DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

July 2, 2024

Lisa Lee
Commissioner, Department for Medicaid Services
Cabinet for Health and Family Services
275 East Main Street,
Frankfort, KY 40601

Dear Commissioner Lisa Lee:

The Centers for Medicare & Medicaid Services (CMS) is approving Kentucky's request to amend its Medicaid section 1115(a) demonstration entitled, "TEAMKY" (Project Numbers 11-W-00306/4 and 21-W-00067/4), which is effective with the date of approval and will remain in effect throughout the demonstration approval period, which is set to expire September 30, 2024. Approval of this demonstration amendment will provide expenditure authority for limited coverage for certain services furnished to certain incarcerated individuals for up to 60 days immediately prior to the individual's expected date of release.

Pre-Release Services under Reentry Demonstration Initiative

Expenditure authority is being provided to Kentucky to provide limited coverage for a targeted set of services furnished to certain incarcerated individuals for 60 days immediately prior to the individual's expected date of release. The state's proposed approach closely aligns with CMS's "Reentry Demonstration Opportunity" as described in the State Medicaid Director Letter (SMDL) released on April 17, 2023.

Eligible Individuals

Kentucky will cover a set of pre-release benefits for certain individuals who are inmates residing in state prisons or youth correctional facilities. To qualify for services covered under this demonstration approval, individuals residing in a state prison or youth correctional facility must have been determined eligible for Medicaid or CHIP (or be eligible for CHIP except for their incarceration status) pursuant to an application filed before or during incarceration, and must have an expected release date no later than 60 days after initiation of demonstration-covered services.

Medicaid and CHIP Eligibility and Enrollment

CMS is requiring, as a condition of approval of this demonstration amendment, that Kentucky make pre-release outreach, along with eligibility and enrollment support, available to all individuals incarcerated where the pre-release demonstration coverage services will be available.

For a Medicaid-covered individual entering a correctional facility, Kentucky will not terminate Medicaid coverage, but will suspend the individual's coverage. For a CHIP-covered individual who is incarcerated, the state must terminate coverage if the individual remains incarcerated at the end of their continuous eligibility period.[1] For individuals not enrolled in Medicaid or CHIP upon entering a correctional facility, Kentucky will ensure the individual receives assistance with completing and submitting a Medicaid or CHIP application sufficiently prior to their anticipated release date, such that the individual can receive the full duration of pre-release services, unless the individual voluntarily refuses such assistance or chooses to decline enrollment.

Scope of Pre-Release Benefit Package

The pre-release benefit package is designed to improve care transitions of such individuals back to the community, including by promoting continuity of coverage, service receipt, and quality of care, as well as the proactive identification of both physical and behavioral health needs. It is designed to address these overarching demonstration goals, while aiming to ensure that participating carceral facilities can feasibly provide all pre-release benefits to qualifying incarcerated individuals.

CMS is authorizing Kentucky to provide coverage for the following services to be detailed in the implementation plan required by the demonstration's Special Terms and Conditions (STCs):

- Case management to assess and address physical and behavioral health needs;
- Medication-assisted treatment (MAT) services for all types of substance use disorder (SUD) as clinically appropriate, with accompanying counseling; and
- A 30-day supply of all prescription medications that have been prescribed for the individual at the time of release, provided to the individual immediately upon release from the correctional facility, consistent with approved Medicaid and CHIP state plan coverage authority and policy.

CMS recognizes that many individuals exiting correctional facilities may not have received sufficient health care to address all of their physical and/or behavioral health care needs while incarcerated. This demonstration initiative will provide individuals leaving correctional facilities the opportunity to receive short-term Medicaid and CHIP enrollment assistance and pre-release coverage for certain services to facilitate successful care transitions, as well as improve the identification and treatment of certain chronic and other serious conditions to reduce acute care utilization in the period soon after release, while providing the state the opportunity to test whether these pre-release services improve uptake and continuity of MAT and other SUD and behavioral health treatment, as appropriate for the individual, to reduce decompensation, suicide-related death, overdose, and overdose-related death. Therefore, CMS is approving a demonstration benefit package in Kentucky that is designed to improve identification of physical and behavioral health needs to facilitate connections to providers with the capacity to meet those needs in the community during the period immediately before an individual's expected release from a correctional facility. Once an individual is released, the coverage for which the

[1] In accordance with the CAA, 2023, after January 1, 2025, states may no longer terminate CHIP coverage due to incarceration, but they will have the option to suspend coverage.

individual is otherwise eligible must be provided consistent with all requirements applicable to such coverage.

Eligible Juveniles and Targeted Low-Income Children and This 1115 Reentry Demonstration Initiative

Section 5121 of the Consolidated Appropriations Act, 2023 (CAA, 2023; P.L. 117-328) amends the Social Security Act (the Act) and describes a mandatory population (eligible juveniles and targeted low-income children) and set of pre-release and post-release services, while section 5122 of the CAA, 2023 amends the Act and gives a state the option to receive federal financial participation for the full range of coverable services for eligible juveniles and targeted low-income children while pending disposition of charges. Every state is required to submit Medicaid and CHIP State Plan Amendments (SPAs) attesting to meeting the requirements in Section 5121 beginning January 1, 2025. To the extent there is overlap between the services required to be covered under sections 1902(a)(84)(D) and 2102(d)(2) of the Act and coverage under this demonstration, we understand that it would be administratively burdensome for states to identify whether each individual service is furnished to a beneficiary under the state plan or demonstration authority. Accordingly, to eliminate unnecessary administrative burden and ease implementation of statutorily required coverage and this demonstration, we are approving waivers of the otherwise mandatory state plan coverage requirements to permit the state instead to cover at least the same services for the same beneficiaries under this demonstration. This approach will ease implementation, administration, and claiming, and provide a more coherent approach to monitoring and evaluation of the state's reentry coverage under the demonstration. The state will provide coverage under the reentry demonstration to eligible juveniles described in section 1902(nn)(2) in alignment with sections 1902(a)(84)(D) and 2102(d)(2) of the Act, at a level equal to or greater than otherwise would be covered under the state plan. Compliance and state plan submission requirements under Sections 5121 and 5122 of the CAA, 2023 will remain unchanged. Coverage of the population and benefits identified in sections 1902(a)(84)(D) and 2102(d)(2) of the Act, as applicable, would automatically revert to state plan coverage in the event that this demonstration ends or eliminates coverage of beneficiaries and/or services specified in those provisions. CMS will provide additional information in the future about these CAA, 2023 provisions.

Implementation and Reinvestment Plans

As described in the demonstration STCs, Kentucky will be required to submit for CMS approval a Reentry Initiative Implementation Plan (Implementation Plan) and Reinvestment Plan documenting how the state will operationalize coverage and provision of pre-release services and how existing state funding for carceral health services will continue to support access to necessary care and achievement of positive health outcomes for the justice-involved population.

The Implementation Plan, to be submitted to and reviewed by CMS consistent with the STCs, will describe the milestones and associated actions being addressed under this demonstration amendment and provide operational details not captured in the STCs regarding implementation of those demonstration policies. At a minimum, the Implementation Plan will include definitions and parameters related to the implementation of the reentry authorities and describe the state's

strategic approach for making significant improvements on the milestones and actions, as well as associated timelines for meeting them, for both program policy implementation and investments in transitional nonservice elements, as applicable. The Implementation Plan will also outline any potential operational challenges that the state anticipates and the state's intended approach to resolving these and other challenges the state may encounter in implementing the reentry demonstration initiative. The operational plan requirement in sections 1902(a)(84)(D) or 2102(d)(2) of the Act is satisfied by the reentry implementation plan only for the population and for the services covered under this demonstration and for which the requirements of section 1902(a)(84)(D) and 2102(d)(2) therefore are waived. The state is still required to create an operational plan, provide coverage, and otherwise meet state plan requirements with respect to any population or service specified in section 1902(a)(84)(D) or 2102(d)(2) of the Act that is not covered under this demonstration.

The reentry demonstration initiative is not intended to shift current carceral health care costs to the Medicaid and CHIP program(s). Section 5032(b) of the SUPPORT for Patients and Communities Act (P.L. 115-271) makes clear that the purpose of the demonstration opportunity contemplated under that statute is "to improve care transitions for certain individuals who are soon-to-be former inmates of a public institution and who are otherwise eligible to receive medical assistance under title XIX." Furthermore, demonstration projects under section 1115 of the Act must be likely to promote the objectives of title XIX and XXI, which includes the inmate payment exclusion and inmate eligibility exclusion, respectively, in recognition that the carceral authority generally bears the costs for health care furnished to incarcerated individuals. This demonstration does not absolve carceral authorities in Kentucky of their constitutional obligation to ensure needed health care is furnished to inmates in their custody and is not intended as a means to transfer the financial burden of that obligation from a federal, state, or local carceral authority to the Medicaid or CHIP program.

Kentucky agrees to reinvest the total amount of new federal matching funds for the reentry demonstration initiative received under this demonstration amendment into activities and/or initiatives that increase access to or improve the quality of health care services for individuals who are incarcerated (including individuals who are soon-to-be released) or were recently released from incarceration, or for physical and behavioral health needs that may help prevent or reduce the likelihood of criminal justice system involvement. Consistent with this requirement, Kentucky will develop and submit a Reinvestment Plan to CMS outlining how the federal matching funds under the demonstration will be reinvested. The Reinvestment Plan should align with the goals of the state's reentry demonstration initiative. It should detail the state's plans to increase access to or improve the quality of health care services for those who have recently been released, and those who may be at higher risk of future criminal justice system involvement, particularly due to untreated behavioral health conditions. The Reinvestment Plan should describe the activities and/or initiatives selected by Kentucky for investment and a timeline for implementation. Any investment in carceral health care must add to and/or improve the quality of health care services and resources for individuals who are incarcerated and those who are soon to be released from carceral settings, and not supplant existing state or local spending on such services and resources. The reinvestment plan may include the services provided to eligible juveniles and targeted low-income children under 1902(nn)(2) and 2102(d)(2) of the Act, respectively, which are covered under this demonstration.

Budget Neutrality

Under section 1115(a) demonstrations, states can test innovative approaches to operating their Medicaid programs if CMS determines that the demonstration is likely to assist in promoting the objectives of the Medicaid statute. CMS has long required, as a condition of demonstration approval, that demonstrations be "budget neutral," meaning the federal costs of the state's Medicaid program with the demonstration cannot exceed what the federal government's Medicaid costs in that state likely would have been without the demonstration. In requiring demonstrations to be budget neutral, CMS is constantly striving to achieve a balance between its interest in preserving the fiscal integrity of the Medicaid program and its interest in facilitating state innovation through section 1115 approvals. In practice, budget neutrality generally means that the total computable (i.e., both state and federal) costs for approved demonstration expenditures are limited to a certain amount for the demonstration approval period. This limit is called the budget neutrality expenditure limit and is based on a projection of the Medicaid expenditures that could have occurred absent the demonstration, the "without waiver" (WOW) costs.

As described in the August 22, 2018, SMDL entitled "Budget Neutrality Policies for Section 1115(a) Medicaid Demonstration Projects", when calculating budget neutrality, CMS effectively treats a hypothetical expenditure like an expenditure that the state could have made absent the demonstration. As a result, hypothetical expenditures are included in both the WOW baseline and the estimate of the "with waiver" (WW) expenditures under the demonstration, and states do not have to find demonstration "savings" to offset hypothetical expenditures. However, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued "savings" from hypothetical expenditures. That is, "savings" are not generated from a hypothetical population or service if the state does not spend up to the hypothetical expenditure limit. To allow for hypothetical expenditures, while preventing them from resulting in "savings," CMS applies a separate, independent budget neutrality "supplemental test" for hypothetical expenditures. These supplemental budget neutrality tests subject the hypothetical expenditures to predetermined limits to which the state and CMS agree, and that CMS approves, during negotiations. If the state's WW hypothetical spending exceeds the supplemental test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending by finding "savings" elsewhere in the demonstration or to refund the federal matching funds to CMS. CMS is applying the traditional hypothetical approach to the state's reentry demonstration initiative.

The Medicaid expenditures for pre-release services furnished to incarcerated beneficiaries under the reentry demonstration initiative include coverage of services that states can and do cover through Medicaid state plan or other title XIX authority, for beneficiaries who are not subject to the inmate payment exclusion. CMS considers these expenditures to be "hypothetical" because the pre-release services would be coverable under the Medicaid state plan or other title XIX authority if furnished to a beneficiary outside a carceral setting, similar to how CMS treats expenditures for services furnished to certain beneficiaries who are short-term residents in an institution for mental diseases primarily to receive treatment for SUD, or SMI or SED, under the SUD and SMI/SED section 1115 demonstration opportunities. Any population identified in

section 1902(a)(84)(D) of the Act and covered instead under this demonstration will be included in the reentry Medicaid expenditure group (MEG).

CHIP Allotment Neutrality

Under this amendment, the state will be subject to a limit on the amount of federal title XXI funding that the state may receive on allowable demonstration expenditures during the demonstration period. CMS has long required, as a condition of demonstration approval, that demonstrations be "allotment neutral," meaning the federal title XXI funds for the state's CHIP program are restricted to the state's available allotment and reallocated funds. The state is eligible to receive title XXI funds for allowable title XXI demonstration expenditures, up to the amount of its title XXI allotment. Title XXI funds must be first used to fully fund costs associated with CHIP state plan populations. The demonstration expenditures are limited to remaining funds. In requiring demonstrations to be allotment neutral, CMS is constantly striving to achieve a balance between its interest in preserving the fiscal integrity of the CHIP program and its interest in facilitating state innovation and coverage through section 1115 demonstration approvals. For the targeted low-income children eligible under 2102(d)(2) of the Act that are covered under this demonstration and all related services as approved under this demonstration, including any services required to the extent they are available under this demonstration, should be included.

Monitoring and Evaluation

The state is required to conduct systematic monitoring and robust evaluation of the demonstration amendment in accordance with the STCs. The state must update its demonstration Monitoring Protocol to incorporate how it will monitor the amendment components, including relevant metrics data as well as narrative details describing progress with implementing the amendment. In addition, the state is also required to conduct an independent Mid-Point Assessment of the reentry demonstration initiative, as provided in the STCs, to support identifying risks and vulnerabilities and subsequent mitigation strategies.

The state is required to incorporate the amendment into its evaluation activities to support a comprehensive assessment of whether the initiatives approved under the demonstration are effective in producing the desired outcomes for the individuals and the state's overall Medicaid and CHIP program(s). Evaluation of the reentry demonstration initiative must align with the requirements detailed in the STCs, including examining impacts on Medicaid and CHIP coverage, continuity of care, access to and quality and efficiency of care, utilization of services, health outcomes, and carceral and community coordination in service provision, among others. The state's monitoring and evaluation efforts must facilitate understanding the extent to which the amendment might support reducing existing disparities in access to and quality of care and health outcomes.

Eligible juveniles and targeted low-income children eligible under 1902(a)(84)(D) and 2102(d)(2) of the Act, respectively, are included under this 1115 reentry demonstration initiative and must be included in applicable monitoring and evaluation activities.

Elements of the Amendment Request CMS is Not Approving at This Time

As part of its reentry amendment application, Kentucky also requested to cover Residential Recovery Support Service (RRSS), which is a service for beneficiaries with substance use disorder. CMS continues to review Kentucky's request to cover RRSS but is not approving this service at this time.

Consideration of Public Comments

The state held a public comment period from November 9, 2023, through December 9, 2023. The state received 14 comments during the public comment period. The federal comment period was open from January 12, 2024, through February 11, 2024, for the amendment application submitted December 30, 2023, during which CMS received 10 comments. One comment was from an individual and 9 were from organizations. All commenters supported Kentucky's request to provide pre-release coverage to incarcerated beneficiaries, however some commenters mentioned some concerns and proposed additional considerations for CMS.

One organization noted that while they support Kentucky's effort to cover pre-release services, they also encourage the state to place a special focus on pregnant and postpartum individuals and those with behavioral and reproductive health needs. Another organization requested for Kentucky and CMS to consider increasing human immunodeficiency virus (HIV) care and case management, and access to Pre-Exposure Prophylaxis (PrEP) pre-release. Also, an organization urged the state to consider covering a full Medicaid benefit package (including dental and vision services) and additional targeted substance use, mental health, or reentry-specific services in its implementation, and provide durable medical equipment (DME) immediately upon release (instead of providing a prescription for DME). CMS will continue to work with Kentucky on any requests to cover additional items and services that could help improve care transitions and otherwise improve the health and wellbeing of incarcerated individuals and those soon to be released from incarceration.

One organization expressed support for Kentucky's demonstration goals, but strongly emphasized that preventing incarceration should be the state's main goal. They recommended that any state savings from the reentry demonstration initiative should be reinvested into preventing incarceration by improving community-based physical and behavioral health services, improving health information technology and data sharing, and building community-based provider capacity. Also, they sought assurance that the demonstration will not contribute to an increase in the number of Kentuckians who are incarcerated, nor their length of incarceration. Lastly, another organization commented that the state should address racialized health inequities, prioritize person-centered and trauma-informed approaches in program design, and target workforce investments to community-based providers instead of providers based in the carceral setting.

Through the Reentry Section 1115 Demonstration Opportunity, states agree to reinvest the total amount of new federal matching funds received for such services under the demonstration into activities and/or initiatives that increase access to or improve the quality of health care services for individuals who are incarcerated (including individuals who are soon-to-be released) or were

recently released from incarceration, or for health-related social services that may help divert individuals from criminal justice involvement. Consistent with this expectation, states will need to commit at the time of the demonstration approval to a reinvestment plan. Any investment in carceral health care must add to and/or improve the quality of health care services and resources for individuals who are incarcerated and those who are soon to be released from carceral settings, and not supplant existing state or local spending on such services and resources. Reinvestment funds should be used to support the successful transition of beneficiaries to the community, e.g. investments to facilitate the provision of pre-release services, such as case management, or expansion of community-based capacity, e.g. increasing or improving mental health and SUD services.

CMS and the state recognize the significant coordination and collaboration that implementation will require between state health and correctional authorities, health providers, community-based organizations, and others. Kentucky has ongoing partnerships with many of these entities and will continue soliciting feedback and emphasizing coordination as this demonstration initiative is implemented. Also, the goal of the reentry demonstration initiative is to improve care transitions for certain individuals who are soon-to-be former inmates of a public institution and who are otherwise eligible to receive coverage under title XIX or title XXI and is not intended or expected to promote or encourage incarceration.

After carefully reviewing the amendment proposal and the public comments received during the federal comment period, and all other relevant materials provided by the state, CMS has concluded that the approval of this amendment to the TEAMKY demonstration is likely to assist in promoting the objectives of Medicaid and CHIP.

Other Information

CMS' approval of this amendment is conditioned upon compliance with the enclosed amended set of waiver and expenditure authorities and the STCs defining the nature, character, and extent of anticipated federal involvement in the demonstration. The award is subject to our receiving your acknowledgement of the award and acceptance of these STCs within 30 days of the date of this letter.

Your project officer for this demonstration is Valisha Andrus. She is available to answer any questions concerning this amendment. Ms. Andrus' contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop S2-25-26
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Email: Valisha.Andrus@cms.hhs.gov

If you have any questions regarding this approval, please contact Ms. Jacey Cooper, Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (410) 786-9686.

Sincerely,

[redacted]

Chiquita Brooks-LaSure

Enclosure

cc: Keri Toback, State Monitoring Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBERS: **11-W-00306/4**
21-W-00067/4

TITLE: **TEAMKY 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 TEAMKY (formerly KY Helping to Engage and Achieve Long Term Health (HEALTH)) section 1115 demonstration. Expenditures associated with TEAMKY are approved from January 12, 2018 through September 30, 2024.

As discussed in the Centers for Medicare & Medicaid Services' (CMS) approval letter, the Secretary of Health and Human Services has determined that the TEAMKY 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 TEAMKY demonstration:

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

2. **Expenditures for Pre-Release Services.** Expenditures for pre-release services, as described in these STCs, provided to qualifying Medicaid individuals for up to 60 days immediately prior to the expected date of release from a correctional facility that is participating in the Reentry Demonstration Initiative under this demonstration.

3. **Expenditures for Pre-Release Administrative Costs.** Capped expenditures for payments for allowable administrative costs, services, supports, transitional non-service expenditures, infrastructure and interventions, as is detailed in STC 30, which may not be recognized as medical assistance under section 1905(a) and may not otherwise qualify for federal matching funds under section 1903, to the extent such activities are authorized as part of the Reentry Demonstration Initiative.

Title XIX Requirements Not Applicable to the Medicaid Expenditure Authority for Pre-Release Services:

Amount, Duration, and Scope of Services and Comparability **Section 1902(a)(10)(B)**
To enable the state to provide only a limited set of pre-release services, as specified in these STCs, to qualifying individuals that is different than the services available to all other individuals outside of correctional facility settings in the same eligibility groups authorized under the state plan or demonstration authority.

Freedom of Choice **Section 1902(a)(23)(A)**
To enable the state to require qualifying individuals to receive pre-release services, as authorized under this demonstration, through only certain providers.

Title XXI Expenditure Authority:

Under the authority of section 1115(a)(2) of the Act as incorporated into Title XXI by section 2107(e)(2)(A), state expenditures described below, shall, for the period of this demonstration, through September 30, 2024, and to the extent of the state's available allotment under section 2104 of the Act, be regarded as matchable expenditures under the state's Title XXI plan. All requirements of Title XXI will be applicable to such expenditures for demonstration populations.

Expenditures for Pre-Release Services. Expenditures for pre-release services, as described in these STCs, provided to qualifying Children's Health Insurance Program (CHIP) individuals who are or would be eligible for CHIP if not for their incarceration status, for up to 60 days immediately prior to the expected date of release from a correctional facility that is participating in the Reentry Demonstration Initiative.

CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER LIST

NUMBERS: **11-W-00306/4**
21-W-00067/4

TITLE: **TEAMKY 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, 2024. In addition, these waivers may only be implemented consistent with the approved STCs. Waivers associated with TEAMKY (formerly KY HEALTH) are approved from January 12, 2018 through September 30, 2024.

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 TEAMKY section 1115 demonstration, subject to these STCs.

1. 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.

2. Coverage of Certain Screening, Diagnostic, and Targeted Case Management Services for Eligible Juveniles in the 30 Days Prior to Release **Section 1902(a)(84)(D)**

To enable the state not to provide coverage of the screening, diagnostic, and targeted case management services identified in section 1902(a)(84)(D) of the Act for eligible juveniles described in section 1902(nn)(2) of the Act as a state plan benefit in the 30 days prior to the release of such eligible juveniles from a public institution, to the extent and for the period that the state instead provides such coverage to such eligible juveniles under the approved expenditure authorities under this demonstration. The state will provide coverage to eligible

juveniles described in section 1902(nn)(2) in alignment with section 1902(a)(84)(D) of the Act at a level equal to or greater than would be required under the state plan.

Title XXI Waiver Authority

All requirements of the 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 through September 30, 2024. In addition, these waivers may only be implemented consistent with the approved STCs. Waivers associated with TEAMKY are approved through September 30, 2024.

Under the authority of section 1115(a)(1) of the Act, the following waiver of state plan requirements contained in section 2102 of the Act are granted for the TEAMKY section 1115 demonstration, subject to these STCs.

1. **Coverage of Certain Screening, Diagnostic, Referral, and Case Management Services for Targeted Low-Income Children in the 30 Days Prior to Release Section 2102(d)(2)**

   To enable the state not to provide coverage of the screening, diagnostic, referral, and case management services identified in section 2102(d)(2) of the Act for a targeted low-income child as a state plan benefit in the 30 days prior to the release of such targeted low-income child from a public institution, to the extent and for the period that the state instead provides such coverage to such targeted low-income children under the approved expenditure authorities under this demonstration. The state will provide coverage to targeted low-income children in alignment with section 2102(d)(2) of the Act at a level equal to or greater than would be required under the state plan.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBERS: **11-W-00306/4**
21-W-00067/4

TITLE: **TEAMKY 1115 Demonstration**

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

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the "TEAMKY" (formerly KY Helping to Engage and Achieve Long Term Health (KY HEALTH)) section 1115(a) Medicaid and CHIP demonstration (hereinafter "demonstration") to enable Kentucky (referred to herein as the 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 TEAMKY demonstration will be statewide and is approved from January 12, 2018 through September 30, 2024.

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. Reentry Demonstration Initiative
VII. Delivery System
VIII. General Reporting Requirements
IX. General Financial Requirements
X. Budget Neutrality
XI. CHIP Monitoring Allotment Neutrality
XII. Evaluation
XIII. 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
- Attachment G: Reentry Demonstration Initiative Implementation Plan
- Attachment H: Reentry Demonstration Initiative Reinvestment Plan
- Attachment I: Monitoring Protocol

II. PROGRAM DESCRIPTION AND OBJECTIVES

The TEAMKY (formerly 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.

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. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 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).

VI. REENTRY DEMONSTRATION INITIATIVE

19. Overview of Pre-Release Services and Program Objectives. This component of the demonstration will provide coverage for pre-release services up to 60 days immediately prior to the expected date of release to certain individuals who are inmates residing in state prisons or youth correctional facilities. To qualify for services covered under this demonstration, individuals residing in a state prison or youth correctional facility must be eligible for Medicaid or CHIP (or be eligible for CHIP if not for their incarceration status) as determined pursuant to an application filed before or during incarceration, and must have an expected release date no later than 60 days after initiation of demonstration-covered services as further specified in the STCs below.

20. The objective of this component of the demonstration is to facilitate individuals' access to certain healthcare services and case management, provided by Medicaid and CHIP participating providers, while individuals are incarcerated and allow them to establish relationships with community-based providers from whom they can receive services upon reentry to their communities. This bridge to coverage begins within a short time prior to release and is expected to promote continuity of coverage and care and improve health outcomes for justice-involved individuals. The Reentry Demonstration Initiative provides short-term Medicaid and CHIP enrollment assistance and pre-release coverage for certain services to facilitate successful care transitions, as well as improve the identification and treatment of certain chronic and other serious conditions to reduce acute care utilization in the period soon after release, and test whether it improves uptake and continuity of

medication-assisted treatment (MAT) and other SUD and behavioral health treatments, as appropriate for the individual.

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

a. Increase coverage, continuity of care, and appropriate service uptake through assessment of eligibility and availability of coverage for benefits in correctional facility settings prior to release;

b. Improve access to services prior to release and improve transitions and continuity of care into the community upon release and during reentry;

c. Improve coordination and communication between correctional systems, Medicaid and CHIP systems, managed care plans (as applicable), and community-based providers;

d. Increase additional investments in health care and related services, aimed at improving the quality of care for individuals in correctional facility settings, and in the community to maximize successful reentry post-release;

e. Improve connections between correctional facility settings and community services upon release to address physical and behavioral health needs;

f. Reduce all-cause deaths in the near-term post-release;

g. Reduce the number of emergency department visits and inpatient hospitalizations among recently incarcerated Medicaid and CHIP individuals through increased receipt of preventive and routine physical and behavioral health care; and

h. Provide interventions for certain behavioral health conditions, including use of stabilizing medications like long-acting injectable antipsychotics and medications for addiction treatment for SUDs where appropriate, with the goal of reducing overdose and overdose-related death in the near-term post-release.

21. Qualifying Criteria for Pre-Release Services. To qualify to receive services under this component of the demonstration, an individual must meet the following qualifying criteria:

a. Meet the definition of an inmate of a public institution, as specified in 42 CFR 435.1010, and be incarcerated in a correctional facility specified in STC 19; and

b. Have been found eligible for Medicaid or CHIP or be otherwise eligible for CHIP if not for their incarceration status.

22. Scope of Pre-Release Services. The pre-release services authorized under the Reentry Demonstration Initiative include the following services to be detailed in the implementation plan required under STC 28.

a. The covered pre-release services are:

   i. Case management to assess and address physical and behavioral health needs;

   ii. MAT for all types of SUDs as clinically appropriate, including coverage for medications in combination with counseling/behavioral therapies; and

   iii. A 30-day supply of all prescription medications and over-the-counter drugs (as clinically appropriate), provided to the individual immediately upon release from the correctional facility, consistent with approved Medicaid or CHIP state plan coverage authority and policy.

b. The expenditure authority for pre-release services through this initiative constitutes a limited exception to the federal claiming prohibition for medical assistance furnished to inmates of a public institution at clause (A) following section 1905(a) of the Act ("inmate exclusion rule"). Similarly, for CHIP, the expenditure authority for pre-release services constitutes a limited exception to the general exclusion of children who are inmates of a public institution from the definition of a targeted low-income child under section 2110(b)(2)(A) of the Act ("child exclusion rule"). Benefits and services for inmates of a public institution that are not approved in the Reentry Demonstration Initiative as described in these STCs and accompanying protocols, and not otherwise covered under the inpatient exception to the inmate exclusion rule or an exception in section 2110(b)(7) of the Act to the child exclusion rule, effective January 1, 2025, remain subject to the inmate exclusion rule or the child exclusion rule, as applicable. Accordingly, other benefits and services covered under the Kentucky Medicaid or CHIP State Plan(s), as relevant, that are not included in the above-described pre-release services benefit for qualifying Medicaid or CHIP individuals are not available to qualifying individuals through the Reentry Demonstration Initiative.

23. Participating Correctional Facilities. The pre-release services will be provided at correctional facilities, or outside of the correctional facilities, with appropriate transportation and security oversight provided by the correctional facility, subject to the Kentucky Cabinet for Health and Family Services' approval of a facility's readiness, according to the implementation timeline described in STC 27/28. Correctional facilities that are also institutions for mental diseases (IMDs) are not allowed to participate in the Reentry Demonstration Initiative.

24. Participating Providers.

a. Licensed, registered, certified, or otherwise appropriately credentialed or recognized practitioners under Kentucky's scope of practice statutes shall provide services within their individual scope of practice and, as applicable, receive

supervision required under their scope of practice laws and must be enrolled as Medicaid or CHIP providers.

b. Participating providers eligible to deliver services under the Reentry Demonstration Initiative may be either community-based or correctional facility-based providers.

c. All participating providers and provider staff, including correctional providers, shall have necessary experience and receive appropriate training, as applicable to a given correctional facility, prior to furnishing demonstration-covered pre-release services under the Reentry Demonstration Initiative.

d. Participating providers of reentry case management services may be community-based or correctional providers who have expertise working with justice-involved individuals.

25. Suspension of Coverage. Upon entry of a Medicaid or CHIP individual into a correctional facility, the Kentucky Cabinet for Health and Family Services must not terminate and generally shall suspend their Medicaid coverage or CHIP eligibility.

a. If an individual is not enrolled in Medicaid or CHIP when entering a correctional facility, the state must ensure that such an individual receives assistance with completing an application for Medicaid or CHIP and with submitting an application, unless the individual declines such assistance or wants to decline enrollment.

26. Interaction with Mandatory State Plan Benefits for Eligible Juveniles and Targeted Low-Income Children. To the extent Kentucky's reentry demonstration includes coverage otherwise required to be provided under section 1902(a)(84)(D) and section 2102(d)(2) of the Act, and because this coverage is included in the base expenditures used to determine the budget neutrality or allotment neutrality expenditure limit, the state will claim for these expenditures and related transitional non-service expenditures under this demonstration as well as include this coverage in the monitoring and evaluation of this demonstration.

27. Reentry Demonstration Initiative Implementation Timeline. Delivery of pre-release services under this demonstration will be implemented as described below. All participating correctional facilities must demonstrate readiness, as specified below, prior to participating in this initiative (FFP will not be available in expenditures for services furnished to qualifying individuals who are inmates in a facility before the facility meets the below readiness criteria for participation in this initiative). The Kentucky Cabinet for Health and Family Services will determine that each applicable facility is ready to participate in the Reentry Demonstration Initiative under this demonstration based on a facility-submitted assessment (and appropriate supporting documentation) of the facility's readiness to implement:

a. Pre-release Medicaid and CHIP application and enrollment processes for individuals who are not enrolled in Medicaid or CHIP prior to incarceration and who do not otherwise become enrolled during incarceration;

b. The screening process to determine an individual's qualification for pre-release services, per the eligibility requirements described in STC 21;

c. The provision or facilitation of pre-release services for a period of up to 60 days immediately prior to the expected date of release, including the facility's ability to support the delivery of services furnished by providers in the community that are delivered via telehealth, as applicable.

d. Coordination amongst partners with a role in furnishing health care services to individuals who qualify for pre-release services, including, but not limited to, physical and behavioral health community-based providers, social service departments, and managed care plans.

e. Appropriate reentry planning, pre-release case management, and assistance with care transitions to the community, including connecting individuals to physical and behavioral health providers and their managed care plan (as applicable), and making referrals to case management and community supports providers that take place throughout the 60-day pre-release period, and providing individuals with covered outpatient prescribed medications and over-the-counter drugs (a minimum 30-day supply as clinically appropriate) upon release, consistent with approved Medicaid or CHIP state plan coverage authority and policy;

f. Operational approaches related to implementing certain Medicaid and CHIP requirements, including but not limited to applications, suspensions, notices, fair hearings, reasonable promptness for coverage of services, and any other requirements specific to receipt of pre-release services by qualifying individuals under the Reentry Demonstration Initiative;

g. A data exchange process to support the care coordination and transition activities described in (d), (e), and (f) of this subsection subject to compliance with applicable federal, state, and local laws governing confidentiality, privacy, and security of the information that would be disclosed among parties;

h. Reporting of data requested by the Kentucky Cabinet for Health and Family Services to support program monitoring, evaluation, and oversight; and

i. A staffing and project management approach for supporting all aspects of the facility's participation in the Reentry Demonstration Initiative, including information on qualifications of the providers with whom the correctional facilities will partner for the provision of pre-release services.

28. Reentry Demonstration Initiative Implementation Plan. The state is required to submit a Reentry Demonstration Initiative Implementation Plan in alignment with the expectations outlined in the State Medicaid Director Letter (#23-003 Opportunities to Test Transition-Related Strategies to Support Community Reentry and Improve Care Transitions for Individuals who are Incarcerated). As such, the implementation plan will identify for each milestone, as well as each associated action, what the state anticipates to be the key implementation challenges and the state's specific plans to address these challenges. This will include any plans to phase in demonstration components over the lifecycle of the demonstration.

The state must submit the draft Implementation Plan to CMS no later than 120 calendar days after approval of the Reentry Demonstration Initiative. The state must submit any required clarifications or revisions to its draft Implementation Plan no later than 60 calendar days after receipt of CMS feedback. Once approved, the finalized Implementation Plan will be incorporated into the STCs as Attachment G titled "Reentry Demonstration Initiative Implementation Plan," and may be revised only with CMS approval.

CMS will provide the state with a template to support developing and obtaining approval of the Implementation Plan. Contingent upon CMS's approval of the state's Implementation Plan, the state may begin claiming FFP for services provided through the Reentry Demonstration Initiative starting from the date of inclusion of the Implementation Plan as an attachment to these STCs.

29. Reentry Demonstration Initiative Reinvestment Plan. To the extent that the Reentry Demonstration Initiative covers services that are the responsibility of and were previously provided or paid by the correctional facility or carceral authority with custody of qualifying individuals, the state must reinvest all new federal dollars, equivalent to the amount of FFP projected to be expended for such services, as further defined in the Reentry Demonstration Initiative Reinvestment Plan (Attachment H). The Reinvestment Plan will define the amount of reinvestment required over the term of the demonstration, based on an assessment of the amount of projected expenditures for which reinvestment is required pursuant to this STC. FFP projected to be expended for new services covered under the Reentry Demonstration Initiative, defined as services not previously provided or paid by the correctional facility or carceral authority with custody of qualifying individuals prior to the facility's implementation of the Reentry Demonstration Initiative (including services that are expanded, augmented, or enhanced to meet the requirements of the Reentry Demonstration Initiative, with respect to the relevant increase in expenditures, as described in Attachment H the Reentry Demonstration Initiative Reinvestment Plan), is not required to be reinvested pursuant to this STC.

a. Reinvestments in the form of non-federal expenditures totaling the amount of new federal dollars, as described above, must be made over the course of the demonstration period. Allowable reinvestments include, but are not limited to:

    i. The state share of funding associated with new services covered under the Reentry Demonstration Initiative, as specified in this STC;

ii. Improved access to behavioral and physical community-based health care services and capacity focused on meeting the health care needs and addressing the needs of individuals who are incarcerated (including those who are soon-to-be released), those who have recently been released, and those who may be at higher risk of criminal justice involvement, particularly due to untreated behavioral health conditions;

iii. Improved access to and/or quality of carceral health care services, including by covering new, enhanced, or expanded pre-release services authorized via the Reentry Demonstration Initiative opportunity;

iv. Improved health information technology (IT) and data sharing subject to compliance with applicable federal, state, and local laws governing confidentiality, privacy, and security of the information that would be disclosed among parties;

v. Increased community-based provider capacity that is particularly attuned to the specific needs of, and able to serve, justice-involved individuals or individuals at risk of justice involvement;

vi. Expanded or enhanced community-based services and supports, including services and supports to meet the needs of the justice-involved population; and

vii. Any other investments that aim to support reentry, smooth transitions into the community, divert individuals from incarceration or re-incarceration, or better the health of the justice-involved population, including investments that are aimed at interventions occurring both prior to and following release from incarceration into the community.

b. The reinvestment plan will describe whether privately-owned or -operated carceral facilities would receive any of the reinvested funds and, if so, the safeguards the state proposes to ensure that such funds are used for the intended purpose and do not have the effect of increasing profit or operating margins for privately-owned or -operated carceral facilities.

c. Within six months of approval, the state will submit a Reentry Demonstration Initiative Reinvestment Plan (Attachment H) for CMS approval that memorializes the state's reinvestment approach. The Reinvestment Plan will also identify the types of expected reinvestments that will be made over the demonstration period. Actual reinvestments will be reported to CMS in Attachment H titled "Reentry Demonstration Initiative Reinvestment Plan."

30. Reentry Demonstration Initiative Planning and Implementation.

a. The Reentry Demonstration Initiative Planning and Implementation Program will provide expenditure authority to fund supports needed for Medicaid and CHIP pre-release application and suspension/unsuspension planning and purchase of

certified electronic health record (EHR) technology to support Medicaid and CHIP pre-release applications In addition, Reentry Demonstration Initiative planning and implementation funds will provide funding over the course of the demonstration to support planning and IT investments that will enable implementation of the Reentry Demonstration Initiative services covered in a period for up to 60 days immediately prior to the expected date of release, and for care coordination to support reentry. These investments will support collaboration and planning among the Kentucky Cabinet for Health and Family Services and Qualified Applicants listed in STC 30(d) below. The specific use of this funding will be proposed by the qualified applicant submitting the application, as the extent of approved funding will be determined according to the needs of the entity. Allowable expenditures are limited to only those that support Medicaid-related expenditures and/or demonstration-related expenditures (and not other activities or staff in the correctional facility) and must be properly cost-allocated to Medicaid and CHIP. These allowable expenditures may include the following:

i. **Technology and IT Services.** Expenditures for the purchase of technology for Qualified Applicants which are to be used for assisting the Reentry Demonstration Initiative population with Medicaid and CHIP application and enrollment for demonstration coverage (e.g., for inmates who would be eligible for CHIP but for their incarceration status and coordinating pre-release and post-release services for enrollees). This includes the development of electronic interfaces for Qualified Applicants listed in STC 30(d). to communicate with Medicaid and CHIP IT systems to support Medicaid and CHIP enrollment and suspension/unsuspension and modifications. This also includes support to modify and enhance existing IT systems to create and improve data exchange and linkages with Qualified Applicants listed in STC 30(d), in order to support the provision of pre-release services delivered in the period up to 60 days immediately prior to the expected date of release and reentry planning.

ii. **Hiring of Staff and Training.** Expenditures for Qualified Applicants listed in STC 30(d). to recruit, hire, onboard, and train additional and newly assigned staff to assist with the coordination of Medicaid and CHIP enrollment and suspension/unsuspension, as well as the provision of pre-release services in a period for up to 60 days immediately prior to the expected date of release and for care coordination to support reentry for justice-involved individuals. Qualified Applicants may also require training for staff focused on working effectively and appropriately with justice-involved individuals.

iii. **Adoption of Certified Electronic Health Record Technology.** Expenditures for providers' purchase or necessary upgrades of certified electronic health record (EHR) technology and training for the staff that will use the EHR.

iv. **Purchase of Billing Systems**. Expenditures for the purchase of billing systems for Qualified Applicants.

v. **Development of Protocols and Procedures**. Expenditures to support the specification of steps to be taken in preparation for and execution of the Medicaid and CHIP enrollment process, suspension/unsuspension process for eligible individuals, and provision of care coordination and reentry planning for a period for up to 60 days immediately prior to the expected date of release for individuals qualifying for Reentry Demonstration Initiative services.

vi. **Additional Activities to Promote Collaboration**. Expenditures for additional activities that will advance collaboration among Kentucky's Qualified Applicants in STC 30(d). This may include conferences and meetings convened with the agencies, organizations, and other stakeholders involved in the initiative.

vii. **Planning**. Expenditures for planning to focus on developing processes and information sharing protocols to: (1) identifying individuals who are potentially eligible for Medicaid and CHIP; (2) assisting with the completion of a Medicaid or CHIP application; (3) submitting the Medicaid or CHIP application to the county social services department or coordinating suspension/unsuspension; (4) screening for eligibility for pre-release services and reentry planning in a period for up to 60 days immediately prior to the expected date of release; (5) delivering necessary services to eligible individuals in a period for up to 60 days immediately prior to the expected date of release and care coordination to support reentry; and (6) establishing on-going oversight and monitoring process upon implementation.

viii. **Other activities to support a milieu appropriate for provision of pre-release services.** Expenditures to provide a milieu appropriate for pre-release services in a period for up to 60 days immediately prior to the expected date of release, including accommodations for private space such as movable screen walls, desks, and chairs, to conduct assessments and interviews within correctional institutions, and support for installation of audio-visual equipment or other technology to support provision of pre-release services delivered via telehealth in a period for up to 60 days immediately prior to the expected date of release and care coordination to support reentry. Expenditures may not include building, construction, or refurbishment of correctional facilities.

b. The state may claim FFP in Reentry Demonstration Initiative Planning and Implementation Program expenditures for no more than the annual amounts outlined in Table 1. In the event that the state does not claim the full amount of FFP for a given demonstration year as defined in STC 55, the unspent amounts will roll over to one or more demonstration years not to exceed this demonstration

period and the state may claim the remaining amount in a subsequent demonstration year.

Table 1. Annual Limits of Total Computable Expenditures for Reentry Demonstration Initiative Planning and Implementation Program

	DY 7
Total Computable Expenditures	$776,250

c. Reentry Demonstration Initiative Planning and Implementation funding will receive the applicable administrative match for the expenditure.

d. Qualified Applicants for the Reentry Demonstration Initiative Planning and Implementation Program will include the state Medicaid/CHIP Agency, correctional facilities, other state agencies supporting carceral health, Probation Offices, and other entities as relevant to the needs of justice-involved individuals, including health care providers, as approved by the state Medicaid/CHIP agency.

VII. DELIVERY SYSTEM

31. Overview. TEAMKY 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.

VIII. GENERAL REPORTING REQUIREMENTS

32. 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.

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

34. 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.

35. Monitoring Protocol. The state must submit to CMS a Monitoring Protocol no later than 150 calendar days after the approval of the demonstration. The state must submit a revised Monitoring Protocol within 60 calendar days after receipt of CMS's comments. Once approved, the Monitoring Protocol will be incorporated in the STCs as Attachment I. In addition, the state must submit an updated or a separate Monitoring Protocol for any amendments to the demonstration no later than 150 calendar days after the approval of the demonstration amendment. Such amendment Monitoring Protocols are subject to the same requirement of revisions and CMS approval, as described above.

At a minimum, the Monitoring Protocol must affirm the state's commitment to conduct Quarterly and Annual Monitoring Reports in accordance with CMS's guidance and technical assistance and using CMS-provided reporting templates, as applicable and relevant for different policies. Any proposed deviations from CMS's guidance should be documented in the Monitoring Protocol. The Monitoring Protocol must describe the quantitative and qualitative elements on which the state will report through Quarterly and Annual Monitoring Reports. For the overall demonstration as well as specific policies where CMS provides states with a suite of quantitative monitoring metrics (e.g., those described under the performance metrics section in STC 36.b), the state is required to calculate and report such metrics leveraging the technical specifications provided by CMS, as applicable. The Monitoring Protocol must specify the methods of data collection and timeframes for reporting on the demonstration's progress as part of the Quarterly and Annual Monitoring Reports. In alignment with CMS guidance, the Monitoring Protocol must additionally specify the state's plans and timeline on reporting metrics data stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, primary language, disability status, sexual orientation and gender identity, and geography) and demonstration component.

The Monitoring Protocol requires specifying a selection of quality of care and health outcomes metrics and population stratifications based on CMS's upcoming guidance on the Disparities Sensitive Measure Set, and outlining the corresponding data sources and reporting timelines, as applicable to the demonstration initiatives and populations. If needed, the state may submit an amendment to the Monitoring Protocol within 150 days after the receipt of the final Disparities Sensitive Measure Set from CMS. This set of measures consists of metrics known to be important for addressing disparities in Medicaid/CHIP (e.g. the National Quality Forum (NQF) "disparities-sensitive" measures) and prioritizes key outcome measures and their clinical and non-clinical (i.e. social) drivers. The Monitoring Protocol must also outline the state's planned approaches and parameters to track implementation progress and performance relative to the goals and milestones including relevant transitional, non-service expenditures investments, as captured in these STCs, or other applicable implementation and operations protocols.

In addition, the state must describe in the Monitoring Protocol methods and the timeline to collect and analyze relevant non-Medicaid administrative data to help calculate applicable monitoring metrics. These sources may include but are not limited to data related to carceral status, Medicaid eligibility, and the health care needs of individuals who are incarcerated and returning to the community. Across data sources, the state must make efforts to consult with relevant non-Medicaid agencies to collect and use data in ways that support analyses of data on demonstration beneficiaries and subgroups of beneficiaries, in accordance with all applicable requirements concerning privacy and the protection of personal information.

For the qualitative elements (e.g., operational updates as described in STC 36.a), CMS will provide the state with guidance on narrative and descriptive information which will supplement the quantitative metrics on key aspects of the demonstration policies. The quantitative and qualitative elements will comprise the state's Quarterly and Annual Monitoring Reports.

36. 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. Operational Updates. 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 state's selection and reporting of quality of care and health outcome metrics outlined above must also accommodate the Reentry Demonstration Initiative. In addition, the state is required to report on metrics aligned with tracking progress with implementation and toward meeting the milestones of the Reentry Demonstration Initiative. CMS expects such metrics to include, but not be limited to: administration of screenings to identify individuals who qualify for pre-release services, utilization of applicable pre-release and post-release services as defined in STC 22, provision of health or social service referral pre-release, participants who received case management pre-release and were enrolled in case management post-release, and take-up of data system enhancements among participating correctional facility settings. In addition, the state is expected to monitor the number of individuals served and types of services rendered under the demonstration. Also, in alignment with the state's Reentry Initiative Implementation Plan, the state must also provide in its Monitoring Reports narrative details outlining its progress with implementing the initiative, including any challenges encountered and how the state has addressed them or plans to address them. This information must also capture the transitional, non-service expenditures, including enhancements in the data infrastructure and information technology.

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.

37. Reentry Demonstration Initiative Mid-Point Assessment. The state must contract with an independent entity to conduct a mid-point assessment of the Reentry Demonstration Initiative and complete a Reentry Demonstration Initiative Mid-Point Assessment.

The Mid-Point Assessment must integrate all applicable implementation and performance data from the first 2.5 years of implementation of the Reentry Demonstration Initiative. The report must be submitted to CMS by the end of the third year of the demonstration. In the event that the Reentry Demonstration Initiative is implemented at a timeline within the demonstration approval period, the state and CMS will agree to an alternative timeline for submission of the Mid-Point Assessment. The state must submit a revised Mid-Point Assessment within 60 calendar days after receipt of CMS's comments, if any. If requested, the state must brief CMS on the report.

The state must require the independent assessor to provide a draft of the Mid-Point Assessment to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies used, the findings on demonstration progress and performance, including identifying any risks of not meeting milestones and other operational vulnerabilities, and recommendations for overcoming those challenges and vulnerabilities. In the design, planning, and execution of the Mid-Point Assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: provider participation in the state's Reentry Demonstration Initiative, eligible individuals, and other key partners in correctional facility and community settings.

For milestones and measure targets at medium to high risk of not being achieved, the state and CMS will collaborate to determine whether modifications to the Reentry Demonstration Initiative Implementation Plan and the Monitoring Protocol are necessary for ameliorating these risks, with any modifications subject to CMS approval. Elements of the Mid-Point Assessment must include, but not be limited to:

a. An examination of progress toward meeting each milestone and timeframe approved in the Reentry Demonstration Initiative Implementation Plan and toward meeting the targets for performance metrics as approved in the Monitoring Protocol;

b. A determination of factors that affected achievement on the milestones and progress toward performance metrics targets to date;

c. A determination of factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets; and

d. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state's Reentry Demonstration Initiative Implementation Plan or to pertinent factors that the state can influence that will support improvement.

CMS will provide additional guidance for developing the state's Reentry Initiative Mid-Point Assessment.

38. 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.

39. 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 32.

40. 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.

41. 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.

IX. 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.

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

43. 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

44. 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").

45. 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.

46. 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 36, 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.

47. 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.

48. 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.

49. 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**.**

50. 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.

X. BUDGET NEUTRALITY

51. 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 53. 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.

52. 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 54 and STC 55, 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.

53. 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 53(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 57. 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 TEAMKY 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.

54. Substance Use Disorder Expenditures. As part of the SUD initiative, the state may receive FFP for the continuum of services specified in Table 4 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 4 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 2 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 57).

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 2: Hypothetical Budget Neutrality Test 1								
Eligibility group	**Trend Rate**	**DY 1**	**DY 2**	**DY 3**	**DY 4**	**DY 5**	**DY 6**	**DY7**
SUD PMPM	5.0%	$1,430.18	$1,501.69	$1,576.77	$1,655.61	$1,738.39	$1,759.72	$1,759.72

55. Hypothetical Budget Neutrality Test 2: Reentry Demonstration Initiative Expenditures. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 2. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test 2 are counted as WW expenditures under the Main Budget Neutrality Test.

MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 7
Reentry	PC	Both	6.4%	$1,496.70
Reentry Non-Services	Agg	Both	N/A	$776,250

56. 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.

57. 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.

58. 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%**

DY7 October 1, 2023- September 30, 2024	Cumulative budget neutrality expenditure cap plus:	**0%**

59. 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.

60. 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.

XI. CHIP MONITORING ALLOTMENT NEUTRALITY

61. Reporting Expenditures Subject to the Title XXI Allotment Neutrality Agreement. The following describes the reporting of expenditures subject to the allotment neutrality agreement for this demonstration:

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-21 reporting instructions outlined in section 2115 of the State Medicaid Manual.

b. Use of Waiver Forms. Title XXI demonstration expenditures will be reported on the following separate forms designated for CHIP (i.e., Forms CMS-21 Waiver and/or CMS-21P Waiver), identified by the demonstration project number assigned by CMS (including project number extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made). The state must submit separate CMS-21 waiver forms for each title XXI demonstration population.

c. Premiums. Any premium contributions collected under the demonstration shall be reported to CMS on the CMS-21 Waiver form (specifically lines 1A through 1D as applicable) for each title XXI demonstration population that is subject to

premiums, in order to assure that the demonstration is properly credited with the premium collections.

d. Claiming Period. All claims for expenditures related to the demonstration (including any cost settlements) must be made within two years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state must continue to identify separately, on the Form CMS-21 Waiver, net expenditures related to dates of service during the operation of the demonstration.

62. Standard CHIP Funding Process. The standard CHIP funding process will be used during the demonstration. The state will continue to estimate matchable CHIP expenditures on the quarterly Forms CMS-21B for CHIP. On these forms estimating expenditures for the title XXI funded demonstration populations, the state shall separately identify estimates of expenditures for each applicable title XXI demonstration population.

a. CMS will make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state must report demonstration expenditures through Form CMS-21W and/or CMS-21P Waiver for the CHIP population. Expenditures reported on the waiver forms must be identified by the demonstration project number assigned by CMS (including project number extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made). CMS will reconcile expenditures reported on the CMS-21W/CMS-21P Waiver form with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

63. Title XXI Administrative Costs. All administrative costs (i.e., costs associated with the title XXI state plan and the title XXI funded demonstration populations identified in these STCs) are subject to the title XXI 10 percent administrative cap described in section 2105(c)(2)(A) of the Act.

64. Limit on Title XXI Funding. The state will be subject to a limit on the amount of federal title XXI funding that the state may receive on eligible CHIP state plan populations and the CHIP demonstration populations described in STC XX during the demonstration period. Federal title XXI funds for the state's CHIP program (i.e., the approved title XXI state plan and the demonstration populations identified in these STCs) are restricted to the state's available allotment and reallocated funds. Title XXI funds (i.e., the allotment or reallocated funds) must first be used to fully fund costs associated with CHIP state plan populations. Demonstration expenditures are limited to remaining funds.

65. Exhaustion of Title XXI Funds for CHIP Population. If the state exhausts the available title XXI federal funds in a federal fiscal year during the period of the demonstration, the

state must continue to provide coverage to the approved title XXI separate state plan population.

XII. EVALUATION

66. 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 32.

67. 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.

68. 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.

69. 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.

70. 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).

Evaluation of the Reentry Demonstration Initiative must be designed to examine whether the initiative expands Medicaid coverage through increased enrollment of eligible individuals, and efficient high-quality pre-release services that promote continuity of care into the community post-release. In addition, in alignment with the goals of the Reentry Demonstration Initiative in the state, the evaluation hypotheses must focus on, but not be limited to: cross-system communication and coordination; connections between correctional and community services; access to and quality of care in correctional and community settings; preventive and routine physical and behavioral health care utilization; non-emergent emergency department visits and inpatient hospitalizations; and all-cause deaths.

The state must also provide a comprehensive analysis of the distribution of services rendered by type of service over the duration of up to 60-days coverage period before the individual's expected date of release—to the extent feasible—and discuss in the evaluation any relationship identified between the provision and timing of particular services with

salient post-release outcomes, including utilization of acute care services for chronic and other serious conditions, overdose, and overdose- and suicide-related and all-cause deaths in the period soon after release. In addition, the state is expected to assess the extent to which this coverage timeline facilitated providing more coordinated, efficient, and effective reentry planning; enabled pre-release management and stabilization of clinical, physical, and behavioral health conditions; and helped mitigate any potential operational challenges the state might have otherwise encountered in a more compressed timeline for coverage of pre-release services.

The demonstration's evaluation efforts will be expected to include the experiences of correctional and community providers, including challenges encountered, as they develop relationships and coordinate to facilitate transition of individuals into the community. Finally, the state must conduct a comprehensive cost analysis to support developing estimates of implementing the Reentry Demonstration Initiative, including covering associated services.

71. 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.

72. 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.

73. 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.

74. 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.

75. 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.

76. 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.

77. 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.

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

Effective upon CMS's approval of the SUD Implementation Protocol, as described in STC 79, 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 4. 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 4: 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 provided to individuals in IMDs

	services covered)	
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

78. Methadone Treatment Services. "Methadone Treatment Services" will be covered in the Medicaid state plan.

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

79. 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.

80. 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 80. 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.

81. 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.

82. 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.

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

84. 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 70. 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.

85. 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.

86. 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

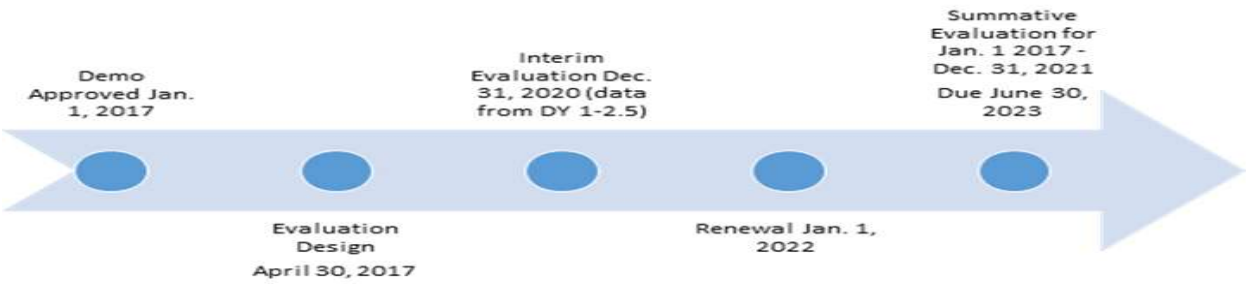
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses,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

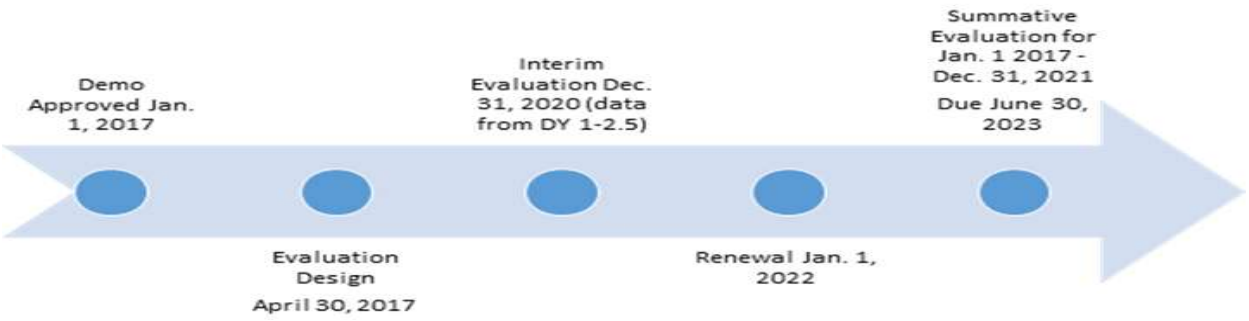
The format for the Interim and Summative Evaluation reports is as follows:

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.

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

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 79) 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 80) 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 36).
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.

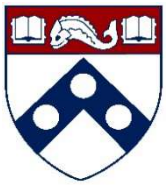
[4] Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*. MMWR Morb Mortal Wkly Rep 2017;66.

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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Tables and Figures

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, "TEAMKY" (formerly 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. increased access to SUD providers 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. waiver of the Medicaid Institutions for Mental Disease (IMD) exclusion, allowing reimbursement for SUD treatment during short-term residential stays at certified IMD facilities with greater than 16 beds; and
3. expanded coverage of medication-assisted treatment (MAT) services, 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

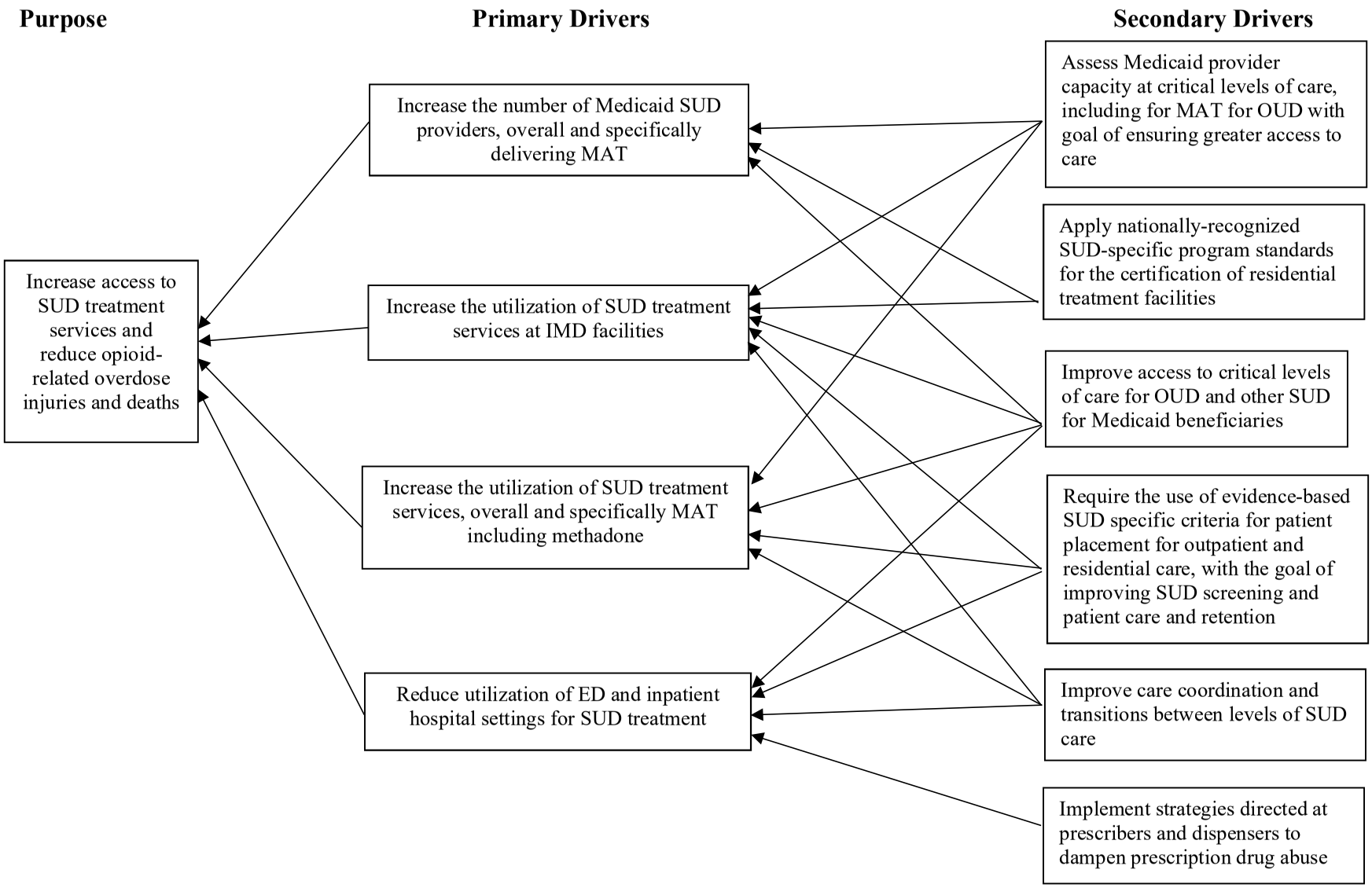

Table 2. Summary of Key Evaluation Questions, Hypotheses, Data Sources, and Analytic Approaches

*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)	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
Primary Driver (Increase the utilization of SUD treatment services, overall and specifically MAT including methadone)	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:

$$Y_{i,m} = \beta_0 + \beta_1 \, time_m + \beta_2 \, I[post]_m + \beta_3 \, time_m \times I[post]_m + \beta' \, controls_{i,m} + \varepsilon_{i,m}$$

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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6. Kentucky Cabinet for Health and Family Services. Encounter Data Submission and Review Process. August 15, 2018.

Attachment G: Reentry Demonstration Initiative Implementation Plan

Attachment H: Reentry Demonstration Initiative Reinvestment Plan