opioid crisis. The proposal for the 1115 SUD demonstration project was approved by the Centers for Medicare and Medicaid Services (CMS) on January 12, 2018. The implementation plan for the demonstration has been approved twice—first on October 5, 2018 [4], and most recently as part of an amended approval granted on November 28, 2018 [5].

The purpose of the SUD demonstration project is to increase access to SUD treatment services and reduce opioid-related overdose injuries and deaths. To achieve this purpose, Kentucky Medicaid will implement a plan to increase beneficiary access to SUD providers offering treatment services and expand SUD treatment benefits available to enrollees.

The **central features of this demonstration** are:

1. <u>increased access to SUD providers</u> by assessing Medicaid SUD provider capacity at critical levels of care and certifying residential treatment providers according to nationally-recognized standards for SUD treatment;
2. <u>waiver of the Medicaid Institutions for Mental Disease (IMD) exclusion</u>, allowing reimbursement for SUD treatment during short-term residential stays at certified IMD facilities with greater than 16 beds; and
3. <u>expanded coverage of medication-assisted treatment (MAT) services</u>, including methadone.

A.2. Brief Description of Demonstration and Implementation Plan

The Commonwealth of Kentucky and Kentucky Medicaid have already launched a range of SUD initiatives, and Kentucky Medicaid currently covers many services across the continuum of care for SUD, including outpatient and intensive outpatient services, partial hospitalization treatment, residential treatment, and medication-assisted treatment with buprenorphine and naltrexone.

The SUD demonstration will build on these initiatives and expand Medicaid SUD benefits to strengthen efforts to combat the opioid crisis. As described in STC 93, the key goals of the SUD demonstration are to:

1. improve access to critical levels of care for Opioid Use Disorder (OUD) and other SUDs for Medicaid beneficiaries;

2. require the use of evidence-based SUD-specific criteria for patient placement in outpatient and residential care, with the goal of improving SUD screening and patient care and retention;
3. apply nationally-recognized SUD-specific program standards for the certification of residential treatment facilities;
4. assess provider capacity at critical levels of care, including for medication-assisted treatment for OUD, with the goal of ensuring greater access to care;
5. implement strategies directed at prescribers and dispensers to dampen prescription drug abuse;
6. improve care coordination and transitions between levels of SUD care.

A brief summary of key actions associated with each goal is listed in Table 1. Please refer to the implementation plan for a detailed description of the full set of proposed actions [5].

Table 1. Summary of Key Actions Associated with Demonstration Goals

Goal	Key Actions (Estimated Completion Date)
1. improve access to critical levels of care for Opioid Use Disorder (OUD) and other SUDs for Medicaid beneficiaries	1a. amend state plan to include coverage of SUD treatment planning (7/1/2019) 1b. amend regulations to include partial hospitalization as an allowable service for Behavioral Health Services Organizations/ BHSOs (7/1/2019) 1c. amend state plan to include coverage of methadone for medication-assisted treatment, with a waiver of the non-emergency medical transportation assurance except for children under age 21, former foster care youth, and pregnant women (7/1/2019) 1d. expand, through state certification process [Goal #3], number of residential treatment providers eligible for the Institution of Mental Disease (IMD) exclusion (1/1/2020) 1e. amend service definitions to include withdrawal management in all levels of care, i.e., beyond hospital setting (7/1/2019)
2. require the use of evidence-based SUD-specific criteria for patient placement in outpatient and residential care, with the goal of improving SUD screening and patient care and retention	2a. amend state plan to require all SUD providers to incorporate ASAM's 6-dimensional assessment into their patient assessment in determining placement into treatment (7/1/2019)

3. apply nationally-recognized SUD-specific program standards for the certification of residential treatment facilities	3a. based on self-attestation to American Society of Addiction Medicine (ASAM) level of care in statewide survey, issue pending certification to eligible IMD facilities with 96 or fewer beds, permitting them to qualify for temporary IMD exclusion (4/1/2019) 3b. certify, through state certification program, residential treatment providers to ASAM levels of care, permitting certified IMD facilities with up to 96 beds to qualify for IMD exclusion (1/1/2020)
4. assess provider capacity at critical levels of care, including for medication-assisted treatment for OUD with the goal of ensuring greater access to care	4a. conduct statewide survey of services, hours, staffing, and other characteristics of Medicaid-enrolled residential SUD providers (10/15/2018) 4b. conduct statewide survey of Medicaid outpatient and residential SUD treatment providers, assessing SUD levels of care, services offered—particularly medication-assisted treatment (on-site or facilitated off-site)—and potential Medicaid enrollment (9/12/2019)
5. implement strategies directed at prescribers and dispensers to dampen prescription drug abuse	5a. as part of an opioid utilization program, develop criteria for applying utilization controls of long acting and short acting opioids (e.g., limitations on short acting opiates for the treatment of acute pain, daily dose limits) (9/4/2018) 5b. as part of an opioid utilization program, establish morphine milligram equivalent (MME) thresholds for short acting, long acting, and combination opioids, and employ a step down methodology to reduce overall MME dosing limitations (9/4/2018)
6. improve care coordination and transitions between levels of SUD care	6a. amend state plan to include care coordination within the definition of residential SUD treatment (7/1/2019) 6b. amend state regulations to include care coordination duties to the definition of residential SUD treatment (7/1/2019)

Although there are many parts to the SUD implementation plan, the **primary focus of the demonstration is to improve access to and utilization of treatment for SUD**, and accordingly, the evaluation will focus on this aspect of the demonstration.

A.3. Population Groups Impacted by the Demonstration

The population group affected by this demonstration will be Kentucky Medicaid beneficiaries with a substance use disorder.

B. EVALUATION QUESTIONS AND HYPOTHESES

B.1. Overview

Given the focus of the demonstration on increasing access to SUD treatment, the evaluation will concentrate on the areas most likely to be affected by demonstration initiatives, namely:

1. availability of provider services and capacity of treatment facilities available to Medicaid beneficiaries;
2. utilization of SUD services in residential facilities, particularly facilities affected by the IMD exclusion; and
3. utilization of SUD treatment services, especially medication-assisted treatment (MAT) and methadone as part of MAT.

As secondary outcomes, the evaluation will also examine selected opioid-related metrics, including overdose deaths, ED and hospital admissions for SUD, and self-reported survey measures of health and substance use. Per CMS technical specifications, the evaluation will also analyze Medicaid SUD expenditures.

B.2. Driver Diagram

The driver diagram—depicting the relationship between the purpose of the demonstration, the primary drivers that contribute directly to realizing that purpose, and the secondary drivers necessary to achieve the primary drivers—is shown in Figure 1.

Figure 1. Driver Diagram

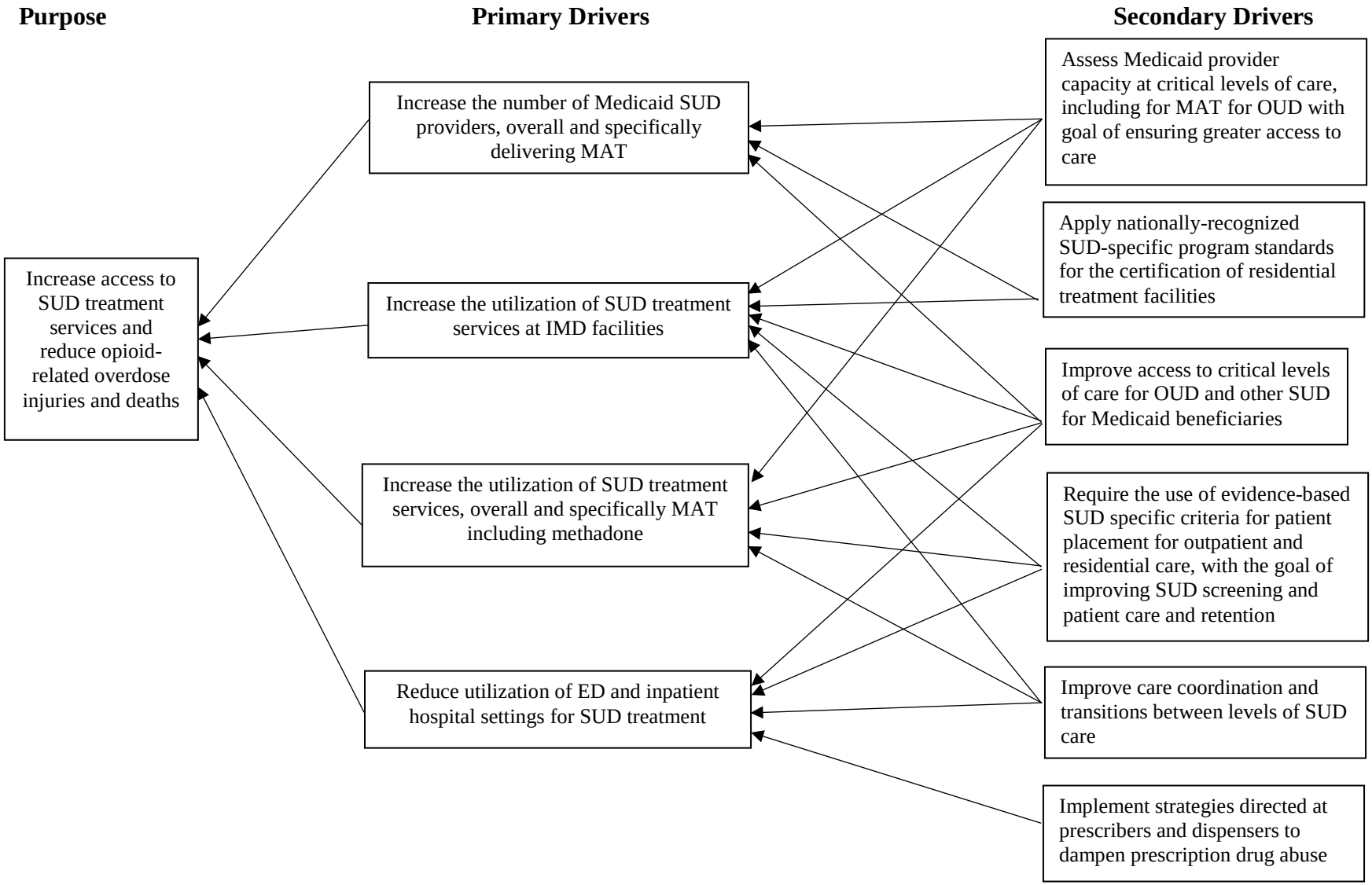

Table 2. Summary of Key Evaluation Questions, Hypotheses, Data Sources, and Analytic Approaches

*Denotes a metric that is also part of the Monitoring Plan

Evaluation Question 1: Did access to and utilization of SUD treatment services improve?						
Demonstration Goal: Increased number of outpatient Medicaid SUD providers, especially those offering medication-assisted treatment (MAT) and methadone as part of MAT, in areas of greatest need. Evaluation Hypothesis: The demonstration will increase the number of outpatient Medicaid SUD providers overall, and those specifically offering MAT and methadone as part of MAT, in areas of greatest need.						
Driver	Measure Description	Steward	Numerator	Denominator	Data Sources	Analytic Approach
Primary Driver (Increase the number of Medicaid SUD providers, overall and specifically delivering MAT)	Providers offering SUD services	N/A	Number of providers billing for SUD treatment services	Total number of beneficiaries	Claims data Provider enrollment data	Descriptive statistics Interrupted time series without comparison group
	Providers offering MAT	N/A	Number of providers prescribing any medication that is part of MAT	Total number of beneficiaries		
	Providers offering methadone as part of MAT	N/A	Number of providers prescribing methadone as part of MAT	Total number of beneficiaries		
	Providers offering SUD services in areas of greatest need	CCBHC 2.a.3	Number of providers billing for SUD treatment services, by county	Total number of beneficiaries, by county	Claims data Provider enrollment data	Descriptive statistics
	Providers offering MAT in areas of greatest need	CCBHC 2.a.3	Number of providers prescribing any medication that is part of MAT, by county	Total number of beneficiaries, by county		
	Providers offering methadone as part of MAT in areas of greatest need	CCBHC 2.a.3	Number of providers prescribing methadone as part of MAT, by county	Total number of beneficiaries, by county		

Demonstration Goal: Increased number of SUD providers offering residential treatment, especially IMDs. Evaluation Hypothesis: The demonstration will increase the number of SUD providers offering residential treatment, especially IMDs.						
Primary Driver (Increase the number of Medicaid SUD providers, overall and specifically delivering MAT)	Providers offering residential treatment for SUD	N/A	Number of providers billing for residential treatment for SUD	Total number of beneficiaries	Claims data Provider enrollment data	Descriptive statistics Interrupted time series without comparison group
	IMD facilities offering treatment for SUD	N/A	Number of IMD facilities billing for treatment for SUD	Total number of beneficiaries		
	Providers offering residential treatment for SUD in areas with greatest need	N/A	Number of providers billing for residential treatment for SUD, by county	Total number of beneficiaries, by county	Claims data Provider enrollment data	Descriptive statistics
	IMD facilities offering treatment for SUD in areas with greatest need	N/A	Number of IMD facilities billing for treatment for SUD, by county	Total number of beneficiaries, by county		
Demonstration Goal: Increased utilization of SUD treatment services. Evaluation Hypothesis: The demonstration will increase the utilization of SUD treatment services.						
Primary Driver (Increase the utilization of SUD treatment services, overall and specifically MAT including methadone)	Percentage of beneficiaries with newly initiated SUD treatment/diagnosis	N/A	Number of beneficiaries with SUD diagnosis and SUD-related service but not in 3 months preceding measurement period	Total number of beneficiaries	Claims data	Descriptive statistics Interrupted time series without comparison group
	Percentage of beneficiaries with SUD diagnosis who used outpatient services for SUD	N/A	Number of beneficiaries with SUD diagnosis who used outpatient services for SUD	Total number of beneficiaries		
	Percentage of beneficiaries with SUD diagnosis who used residential treatment services for SUD	N/A	Number of beneficiaries with SUD diagnosis who used residential treatment services for SUD	Total number of beneficiaries		
	Percentage of beneficiaries with SUD (OUD) diagnosis who used MAT	N/A	Number of beneficiaries with SUD diagnosis who used MAT	Total number of beneficiaries		
	Percentage of beneficiaries with SUD (OUD) diagnosis who received methadone as part of MAT	N/A	Number of beneficiaries with SUD diagnosis who received methadone as part of MAT	Total number of beneficiaries		
	Continuity of pharmacotherapy for OUD*	NQF #3175	Number of beneficiaries who have at least 180 days of continuous pharmacotherapy	Number of beneficiaries with a diagnosis of OUD		

			for OUD without a gap of more than 7 days	and at least one claim for OUD medication		
Primary Driver (Increase the utilization of SUD treatment services at IMD facilities)	Percentage of beneficiaries with SUD diagnosis who used SUD services at IMD facility	N/A	Number of beneficiaries with SUD diagnosis who used SUD services at IMD facility	Total number of beneficiaries		
Demonstration Goal: Reduced utilization of ED and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services. Evaluation Hypothesis: The demonstration will decrease the rate of emergency department visits and inpatient admissions within the beneficiary population for SUD.						
Primary Driver (Reduce utilization of ED and inpatient hospital settings for SUD treatment)	Emergency department visits for SUD (OUD) related diagnosis*	N/A	Number of ED visits for SUD (OUD) related diagnosis	Total number of beneficiaries	Claims data	Descriptive statistics Interrupted time series without comparison group
	Inpatient admissions for SUD and specifically OUD*	N/A	Number of beneficiaries with an inpatient admission for SUD and specifically for OUD	Total number of beneficiaries		

Evaluation Question 2: Did beneficiaries receiving SUD services experience improved health outcomes?						
Demonstration Goal: Reduced utilization of emergency department services for SUD for beneficiaries receiving SUD care. Evaluation Hypothesis: Among beneficiaries receiving care for SUD, the demonstration will decrease the rate of emergency department visits for SUD.						
Primary Driver (Reduce utilization of ED and inpatient hospital settings for SUD treatment)	Emergency department visits with primary SUD (OUD) related diagnosis for individuals receiving SUD (OUD) treatment	N/A	Number of emergency department visits with primary SUD (OUD) related diagnosis among beneficiaries who used SUD (OUD) services within 30 days	Number of beneficiaries who used SUD (OUD) services within 30 days	Claims data	Descriptive statistics Interrupted time series without comparison group
	Emergency department visits with primary SUD (OUD) related diagnosis for individuals receiving outpatient SUD (OUD) treatment	N/A	Number of emergency department visits with primary SUD (OUD) related diagnosis among beneficiaries receiving outpatient SUD (OUD) services within 30 days	Number of beneficiaries who used outpatient SUD (OUD) services within 30 days		
	Emergency department visits with primary SUD (OUD) related diagnosis, following ED discharge for SUD (OUD)	NQF #2605	Number of emergency department visits with primary SUD (OUD) related diagnosis within 7 days ED discharge for SUD (OUD) Number of emergency department visits with primary SUD (OUD) related diagnosis within 30 days ED discharge for SUD (OUD)	Number of beneficiaries discharged from ED with primary diagnosis of SUD (OUD)		
Demonstration Goal: Fewer hospital readmissions for SUD for beneficiaries receiving SUD care. Evaluation Hypothesis: Among beneficiaries receiving care for SUD, the demonstration will reduce hospital readmissions for SUD care.						
Primary Driver (Reduce utilization of ED and inpatient hospital settings for SUD treatment)	30-day readmission rate following hospitalization with SUD (OUD) related diagnosis	N/A	Number of beneficiaries readmitted to the hospital within 30 days of an index hospitalization with SUD (OUD) related diagnosis	Total number of beneficiaries who were admitted to the hospital with SUD (OUD) related diagnosis	Claims data	Descriptive statistics Interrupted time series without comparison group

Demonstration Goal: Improved physical and mental health for beneficiaries receiving SUD care. Evaluation Hypothesis: Among beneficiaries receiving care for SUD, the demonstration will improve physical and mental health.						
Primary Driver (Increase the utilization of SUD treatment services, overall and specifically MAT including methadone) Secondary Driver (Improve access to critical levels of care for OUD and other SUD for Medicaid beneficiaries) Secondary Driver (Require the use of evidence-based criteria for patient placement in outpatient and residential care) Secondary Driver (Improve care coordination and transitions between levels of SUD care)	Self-reported health in past 6 months	N/A	Rating on 5-point Likert-like scale of overall health	N/A	KTOS KORTOS	Descriptive statistics Interrupted time series without comparison group
	Self-reported days of poor physical health within past 30 days	N/A	Number of days of poor physical health within past 30 days	N/A		
	Self-reported days of poor mental health within past 30 days	N/A	Number of days of poor mental health within past 30 days	N/A		
	Self-reported attendance at AA, NA, MA, or other self-help group meetings within past 30 days	N/A	Number of times attended AA, NA, MA, or other self-help group meetings within past 30 days	N/A		
	Self-reported use of prescription opiates/opioids within past 6 (KORTOS) / 12 (KTOS) months / 30 days (KTOS)	N/A	Use of prescription opiates/opioids within past 6 months	N/A		
	Self-reported use of heroin within past 6 (KORTOS) / 12 (KTOS) months / 30 days (KTOS)	N/A	Use of heroin within past 6 months	N/A		
	Self-reported continued substance use within past 6 months (KORTOS) / 12 months (KTOS)	N/A	Substance use within past 6 months	N/A		

Evaluation Question 3: Did rates of opioid-related overdose deaths decrease?						
Demonstrated Goal: Reduction in opioid-related overdose deaths. Evaluation Hypothesis: The demonstration will decrease the rate of overdose deaths due to opioids.						
Primary Driver (Increase the utilization of SUD treatment services at IMD facilities) Primary Driver (Increase the utilization of SUD treatment services, overall and specifically MAT including methadone)	Use of opioids at high dosage in persons without cancer*	NQF #2940	Number of beneficiaries with opioid prescription claims for a morphine equivalent dose of greater than 120 mg for 90 consecutive days	Number of beneficiaries with 2+ prescription claims for opioids filled on at least 2 separate dates, for which the sum of days' supply ≥ 15	Claims data	Descriptive statistics Interrupted time series without comparison group
	Rate of overdose deaths, specifically overdose deaths due to any opioid*	N/A	Number of overdose deaths	Number of beneficiaries	Claims data Administrative data [vital statistics]	Descriptive statistics Interrupted time series without comparison group
	Rate of overdose deaths, specifically overdose deaths due to any opioid		Number of overdose deaths, by county	Number of beneficiaries	Claims data Administrative data [vital statistics]	Descriptive statistics

In addition, we will be analyzing changes in total costs (expenditures) associated with care provided to Medicaid beneficiaries diagnosed with substance use disorders. Because almost all Kentucky Medicaid beneficiaries are enrolled in managed care plans, expenditures will be calculated from encounter data reported by managed care organizations and regularly compiled by the Kentucky Cabinet for Health and Family Services. We will use descriptive statistics and the interrupted-time-series-without-comparison-group method to estimate the effect of the demonstration on care expenditures.

C. METHODOLOGY

C.1. Overview

Although the broader objective of Kentucky's opioid strategy is to reduce the number of opioid-related injuries and deaths, the sheer magnitude of SUD challenges in the state and the many ongoing federal, state, and privately funded initiatives directed towards the state's SUD crisis mean that the incremental effect of the 1115 SUD demonstration will be challenging to detect using population-level health measures such as opioid-related deaths. This is because these injuries and deaths are the result of complex and overlapping demographic, social, economic, disease, health care, public health, and institutional factors. For this reason, **the evaluation will focus on monitoring and evaluating outcome measures** that are **most directly affected by the central features of the demonstration**, which are the enhancement of the Medicaid SUD provider capacity, waiver of the IMD exclusion, and expansion of MAT coverage for SUD.

Because the SUD demonstration will be implemented statewide, there is **no obvious contemporaneous internal comparison group.** The evaluation team considered comparison states with similar demographic profiles as Kentucky, but these candidate states were launching similar SUD initiatives and therefore could not serve as comparison populations for evaluating the key features of Kentucky's SUD demonstration. For this reason, we will use an **interrupted time series analysis without comparison group** approach to evaluate the effect of the SUD demonstration.

C.2. Target and Comparison Population

The target population for the evaluation will be Kentucky Medicaid beneficiaries with a substance use disorder. More specifically, following CMS guidance, beneficiaries observed to have been diagnosed with an SUD or who have used SUD treatment services in a given month will be considered to have an active substance use disorder (and included in the target population) that month as well as for an additional 11 months after the initial diagnosis or care episode. Individuals without an SUD diagnosis or record of SUD treatment after this 12-month period will be considered to not have an active SUD and will be excluded from the target population in subsequent months unless there is another triggering SUD diagnosis or care visit. For the reasons noted above, there is no comparison population available.

C.3. Evaluation Period

The SUD demonstration is scheduled to begin July 2019. We are requesting data for the period July 2017-September 2023, i.e., beginning two years prior to implementation and continuing through the expiration of the demonstration waiver.

C.4. Data Sources

The core data for the evaluation will be Medicaid encounter data. These data will be supplemented with data from administrative vital statistics; a provider enrollment database; ongoing smaller-scale surveys of individuals enrolling in treatment for SUD; and a qualitative survey of Medicaid beneficiaries with SUD.

C.4.1. Medicaid encounter data

Because most of Kentucky's Medicaid beneficiaries receive benefits administered by managed care organizations (MCOs), we will be using Kentucky Medicaid encounter data reported by these MCOs. These encounter data contain records of outpatient, emergency department, inpatient, and long-term care services provided for SUD, as well as prescription drugs dispensed. They also include information on billing providers (facilities and physicians) and on payments made to these providers by the MCOs.

In submitting its encounters to the state Medicaid Management Information System (MMIS), each MCO is required to submit data that follows a consistent format and that must pass a range of edits and audits. These validated encounter data then undergo state review for quality—including completeness/missingness assessments, internal consistency checks, and other data validation reviews—prior to submission by the state to the federal Transformed Medicaid Statistical Information System (T-MSIS). According to the state, "these processes… ensure a high level of confidence in the quality of the encounter data."[6] Encounter data are available on a quarterly basis with a 6-month lag. Limitations of these data are that they do not include direct measures of health status or substance use.

C.4.2. Administrative vital statistics data

Vital statistics data capture deaths attributable to accidental poisonings, including overdoses. These data are available on a quarterly basis with a 9-month lag. Limitations of these data are the measurement error in the attribution of overdose deaths to opioids.

C.4.3. Provider enrollment data

Kentucky Medicaid will launch the Kentucky Medicaid Partner Portal Application (KY MPPA), a Medicaid provider enrollment system, in mid-2019. Data from KY MPPA will be available annually with a 6-month lag and will be used to cross-validate provider information obtained from Medicare claims. Prior to KY MPPA, provider enrollment was done through a manual reporting process. A limitation of this data source is that data on provider enrollment prior to implementation will need to be manually aggregated and processed to convert it into a format suitable for the evaluation.

C.4.4. Kentucky Treatment Outcome Study (KTOS) and Kentucky Opiate Replacement Treatment Outcome Study (KORTOS)

KTOS and KORTOS are two ongoing studies conducted by the University of Kentucky Center on Drug and Alcohol Research in collaboration with the Kentucky Department of Behavioral Health, Developmental, and Intellectual Disabilities. KTOS is a study of patients enrolling in SUD treatment programs (including outpatient, residential, and inpatient programs), and KORTOS is a study of patients enrolling in opiate treatment programs. KTOS enrolls about 1200 patients annually (of whom 950 are Medicaid-insured) who complete surveys at intake and at 12 months; KORTOS enrolls about 240 patients annually (of whom 150 are Medicaid-insured) who complete surveys at intake and at 6 months. We will use self-reported measures of physical health, mental health, and substance use from KTOS and KORTOS to evaluate the effect of the demonstration on improvements in beneficiary health and care.

The major limitations of these surveys are the voluntary participation in the surveys, the 35%-40% attrition rates for Medicaid-insured respondents, and the relatively small sample sizes, all of which may lead to selection bias and limit the scope of inferences. Because of these limitations, evaluation of these measures should be viewed with particular caution. Nevertheless, KTOS and KORTOS provide important measures of health and substance use of the demonstration's target population that are not easily obtainable elsewhere.

We have been informed that, because of funding difficulties, there is a possibility that these surveys could be discontinued during the demonstration period. If this is the case, or if KTOS and KORTOS are not able to provide sufficient information for the proposed evaluation of patient outcomes, the Penn team will re-evaluate and may propose conducting a separate beneficiary survey. As well, if the available information on provider enrollment is insufficient to meet the stated goals of the evaluation, the Penn team may propose conducting a novel provider survey.

C.4.5. Qualitative beneficiary survey

As part of the evaluation of the larger non-SUD 1115 demonstration, the University of Pennsylvania fielded a survey of Medicaid beneficiaries in 2018. For the qualitative SUD beneficiary survey, respondents from the general demonstration survey who meet SUD criteria will be contacted for qualitative interviews on substance use, enrollment in SUD treatment, and experience with SUD providers.

C.5. Analytic Methods

A mixed methods approach will be used in the evaluation of the SUD demonstration. Quantitative analyses will be used to assess the impact of the demonstration, while qualitative analyses will be used to provide detail and depth to beneficiary experience of provider and treatment aspects of the demonstration.

C.5.1. Quantitative analyses

The purpose of these analyses is to quantitatively describe and statistically evaluate the effect of the demonstration. Although a quasi-experimental design would have been ideal, the comprehensive statewide implementation of the demonstration means that internal comparisons are not feasible. As stated above, we investigated the possibility of an external comparison group but were unable to identify states with similar demographic and institutional characteristics that were not also implementing comparable SUD programs, namely the waiver of the IMD exclusion

and expanded coverage of MAT to include methadone. For these reasons, we will use the interrupted time series without comparison group method to evaluate the demonstration.

For each of the outcomes identified in Table 2 (provider capacity, utilization, health, substance use, mortality), we will provide descriptive summary statistics for the two pre-demonstration years, as well as each successive year of the evaluation.

For the outcomes identified in Table 1 that are available monthly (provider capacity, utilization, mortality), we will estimate the following model:

$$Y_{m,c} = \beta_0 + \beta_1 \text{time}_m + \beta_2 I[\text{post}]_{m,c} + \beta_3 \text{time}_m \times I[\text{post}]_{m,c} + \beta' \text{controls}_{m,c} + \gamma'_c + \varepsilon_{m,c}$$

where Y is the outcome of interest; time is a linear time trend; I[post] is a binary indicator of demonstration implementation (1 if yes, 0 otherwise); controls are a vector of covariates (e.g., provider and population characteristics); γ_c is a vector of county fixed effects; ε is the disturbance term; m indexes the month; and c indexes the county.

The coefficient β_2 reflects the shift in outcome levels in the post-demonstration period (after accounting for secular time trends), while β_3 reflects the effect of the demonstration. Both coefficients will be of interest in the evaluation.

Our power analyses suggest that we will be able to detect moderate changes in the utilization of treatment services. We were not able to obtain data from all proposed measures for which to conduct power analyses, but as an illustration, we will be able to detect, at α=0.05 with 80% power:

- a change of 1.14 in the monthly number of inpatient stays for SUD per 1,000 beneficiaries (monthly average: 6.01)
- a change of 15.3 in the monthly number of beneficiaries who have a claim for MAT (monthly average: 594).

C.5.2. Qualitative analyses

The purpose of the qualitative interviews is to describe the Medicaid experiences of individuals affected by SUD, including access to care and uptake of treatment. Qualitative interviews will address questions such as how well Medicaid members understand new treatment options, how people learned about these services, and what engagement in these services has been like in comparison to past services. Interviews will also explore a narrative of the person's SUD, the impact on daily life, current medical needs and health status, past and current experiences with Medicaid, both for overall health and SUD, access to SUD treatment through any means of payment as well as Medicaid, barriers to SUD treatment services, and any SUD treatment needs not currently covered by Medicaid or other insurance.

The interviews will be semi-structured, using written agendas with flexibility to explore unexpected responses. Interviews will be conducted by phone, and voice recorded and transcribed for analysis. We will aim for approximately 25 beneficiaries in each interview cycle—a sample size consistent with best practices for qualitative interviews—monitoring for data saturation. Data

collection will occur yearly in order to monitor changes in each year of the program, with the first data collection period anticipated to occur around March 2020-May 2020.

Throughout the duration of the SUD waiver, we will conduct a mix of longitudinal cohort interviews, with the initially-identified population, and one-time interviews, in order to represent a variety of experiences. That is, we anticipate primarily a cross-sectional design, with a smaller longitudinal cohort.

For the first cohort, we plan to recruit participants from three sources. We will contact beneficiaries identified through the 2018 beneficiary survey whose responses were reflective of a possible substance use disorder, recruit from treatment facilities offering methadone for MAT, and recruit from inpatient facilities expanding access through the lifting of the IMD exclusion. For subsequent cohorts, we will recruit from treatment facilities, as well as consider other direct recruitment options based on the makeup of our sample; for example, we may recruit from non-treatment facilities such as primary care facilities to capture the experience of people not engaged in active treatment.

Thematic analysis will be done with multiple trained coders to identify themes throughout the interviews, and mixed-methods analysis will be performed, using the qualitative interviews to further explain and elucidate results from the quantitative data.

As the evaluation progresses and interviews are analyzed, the Penn team will evaluate the need for additional qualitative interviews to cover any areas where more experiences should be captured. This could include beneficiaries experiencing barriers to treatment or the addition of provider interviews as needed.

C.5.3. Cost (expenditure) analyses

Pursuant to CMS requirements for all SUD section 1115 demonstrations, we will be conducting analyses of costs (expenditures) associated with the Kentucky SUD demonstration. The econometric structure of these analyses will be the same as those outlined in section C.5.1 (Quantitative analyses), using descriptive summary statistics and the interrupted time series without comparison group method to evaluate the effect of the demonstration on expenditures.

Because almost all Kentucky Medicaid beneficiaries are enrolled in managed care plans and because data on negotiated capitated payments will not be available for this analysis, we will be using data on encounters reported by Medicaid managed care organizations (MCOs) and compiled by the Kentucky Cabinet for Health and Family Services. As described in Section C.4 (Data sources), these data provide information on health care services provided to beneficiaries and information on payments made to providers by MCOs for these services. Although these data do not reflect contemporaneous costs incurred by Medicaid for care provided to beneficiaries—because Medicaid pays a capitated rate to the MCOs—they are used by the state Medicaid program, in combination with other factors, to determine capitated MCO rates. For this reason, they can provide a useful if imperfect measure of costs incurred by the Medicaid program.

Following CMS recommendations, we will be conducting analyses at three different levels:

- total expenditures;
- SUD and non-SUD expenditures (with SUD expenditures disaggregated into IMD and non-IMD expenditures);
- expenditures disaggregated by source of treatment—namely, inpatient expenditures, emergency department (ED) expenditures, non-ED outpatient expenditures, pharmacy expenditures, and long-term care expenditures.

Because of the demonstration's focus on SUD care, the sample population for which expenditures will be calculated will consist of Medicaid beneficiaries with an SUD diagnosis or who have used SUD treatment services during the period of interest. In particular, following the protocol specified in Attachment A of the SUD Evaluation Guidance Technical Assistance document, beneficiaries will be included in monthly expenditure calculations if they have received an SUD diagnosis or have used SUD treatment services that month or in the previous 11 months. If there is no SUD diagnosis or SUD treatment service utilization after these 12 months, beneficiaries will be excluded from subsequent expenditure calculations. Monthly expenditures will thus be based on pooled cross-sectional samples rather than a specific cohort of beneficiaries. To identify beneficiaries with an SUD diagnosis or who have used SUD treatment services, we will use codes in the value sets specified in Appendix A of the SUD Evaluation Guidance Technical Assistance document.

As with quantitative analyses of utilization, we will report summary statistics of expenditures for the two pre-demonstration years, as well as each successive year of the evaluation. We will also estimate the following model:

$$Y_{i,m} = \beta_0 + \beta_1 \text{time}_m + \beta_2 I[\text{post}]_m + \beta_3 \text{time}_m \times I[\text{post}]_m + \beta' \text{controls}_{i,m} + \varepsilon_{i,m}$$

where Y denotes expenditures; time is a linear time trend; I[post] is a binary indicator of demonstration implementation (1 if yes, 0 otherwise); controls are a vector of covariates (e.g., beneficiary characteristics); ε is the disturbance term; m indexes the month; and i indexes the individual beneficiary. The outcome measure of interest for the cost analyses is average monthly expenditure per (SUD) beneficiary.

For the expenditure analyses, we are interested in β_2, which reflects the shift in spending in the post-demonstration period, and β_3, which reflects the expenditure effect of the demonstration. We hypothesize that expenditures for outpatient visits will initially increase, while spending for more costly services such as inpatient care and ED visits will decrease, generating net cost-savings over time.

We are aware that the validity of the cost analysis is dependent on the quality and completeness of the financial measures in the MCO encounter data. The Penn team's preliminary analysis of the data suggests a relatively high-quality dataset with plausible beneficiary and case counts, few missing values, and plausible paid amount values and distributions. For the evaluation, we will conduct a more thorough graphical and statistical analysis of the expenditure measures, checking for missing and implausible extreme values, anomalous distributions, and signs of selection bias (based on beneficiary characteristics). Prior to formal statistical analyses, we will take care to clean the data, correcting errors as necessary.

D. Methodological Limitations

An important limitation of this evaluation is the absence of a comparison group. This is due to the statewide nature of the SUD demonstration and the lack of a comparable state not implementing similar SUD policies. The lack of a comparison group could generate bias in our estimate of the effect of the evaluation because we might be erroneously attributing changes in SUD-related outcomes to the demonstration. We will attempt to minimize this bias by including a rich set of covariates, but there remains a chance of bias due to factors we are unable to include in our model.

A second limitation, specific to the cost analysis, is the potential heterogeneity in the quality of the financial measures in the MCO encounter data. CMS's experience has been that Medicaid MCOs vary in the quality and completeness of their reporting; consequently, inference of expenditure effects could be confounded because of variation in financial data quality across plans and over time. If there is measurement error in the expenditure fields, standard errors will be inflated and analyses may understate the expenditure effects of the demonstration. Although we cannot rule out selection bias in the MCO encounter data, the Penn team's preliminary analyses of the financial data suggest that errors in these data fields appear to be small.

E. Attachments

E.1. Independent Evaluator

As experts in the implementation and evaluation of large randomized field experiments, the University of Pennsylvania was selected to be the independent evaluator of the full 1115 Medicaid waiver. Because the SUD demonstration was originally part of this broader 1115 waiver, the state contracted with University of Pennsylvania to evaluate the SUD demonstration as well.

In its role as evaluator of the larger waiver, the University of Pennsylvania team has developed significant experience conducting beneficiary surveys and collecting detailed qualitative interview data in Kentucky. The team also brings pre-existing deep expertise and experience working with administrative data, large datasets, survey data, and causal inference methods. The team will bring these skills and experience to bear on the SUD evaluation.

The University of Pennsylvania evaluation team commits to performing a fully independent evaluation of the Commonwealth of Kentucky's Section 1115 Waiver demonstration. We attest to our independence in this evaluation, and agree to present our results to CMS and the general public through white papers and peer-reviewed journal articles without being influenced by any external partners, including the Commonwealth of Kentucky.

E.2. Evaluation Budget

The budget for the SUD evaluation was initially encapsulated within the budget for the full 1115 waiver and was not developed as a separate budget. Below, we have estimated the total budget for the SUD evaluation as it would be if the evaluation of the SUD-specific part of the waiver were a completely separate evaluation. Since there are efficiencies in conducting both evaluations simultaneously, this SUD-only budget includes fixed costs that would have been spread out across the broader evaluation of the full demonstration.

The budget estimate includes salaries for all University of Pennsylvania faculty and staff involved in the evaluation project, with benefits at the university rate of 30.2%. Data analysis costs are included separately; these costs include data analysts, post-doctoral researchers, and qualitative coding and analysis, as well as the funding for Professor Kristen Underhill, our co-PI who is located at Columbia University, School of Law. We have also accounted for additional costs such as travel to Kentucky to meet with our partners within the Commonwealth of Kentucky, as well as publication and dissemination costs. We separate out our total direct costs and our current overhead Facilities and Administration (F&A) costs, which are set at 61%, the negotiated rate for the university.

Estimated Budget	**Year 01**	**Year 02**	**Year 03**	**Year 04**	**Year 05**	**Total**
Category	7/1/2019 6/30/2020	7/1/2020 6/30/2021	7/1/2021 6/30/2022	7/1/2022 6/30/2023	7/1/2023 6/30/2024	7/1/2019 6/30/2024
Salaries	151,280	155,818	160,492	165,307	170,266	803,163
Benefits @ 30.2%	45,686	47,057	48,469	49,923	51,420	242,555
Data Analysis (including analysts, post-doctoral researchers, and Columbia Subcontract)	192,023	194,784	197,628	200,556	203,573	988,564
Travel	15,000	15,000	15,000	15,000	15,000	75,000
Publication Fees	6,000	6,000	6,000	6,000	6,000	30,000
Total Direct Costs	409,989	418,659	427,589	436,786	446,259	2,139,282
F&A @61%	250,093	255,382	260,829	266,439	272,218	1,304,962
Total	**660,082**	**674,041**	**688,418**	**703,225**	**718,477**	**3,444,244**

E.3. Timeline and Major Milestones

Activity	Jan-June 2018	July-Dec 2018	Jan-June 2019	July-Dec 2019	Jan-June 2020	July-Dec 2020	Jan-June 2021	July-Dec 2021	Jan-June 2022	July-Dec 2022	Jan-June 2023	July-Dec 2023	Jan-June 2024
Demonstration Year 1 Q1-Q2: (Pre-Implementation) Consultation with KY on data sources for evaluation													
Demonstration Year 1 Q3-Q4: (Pre-Implementation) Continuing consultation with KY and preparation for proposed evaluation plan													
Demonstration Year 2 Q1-Q2: (Pre-Implementation) Preparation for and revision of proposed evaluation plan													
KY implementation of waiver of IMD exclusion and expanded coverage of MAT													
Demonstration Year 2 Q3-Q4 (Implementation Year 1) Preparation for data collection and analysis													

Demonstration Year 3 Q1-Q2: (Implementation Year 1) Preparation for data collection and analysis													
Demonstration Year 3 Q3-Q4: (Implementation Year 2) Data collection and analysis[a]													
Demonstration Year 4 Q1-Q2: (Implementation Year 2) Data collection and analysis[a]													
Demonstration Year 4 Q3-Q4: (Implementation Year 3) Preparation for interim evaluation report													
Interim Evaluation Report completed (December 2021)													
Demonstration Year 5 Q1-Q2: (Implementation Year 3) Data collection and analysis[b]													
Demonstration Year 5 Q3-Q4: (Implementation Year 3) Data collection and analysis[b]													
Post-Demonstration Year 1 Q1-Q2 (Implementation Year 4) Data collection and analysis[b]													
Post-Demonstration Year 1 Q3-Q4													

(Implementation Year 4) Data collection and analysis[b]													
Summative Evaluation Report completed (June 2024)													

[a] contingent on plan approval and data availability
[b] contingent on data availability

E.4. References

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