DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-26-12 Baltimore, Maryland 21244-1850



December 12, 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 (the "state") request for a five-year extension of the "TEAMKY" section 1115 demonstration (Project Numbers11-W-00306/4 and 21-W-00067/4) (the "demonstration") in accordance with section 1115(a) of the Social Security Act ("the Act"). Approval of this extension allows Kentucky to (1) continue to provide substance use disorder (SUD) treatment and withdrawal management services for individuals residing in an institution for mental diseases (IMD), (2) continue coverage for former foster care youth (FFCY) who turned 18 on or before December 31, 2022, under age 26, who were in foster care under the responsibility of another state or tribe when they turned 18, and (3) continue authority for the reentry demonstration initiative.

CMS is also approving two pending amendment requests, submitted May 31, 2023 and December 30, 2023, to (1) as an addition to the existing SUD program provide Recovery Residence Support Services, to individuals who meet specific eligibility criteria, (2) permit reimbursement for medically necessary short-term, inpatient treatment services within settings that qualify as IMDs for Medicaid eligible adults with serious mental illness (SMI), and (3) to implement a health-related social needs (HRSN) initiative for episodic housing interventions with clinical services with room and board (including short-term pre-procedure housing and short-term post-procedure housing).

This approval is effective January 1, 2025 through December 31, 2029, upon which date, unless extended or otherwise amended, all authorities granted to operate this demonstration will expire. CMS's approval of this section 1115(a) demonstration is subject to the limitations specified in the attached expenditure authorities, special terms and conditions (STC), and any supplemental attachments defining the nature, character, and extent of federal involvement in this project. The state may deviate from the Medicaid state plan requirements only to the extent those requirements have been specifically listed not applicable to expenditures under the demonstration.

## Extent and Scope of Demonstration Extension

#### Substance Use Disorder (SUD)

Pursuant to the opportunity announced by CMS via State Medicaid Director Letter (SMDL) #17-003, this demonstration currently authorizes expenditure authority for treatment and recovery services provided to Medicaid-enrolled individuals in IMDs for opioid use disorder (OUD) and SUD services. The TEAMKY demonstration extension allows Kentucky to continue providing its OUD/SUD treatment program available to all Medicaid beneficiaries to ensure that a broad continuum of care is available to Kentuckians.

## Former Foster Care Youth (FFCY)

The TEAMKY demonstration will maintain coverage for FFCY 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.

Section 1002(a) of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act created a new Former Foster Care Children (FFCC) Medicaid state plan eligibility group, providing coverage for individuals who were receiving Medicaid while in foster care under the responsibility of any state; however, the new requirements apply exclusively to those who turn 18 on or after January 1, 2023. As a result, Kentucky still needs section 1115 demonstration authority to continue coverage for individuals who turned 18 years old on or before December 31, 2022, until a beneficiary reaches age 26.

#### Reentry Demonstration Initiative

On July 2, 2024, Kentucky received approval 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 aligned with CMS's "Reentry Demonstration Opportunity" as described in the State Medicaid Director Letter (SMDL) released on April 17, 2023. This extension continues demonstration authority for Kentucky to provide a set of pre-release benefits for certain individuals who are inmates residing in state prisons or youth correctional facilities.

The demonstration will also continue to provide coverage under the Reentry Demonstration Initiative to eligible juveniles described in section 1902(nn)(2) of the Act 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.

As described in the demonstration STCs, Kentucky is required to submit a Reentry Initiative 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.

#### **Extent and Scope of New Demonstration Initiatives**

With this extension, CMS is approving the following three new initiatives.

#### Serious Mental Illness (SMI)

Kentucky will provide additional services to enhance the comprehensive and integrated behavioral health system for adults with SMI. This extension will allow the state to continue to improve access to comprehensive behavioral health services by building a Medicaid behavioral health delivery system pointing to integrated and recovery-oriented care that aligns with evidence-based best practices. The state will continue to build on the longstanding authorities granted under this demonstration to enhance the benefit package and continue coverage for a continuum of behavioral health care services that emphasize screening, community-based services, residential treatment when appropriate, and enhanced peer recovery supports.

The SMI program will limit eligibility to individuals age 21-64, who receive a full Medicaid state plan benefit package, either through a Medicaid state plan eligibility group or through the FFCY demonstration population, with income up to 213 percent of the federal poverty level (FPL). The state will not impose an income limit for state plan eligible former foster care children, demonstration eligible FFCY, and individuals determined aged, blind, or disabled. Individuals that receive limited Medicaid benefits or who are receiving long-term care services and supports (LTSS) are not eligible for the SMI program.

In alignment with SMDL #18-011 and consistent with the demonstration's STCs, the state is required to conduct systematic monitoring of the demonstration and secure an independent entity to conduct a Mid-Point Assessment of the demonstration, in accordance with CMS-identified metrics and applicable guidance, which will support tracking Kentucky's statewide progress towards its demonstration milestones and goals and identifying any necessary mitigation strategies. Furthermore, the state will develop a robust Evaluation Design to support a comprehensive independent evaluation of the demonstration to assess whether the demonstration initiatives are effective in producing the desired outcomes for beneficiaries, as well as the state's Medicaid program overall. The state and CMS will also work collaboratively such that the state's demonstration monitoring and evaluation efforts accommodate data collection and analyses stratified by key subpopulations of interest—to the extent feasible—to inform a fuller understanding of existing disparities in access, utilization, and health outcomes, and how the demonstration might support bridging any such inequities.

## Health Related Social Needs (HRSN) Services

CMS is authorizing the state to offer coverage of certain services that address HRSN for qualifying beneficiaries, as evidence indicates that these benefits are critical drivers of an

individual's access to health services that keep them well. <sup>1,2</sup> Under this demonstration, the state will receive authority to cover the following HRSN housing interventions: episodic housing interventions with clinical services with room and board, including short-term pre-procedure housing and short-term post-transition housing. Coverage of targeted HRSN services and supports is likely to assist in promoting the objectives of Medicaid because it is expected to help beneficiaries stay connected to coverage and access to needed health care. The housing support services authorized under the demonstration are expected to stabilize the housing situations of eligible beneficiaries and thus increase the likelihood that they will keep receiving and benefitting from the Medicaid and demonstration-covered services to which they are entitled.

Coverage of targeted HRSN services and supports is likely to assist in promoting the objectives of Medicaid because it is expected to help beneficiaries stay connected to coverage and access to needed health care. The housing support services authorized in the demonstration are expected to stabilize the housing situations of eligible Medicaid beneficiaries and thus increase the likelihood that they will keep receiving and benefitting from the Medicaid-covered services to which they are entitled.

Coverage of targeted, clinically appropriate HRSN services will also provide a regular source of care to meet individuals' comprehensive health needs. This is likely to improve health outcomes directly, as well as improve the use of other clinical services. By providing the short-term services needed to stabilize housing, this demonstration will test whether the individual's health outcomes will improve in addition to their utilization of appropriate care.

Moreover, the Medicaid statute, including both sections 1905 and 1915 of the Social Security Act (the Act), already includes mechanisms that reflect the critical role of upstream services (i.e., those that help avert more intensive medical interventions) in meeting the medical assistance needs of certain Medicaid-eligible populations (e.g., individuals with disabilities).

Medical assistance made available under a state plan option authorized under section 1915(i) of the Act provides that same package of home and community-based services (HCBS) to individuals meeting needs-based criteria that are less stringent than criteria required for institutional placement. These services are also intended to avert a need for nursing facility care.

Available<sup>3</sup> evidence suggests there may be populations in addition to those eligible under 1915(c) or 1915(i) criteria that would benefit clinically from the section 1915(c) or 1915(i)

<sup>&</sup>lt;sup>1</sup> As discussed in a letter to State Health Officials issued on January 7, 2021,

https://www.medicaid.gov/federalpolicy-guidance/downloads/sho21001.pdf, addressing Social Determinants of Health can more effectively improve population health, reduce disability, and lower overall health care costs in the Medicaid program. While "social determinants of health" is a broad term that relates to the health of all people, HRSN relates more specifically to an individual's adverse conditions reflecting needs that are unmet and contribute to poor health. See also https://www.healthaffairs.org/do/10.1377/forefront.20191025.776011/full/

<sup>&</sup>lt;sup>2</sup> Bachrach, D., Pfister, H., Wallis, K., Lipson, M. Addressing Patients' Social Needs: An Emerging Business Case for Provider Investment. The Commonwealth Fund; 2014;

https://www.commonwealthfund.org/sites/default/files/documents/ media files publications fund report 2014 may\_1749\_bachrach\_addressing\_patients\_social\_needs\_v2.pdf.

<sup>&</sup>lt;sup>3</sup> September 23, 2021. ASPE Contractor Project Report: Building the Evidence Base for Social Determinants of Health Interventions. https://aspe.hhs.gov/reports/building-evidence-base-social-determinants-health-interventions

services described above, as well as additional upstream HRSN services. Additional research is needed to better understand the effects of providing these types of services to a broader group of people. To that end, this demonstration will test whether expanding eligibility for these services to additional populations or providing additional services can improve the health outcomes of certain Medicaid beneficiaries. The demonstration will also test whether extending eligibility for a broader range of Medicaid beneficiaries or providing additional services will help to maintain coverage by preventing health-related incidents that could lead to enrollment churn. <sup>4</sup>

Moreover, access to these services for individuals with poorer health outcomes may help to reduce health disparities. Expanding who can receive these services is expected to help a broader range of Medicaid beneficiaries not only receive, and benefit from, the medical assistance to which they are entitled, but also, these services are expected to further reduce health disparities often rooted in socioeconomic factors. <sup>5</sup> Thus, broadening the availability of certain HRSN services is expected to promote coverage and access to care, improve health outcomes, reduce disparities, and create long-term, cost-effective alternatives or supplements to traditional medical services.

Under this demonstration, Kentucky will receive authority for HRSN housing assistance services classified as episodic housing interventions with clinical services with room and board. Duration caps apply to each category of housing assistance (that is, episodic housing interventions with clinical services with room and board). Episodic housing interventions may be covered up to a combined 6 months per beneficiary, per rolling year. For the 6-month cap, coverage will be permitted in one or more spans or episodes as long as the total duration remains under the cap for the rolling year or demonstration period. However, if a beneficiary is considered to have received room and board-only support because that intervention was covered for another member of the beneficiary's household, the beneficiary still may receive up to 6 months of coverage for episodic interventions in the same 12-month period.

As specified further in the STCs, HRSN services authorized in this demonstration must be clinically appropriate for the beneficiary. Beneficiaries qualified to receive HRSN services are those eligible for and enrolled in Medicaid with a documented medical need for the services. Attachment N, which CMS is approving concurrently with this demonstration approval, reflects a comprehensive list of the populations, clinical criteria, and social risk factors that the state will incorporate into the post-approval protocol that will define beneficiary qualifications for HRSN services.

CMS also expects the state to maintain existing state funding and efforts for HRSN services, without this demonstration authority supplanting existing efforts, and to have in place partnerships with other state and local entities to coordinate possible pathways to permanency for services to be provided without demonstration authorities

<sup>5</sup> April 1, 2022. Addressing Social Determinants of Health: Examples of Successful Evidence-Based Strategies and Current Federal Effort.

https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fae7474af82/SDOH-Evidence-Review.pdf

<sup>&</sup>lt;sup>4</sup> April 12, 2021. Medicaid Churning and Continuity of Care: Evidence and Policy Considerations Before and After the COVID-19 Pandemic. <u>https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf</u>

## HRSN Infrastructure

CMS is authorizing expenditure authority for the state to claim federal financial participation for certain infrastructure expenditures to support the development and implementation of HRSN services, as specified further in the STCs.

#### Provider Rate Increase

Given the level of projected HRSN expenditures under this approval, Kentucky is not subject to the provider rate increase requirement.<sup>6</sup>

## Recovery Residence Support Services (RRSS)

CMS is approving Kentucky's amendment request to provide RRSS, which are non-clinical activities necessary to support beneficiaries recovering with SUD. Individuals eligible for RRSS must be receiving full Medicaid coverage, eligible through mandatory or optional Medicaid eligibility groups, or the FFCY demonstration population, who are ages 18 or older. Kentucky will include the following additional eligibility criteria for RRSS:

- a) Be participating in a Behavioral Health Conditional Dismissal Program (BHCDP)
- b) Reside in a BHCDP-approved Recovery Residence,
- c) Meet American Society of Addiction Medicine (ASAM) Level of Care 2.7 or less, and
- d) Be experiencing homelessness, unemployment, or have a history of criminal justice involvement.

Beneficiaries may receive RRSS for up to 90 days per calendar year. RRSS may provide various non-clinical services including, but not limited to, evidence-based non-clinical groups, recovery management planning, release prevention strategies, and transition planning. Kentucky will require that RRSS services be delivered by community-based providers contracted with Kentucky Medicaid managed care organizations. The state will not receive FFP under RRSS for room and board costs for RRSS providers.

# Budget Neutrality<sup>7</sup> / Children's Health Insurance Program (CHIP) Allotment Neutrality

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 likely would have been in that state absent the demonstration. The demonstration extension is projected to be budget neutral to the federal government. The state will be held to the budget neutrality monitoring and reporting requirements as outlined in the STCs. In requiring demonstrations to be budget neutral, CMS is constantly striving to achieve a balance between its interest in preserving

<sup>&</sup>lt;sup>6</sup> CMS developed the de minimis amount by arraying in order the requests we had from states for HRSN expenditures, as well as the range of likely costs for increasing provider rates, and examined the relationship between these ranges. CMS determined the rate increase requirement only applies if the annualized (divided across lifespan of demonstration period) expenditure authority for HRSN services and infrastructure is equal to or greater than the lesser of 0.5% of the state's annual Medicaid expenditures and \$50 million. Kentucky's annual HRSN expenditure authority is below \$50M and 0.5% of the state's total annual Medicaid spend.

<sup>&</sup>lt;sup>7</sup> https://www.medicaid.gov/medicaid/section-1115-demonstrations/budget-neutrality/index.html

the fiscal integrity of the Medicaid program and its interest in facilitating state innovation through section 1115 demonstration approvals.

Under this extension, for existing Medicaid Expenditure Groups (MEGs), except for the reentry demonstration initiative, CMS calculated the "without waiver" (WOW) baseline (which refers to the projected expenditures that could have occurred absent the demonstration and which is the basis for the budget neutrality expenditure limit for each approval period) by using a weighted average of the state's historical WOW per-member-per-month (PMPM) baseline and its recent actual PMPM costs. The projected demonstration expenditures associated with each EGs in the WOW baseline (except MEGs with aggregate cost limits) have been trended forward using the President's Budget trend rate to determine the maximum expenditure authority for the new approval period. Using the President's Budget trend rate aligns the demonstration trend rate with federal budgeting principles and assumptions.

Under this approval, projected demonstration expenditures associated with RRSS and SMI will be treated as hypothetical for the purposes of budget neutrality. This is consistent with CMS's current approach to hypothetical expenditures. Under its current approach to budget neutrality, CMS generally treats expenditures for populations or services which could have otherwise been covered via the Medicaid state plan, or other title XIX authority, such as a section 1915 waiver, as "hypothetical" for the purposes of budget neutrality. In these cases, CMS adjusts budget neutrality in the manner discussed below to account for the spending which the state could have hypothetically provided through the Medicaid state plan or other title XIX authority. CMS does not, however, currently allow for budget neutrality savings accrual as a result of including hypothetical populations or services in section 1115 demonstration projects. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent budget neutrality "supplemental test" for hypothetical expenditures. These supplemental budget neutrality tests subject the hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, during negotiations. If the state's "with waiver" (WW) hypothetical spending exceeds the supplemental test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending with savings elsewhere in the demonstration or to refund the FFP to CMS.

CMS is treating HRSN expenditures authorized under this approval as "hypothetical" for the purposes of the budget neutrality calculation. Some of these expenditures could be covered under other title XIX authority, and treating those expenditures as hypothetical is consistent with how CMS has historically treated similar expenditures. Other HRSN expenditures could not otherwise be covered under title XIX authority, such as expenditures on section 1915 services for beneficiaries who are not otherwise eligible for them under section 1915, but there are insufficient or inconsistent data to calculate a WOW baseline for at least some of these expenditures. Treating those expenditures. Additionally, treating demonstration HRSN expenditures as hypothetical will give the state the flexibility to test these worthy innovations, especially as CMS anticipates that they might result in overall reductions in future Medicaid program costs, based on robust academic-level research (as discussed above), but predicting these downstream effects on overall Medicaid program costs is extremely difficult. To ensure that treating HRSN expenditures as hypothetical does not have a significant negative fiscal

impact on Medicaid, CMS is applying a budget neutrality ceiling to HRSN services expenditures and an additional sub-ceiling to HRSN infrastructure expenditures and is referring to these expenditures collectively as the "Supplemental HRSN Aggregate Ceiling (SHAC)" expenditures in the STCs. The upper limit on the SHAC is based on a range of estimates of the likely cost of these expenditures over a 5-year period and is set at a mid-point in that range, but in no case can it exceed 3 percent of the state's total computable Medicaid spending. The sub-ceiling for infrastructure costs cannot exceed 15 percent of total HRSN expenditure authority. If the state exceeds these limits, it will not be permitted to offset the additional costs with savings from the rest of the demonstration, although unspent HRSN infrastructure authority can be applied to HRSN services in the same demonstration year.

CMS has also updated its approach to mid-course corrections to budget neutrality calculations in this demonstration extension approval to provide flexibility and stability for the state over the life of a demonstration. This update identifies, in the STCs, a list of circumstances under which a state's baseline may be adjusted based on actual expenditure data to accommodate circumstances that are either out of the state's control (for example, if expensive new drugs that the state is required to cover enter the market); and/or the effect is not a condition or consequence of the demonstration (for example, unexpected costs due to a public health emergency); and/or the new expenditure (while not a new demonstration-covered service or population that would require the state to propose an amendment to the demonstration) is likely to further strengthen access to care (for example, a legislated increase in provider rates). CMS also explains in the STCs what data and other information the state should submit to support a potentially approvable request for an adjustment. CMS considers this a more rational, transparent, and standardized approach to permitting budget neutrality modifications during the course of a demonstration.

## CHIP Allotment Neutrality

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 the demonstration population, 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.

## **Monitoring and Evaluation**

Consistent with the demonstration STCs, the state submitted its Interim Evaluation Report for the prior demonstration approval period with the extension application. Despite challenges due to the COVID-19 Public Health Emergency (PHE), the state's Interim Evaluation Report showed promising evidence of progress made toward demonstration goals. The state has been successful in increasing the availability of SUD-related services to Medicaid beneficiaries along several dimensions, as well as decreasing beneficiary reliance on the emergency department (ED) and increasing non-ED outpatient visits. However, there was not a notable change in the rates of beneficiary follow-up at 10- and 30-days—a finding likely confounded by the COVID-19 pandemic. The state's Summative Evaluation Report is expected to provide a fuller

understanding of the demonstration's effectiveness leveraging additional years of data that may enable separating out the confounding effects of the COVID-19 PHE from those of the demonstration itself more effectively.

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

The state is required to incorporate the extension 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 program. The state's monitoring and evaluation efforts must facilitate understanding the extent to which the extension might support reducing existing disparities in access to and quality of care and health outcomes.

## **Consideration of Public Comments**

The federal comment period for the demonstration extension request was open from October 14, 2022, through November 13, 2022, during which CMS received 5 comments. Two comments were from individuals and three were from organizations. Two comments were unrelated to the demonstration. Commenters supported the extension of coverage for FFCY, but one thought section 1115 demonstration authority was moot due to the SUPPORT Act. As mentioned above, section 1115 demonstration authority remains necessary to provide coverage for individuals who turned 18 years old on or before December 31, 2022, until a beneficiary reaches age 26, so FFCY coverage will remain in the TEAMKY demonstration.

Regarding the SUD program, one commenter supported the extension and urged CMS to approve proposals that support individuals experiencing SUD. They also recommended that treatment involve multidisciplinary, comprehensive services. Another commenter supported the SUD program and emphasized the importance of providing access to non-emergency medical transportation (NEMT) to methadone treatment.

Lastly, a commenter supported aspects of the SUD proposal, but said they are achievable via Medicaid state plan or other state or federal authority. The commenter stated that approaches to addressing SUD through section 1115 demonstrations are no longer novel, and Congress could amend the Medicaid statute to permanently allow states to use federal dollars for SUD treatment in IMDs. The commenter also sought for Kentucky to offer new hypotheses in the new demonstration extension period.

KY's extension application initially included a request to continue their waiver of NEMT, which commenters did not support. This request was later withdrawn, and authority for the NEMT waiver was removed from the demonstration September 27, 2023.

The SMI and recuperative care amendment federal comment period was open from June 14, 2023 through July 14, 2023, during which CMS received 5 comments. One comment was from an individual and 4 were from organizations. One comment was unrelated to the demonstration application. One commenter applauded Kentucky's commitment to improving the health and outcomes of Medicaid beneficiaries diagnosed with SMI and encouraged CMS to approve the request. They also described how medical respite will fill critical gaps for individuals experiencing homelessness who are discharged from a hospital and in need of a safe and supportive environment to heal, and urged the state to consider the unique needs of pregnant and postpartum people without stable housing. Another commenter strongly supported the SMI and recuperative care amendment and urged CMS to promptly approve the request.

Another commenter supported the recuperative care program, provided that respite services are provided in integrated settings and are community based. Regarding SMI, the commenter expressed desire for Kentucky to increase access to community-based mental health services to avoid overuse of emergency rooms and hospitals. Two commenters also mentioned that the SMI opportunity should not lead to unnecessary segregation of individuals with disabilities. The two commenters also questioned CMS's authority to waive the IMD exclusion.

As mentioned in SMD #18-011, CMS may approve opportunities for demonstration projects under section 1115(a) of the Act to improve care for adults with SMI by allowing states to receive FFP for services furnished to Medicaid beneficiaries during short term stays for acute care in psychiatric hospitals or residential treatment settings that qualify as IMDs if those states are also taking action, through these demonstrations, to ensure good quality of care in IMDs and to improve access to community-based services. The SMI initiative will enhance coverage of the continuum of behavioral health care services that emphasize screening, community-based services, residential treatment when appropriate, and enhanced peer recovery supports. The SMI demonstration opportunity seeks to improve care for individuals with serious mental health conditions in inpatient or residential settings that qualify as IMDs, as well as through improvements to community based mental health care.

For the reentry demonstration initiative and RRSS amendment, the federal comment period was open from January 12, 2024, through February 11, 2024, during which CMS received 10 comments. One comment was from an individual and 9 were from organizations. All comments primarily pertained to Kentucky's request to provide pre-release services to incarcerated individuals, which was approved by CMS on July 2, 2024. One commenter generally supported the reentry initiative including RRSS. Another commenter agreed with the application's assertion that RRSS has the potential to strengthen coordination of care, enhance health outcomes, and reduce recidivism, but sought more information on RRSS. The other commenters focused on the reentry portion of the application and did not specifically mention RRSS.

After carefully reviewing the demonstration applications and the public comments received during the federal comment periods, CMS has concluded that the demonstration is likely to

promote the objectives of the Medicaid program by increasing access to services for beneficiaries as well as expanding on the coverage of health care services that would otherwise not be available.

## **Other Information**

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

The project officer for this demonstration is Valisha Andrus. She is available to answer any questions concerning this section 1115(a) demonstration. Ms. Andrus's 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: <u>valisha.andrus@cms.hhs.gov</u>

We look forward to our continued partnership on the TEAMKY demonstration. 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.



Deputy Administrator and Director

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:	<b>TEAMKY Section 1115 Demonstration</b>		
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 services described below, which are not otherwise included as expenditures under section 1903 of the Act, must be regarded as matchable expenditures under the state's Title XIX plan, unless otherwise specified, provided however that these expenditures 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 the TEAMKY section 1115 demonstration are approved from January 1, 2025 through December 31, 2029.

As described further 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 Medicaid state plan services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for SUD who are short-term residents in facilities that meet the definition of an institution for mental disease (IMD), as describe in section XIV of the STCs.
- 2. **Residential and Inpatient Treatment for Individuals with Serious Mental Illness** (SMI). Expenditures for Medicaid state plan services furnished to otherwise eligible individuals who are primarily receiving treatment for serious mental illness (SMI) who are short-term residents in facilities that meet the definition of an IMD, and who meet the eligibility criteria described in section XV of the STCs.
- 3. **Recovery Residence Support Services (RRSS)**. Expenditures for RRSS for up to 90 days, for individuals diagnosed with a SUD and meet the eligibility criteria, as described in section XIV of the STCs.
- 4. **Health-Related Social Needs (HRSN) Services**. Expenditures for allowable HRSN services not otherwise covered that are furnished to individuals who meet the qualifying

criteria as described in Section VII of the STCs. This expenditure authority is contingent upon compliance with Section VII of the STCs, as well as all other applicable STCs.

- 5. **HRSN Services Infrastructure**. Expenditures for allowable HRSN administrative and infrastructure costs not otherwise covered under section 1903 of the Act, as described in section VII of the STCs.
- 6. **Pre-Release Services.** Expenditures for pre-release services, as described in section VIII of the STCs, furnished to individuals who meet qualifying criteria in STC 42 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.
- 7. **Pre-Release Administrative Costs.** Expenditures for allowable administrative costs, supports, transitional non-service expenditures, infrastructure and interventions, as described in STC 51. These expenditures 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.

## <u>Title XIX Requirements Not Applicable to the Medicaid Expenditure Authority for Pre-</u> <u>Release Services:</u>

## 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

To enable the state to require qualifying individuals to receive pre-release services, as authorized under this demonstration, through only certain providers.

#### Comparability; Amount, Duration and Scope; Provision of Medical Assistance

To the extent necessary to allow the state to offer HRSN services and to vary the amount, duration, and scope of HRSN services covered for a subset of beneficiaries, depending on beneficiary needs as determined by the application of qualifying criteria, as specified in Section VII of the STCs.

## **<u>Title XXI Expenditure Authority:</u>**

# Section 1902(a)(23)(A)

Section 1902(a)(10)(b)

and Section 1902(a)(17)

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 December 31, 2029, 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 AUTHORITY

NUMBERS:	11-W-00306/4 21-W-00067/4		
TITLE:	<b>TEAMKY Section 1115 Demonstration</b>		
AWARDEE:	Kentucky Cabinet for Health and Family Services		

#### **Title XIX Waiver Authority**

Under the authority of Section 1115(a)(1) of the Social Security Act ("the Act"), the following waivers are granted to enable Kentucky (referred to herein as the state or the State) to operate the TEAMKY (formerly KY HEALTH) Demonstration. These waivers are effective January 1, 2025 through December 31, 2029 and are limited to the extent necessary to achieve the objectives below. These waivers may only be implemented consistent with the approved Special Terms and Conditions (STCs) as set forth in the accompanying document.

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, who turned 18 on or before December 31, 2022, 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 December 31, 2029. In addition, these waivers may only be implemented consistent with the approved STCs.

Under the authority of section 1115(a)(1) of the Act, the following 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 1, 2025 through December 31, 2029.

The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description and Objectives
- III. General Program Requirements
- IV. Eligibility and Enrollment
- V. Benefits
- VII. Health-Related Social Needs
- VIII. Reentry Demonstration Initiative
- IX. Delivery System
- IX. Monitoring and Reporting Requirements
- X. General Financial Requirements
- XI. Budget Neutrality
- XII. CHIP Monitoring Allotment Neutrality
- XIIV. Evaluation of the Demonstration
- XIV. Opioid Use Disorder (OUD)/Substance Use Disorder (SUD) Program and Benefits
- XV. Serious Mental Illness (SMI) Program and Benefits
- XVI. Schedule of Deliverables for the Demonstration Period

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

- Attachment A: Developing the Evaluation Design
- Attachment B: Preparing the Evaluation Report
- Attachment C: SUD/SMI Implementation Plan
- Attachment D: SUD/SMI Monitoring Protocol
- Attachment E: SUD/SMI Health Information Technology (Health IT)
- Attachment F: Evaluation Design
- Attachment G: Reentry Demonstration Initiative Implementation Plan (reserved)
- Attachment H: Reentry Demonstration Initiative Reinvestment Plan (reserved)
- Attachment I: Monitoring Protocol
- Attachment J: RRSS Service Description
- Attachment K: Protocol for Assessment of Beneficiary Eligibility and Needs, and Provider Qualification for HRSN Services(reserved)
- Attachment L: Interim Evaluation Report
- Attachment M: Summative Evaluation Report
- Attachment N: HRSN Service Matrix
- Attachment O: HRSN Infrastructure Protocol
- Attachment P: HRSN Implementation Plan

# II. PROGRAM DESCRIPTION AND OBJECTIVES

The TEAMKY (formerly KY HEALTH) section 1115 demonstration is authorized under section 1115 of the Social Security Act (the Act), and is funded through titles XIX and XXI of the Act. The demonstration began on January 12, 2018, and includes a substance use disorder (SUD) treatment program available to all Kentucky Medicaid beneficiaries. Additionally, the demonstration enables the state to provide Medicaid coverage to former foster care youth (FFCY) under age 26, who turned 18 on or before December 31, 2022, 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 July 2024, CMS approved the reentry demonstration initiative, which provides 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.

In December 2024, the TEAMKY demonstration was extended to continue the SUD treatment program, coverage for FFCY, and the reentry demonstration initiative. The extension approval also amended the demonstration to provide medically necessary short-term inpatient treatment services within settings that qualify as institutions for mental diseases (IMDs) for Medicaid eligible adults with serious mental illness (SMI), and authority for an HRSN initiative to provide a recuperative care pilot program. Lastly, the demonstration extension provided expenditure authority for Kentucky to provide RRSS under the SUD program, which are non-clinical activities necessary to support beneficiaries recovering with SUD.

## III. GENERAL PROGRAM REQUIREMENTS

- 1. Compliance with Federal Non-Discrimination Statues. The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).
- 2. Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy. All requirements of the Medicaid and CHIP programs, expressed in federal law, regulation, and 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) business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

## 4. Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.

- a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7) as a result of the change in FFP.
- b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

- 5. State Plan Amendments. The state will not be required to submit title XIX or XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP state plans govern.
- 6. Changes Subject to the Amendment Process. Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7, 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. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;
  - b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
  - c. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;

- d. An up-to-date CHIP allotment worksheet, if necessary ; and,
- e. The state must identify how it will modify its evaluation design to incorporate the amendment provisions.
- 8. Extension of the Demonstration. States that intend to request an extension of the demonstration must submit an application to CMS at least 12 months in advance from the Governor of the state in accordance with the requirements of 42 CFR 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit a phase-out plan consistent with the requirements of STC 9.
- **9. Demonstration Phase Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements:
  - a. <u>Notification of Suspension or Termination.</u> The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a thirty (30) day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the thirty (30) day public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.
  - b. <u>Transition and Phase-out Plan Requirements.</u> 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. <u>Transition and Phase-out Plan Approval.</u> 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. <u>Transition and Phase-out Procedures.</u> The state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as

required under 42 CFR 435.916(d)(1), consistent with 42 CFR 435.911. For individuals determined ineligible for Medicaid and CHIP, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e). The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206 through 431.214. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230.

- e. <u>Exemption from Public Notice Procedures 42 CFR Section 431.416(g).</u> CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
- f. <u>Enrollment Limitation during Demonstration Phase-Out.</u> 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. <u>Federal Financial Participation (FFP)</u>. 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. Withdrawal of Waiver or Expenditure Authority. CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waivers or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX and title XXI. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.
- **11.** Adequacy of Infrastructure. The state 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.
- **12. Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR 431.408 prior to

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

The state must also comply with tribal and Indian Health Program/Urban Indian 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.

- **13.** 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.
- 14. Administrative Authority. When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, MCOs, and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration
- **15. Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.101(d)(5).

# IV. ELIGIBILITY AND ENROLLMENT

- 16. Eligibility Groups Affected by the Demonstration. There is no change to Medicaid state plan eligibility. All affected groups derive their eligibility through the Medicaid state plan. 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, who turned 18 on or before

December 31, 2022, who 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), who were enrolled in Medicaid at the time of aging out, are now applying for Medicaid in Kentucky, and are not otherwise eligible for Medicaid.

#### 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. HEALTH-RELATED SOCIAL NEEDS

19. Health Related Social Needs (HRSN) Service. The state may claim FFP for expenditures for certain qualifying HRSN services identified in STC 20 and Attachment K, subject to the restrictions described below. Expenditures are limited to expenditures for items and services not otherwise covered under Title XIX, but consistent with Medicaid demonstration objectives that enable the state to continue to increase the efficiency and quality of care. All HRSN interventions must be evidence-based and medically appropriate for the population of focus based on clinical and social risk factors. The state is required to align clinical and health-related social risk criteria across services and with other relevant, non-Medicaid social support agencies, to the extent possible and appropriate. The HRSN services may not supplant any other available funding sources such as housing or nutrition supports available to the beneficiary through other local, state, or federal programs. The HRSN services will be the choice of the beneficiary; a beneficiary can opt out of HRSN services anytime; and the HRSN services do not absolve the state or its managed care plans, as applicable, of their responsibilities to make payment for other covered services. Under no circumstances will the state be permitted to condition Medicaid coverage, or coverage of any benefit or service, on a beneficiary's receipt of HRSN services. The state must submit additional details on covered services as outlined in STC 28 (Service Delivery) and Attachment K.

#### 20. Allowable HRSN Service. The state may cover the following HRSN services:

- a. Housing interventions, including:
  - a) Episodic housing interventions with clinical services with room and board, limited to a clinically appropriate amount of time, including:
    - 1) Short-term pre-procedure housing, where a provider has determined that preparatory steps are required for an upcoming procedure or

treatment and integrated, clinically oriented recuperative or rehabilitative services and supports are provided.

2) Short-term post-transition housing (e.g., post-hospitalization), where integrated, clinically oriented rehabilitative services and supports are provided, but ongoing monitoring of the individual's condition by clinicians is not required.

## 21. HRSN Intervention Duration and Frequency.

- a. Housing interventions with room and board.
  - i. Housing interventions that are classified as episodic interventions, as described in in STC 20.a., with clinical services with room and board may be covered for a qualifying beneficiary, as medically appropriate, up to a combined 6 months per rolling year. For purposes of this demonstration, rolling year is defined as a continuous 12-month period with the start date beginning when the beneficiary begins receiving the service.
  - ii. For the 6-month cap, coverage will be permitted in one or more spans or episodes, as long as the total duration remains under the cap for the rolling year or demonstration period. CMS will also apply a total combined cap of 6 months of all types of HRSN housing interventions with room and board (including episodic interventions and room and board-only supports), per beneficiary, in any 12-month period.
- **22. Excluded HRSN Service**. Excluded items services, and activities that are not covered as HRSN services include, but are not limited to:
  - a. Construction (bricks and mortar) except as needed for approved medically necessary home modifications;
  - b. Capital investments;
  - c. Room and board, outside of specifically enumerated care or housing transitions or beyond 6 months, except as described in STC 20;
  - d. Research grants or expenditures not related to monitoring and evaluation;
  - e. Services furnished to beneficiaries for which payment is not available under the inmate payment exclusion in the matter following the last numbered paragraph of section 1905(a) of the Act except those HRSN-related case management services provided as part of an approved reentry demonstration initiative;
  - f. Services provided to individuals who are not lawfully present in the United States;

- g. Expenditures that supplant services and activities funded by other state and federal governmental entities;
- h. General workforce activities, not specifically linked to Medicaid or Medicaid beneficiaries; and
- i. Any other projects or activities not specifically approved by CMS as qualifying for demonstration coverage as a HRSN item or services under this demonstration.
  - i. For all HRSN housing interventions with room and board, the following setting exclusions apply: Congregate sleeping space, facilities that have been temporarily converted to shelters (e.g., gymnasiums or convention centers), facilities where sleeping spaces are not available to residents 24 hours a day, and facilities without private sleeping space.

## 23. HRSN Infrastructure.

- a. The state may claim FFP for expenditures for infrastructure investments to support the development and implementation of the HRSN service, subject to STC 21. This FFP will be available for the following activities:
  - i. Technology e.g., electronic referral systems, shared data platforms, electronic health record (EHR) modifications or integrations, screening tool and/or case management systems, licensing, databases/data warehouses, data analytics and reporting, data protections and privacy, accounting and billing systems.
  - ii. Development of business or operational practices e.g., developing policies, procedures and workflows, training and technical assistance, and administrative activities to support or expand HRSN operations.
  - Workforce development e.g., recruiting and hiring, salary and fringe benefits for staff, necessary certifications, cultural competency training, trauma-informed training, developing and training staff on new policies, procedures, and training materials.
  - iv. Outreach, education, and interested parties convening e.g., design and production of outreach and education materials, translation, obtaining community input, investments in interested parties convening and community engagement activities.
- b. The state may claim FFP in HRSN infrastructure 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, 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 in Total Computable Expenditures for HRSN
Infrastructure

	DY 8	DY 9	DY 10	DY 11	DY 12	DY 13	TOTAL
Total							
Computable	\$ 2,000,000	\$ 184,575	\$ 184,575	\$ 184,575	\$184,575	<b>\$</b> 0	\$2,738,299
Expenditures							

- c. Infrastructure expenditures will receive the FFP match for applicable administrative costs for the expenditure.
- d. This infrastructure funding is separate and distinct from payments for delivery of HRSN services. The state must ensure that HRSN infrastructure expenditures described in STC 23 are not included in HRSN service payments (including capitation payments, as applicable) and that there is no duplication of payments to entities providing or administering HRSN service benefits.
- e. The state may not claim any FFP in HRSN infrastructure expenditures until Attachment O: HRSN Infrastructure Protocol is approved, as described in STC 27. Once approved, the state can claim FFP in HRSN infrastructure expenditures retrospectively to the beginning of when the demonstration expenditure authority for HRSN infrastructure was approved.
- f. To the extent the state requests any additional infrastructure funding, or changes to its scope as described within this STC, it must submit an amendment to the demonstration for CMS's consideration.
- 24. Covered Populations. Expenditures for HRSN services may be made for the targeted populations specified in Attachment K, consistent with this STC. To qualify to receive coverage for HRSN services, individuals must be Medicaid (or Medicaid demonstration)-eligible and have a documented medical/clinical need for the services and the services must be determined medically/clinically appropriate, as described STC 19, to address the documented need. Medical appropriateness must be based on clinical and health-related social risk factors. This determination must be documented in the beneficiary's care plan or medical record. Additional detail, including the clinical and other health related-social needs criteria, is outlined in Attachment K. Attachment N, the HRSN Service Matrix, describes the full list of clinical and social risk factors the state anticipates incorporating into Attachment K over the course of the demonstration at the time of the demonstration approval of the expenditure authority for HRSN services. While Attachment K reflects the full list of clinical and social risk factors the state is authorized to implement, the state is not required to implement all of the clinical and social risk factors outlined in Attachment

N. Additionally, the state can later include additional clinical and social risk factors in compliance with STC 25 and 26.

25. Protocol for Assessment of Beneficiary Eligibility and Needs, and Provider **Oualifications for HRSN Services.** The state must submit, for CMS approval, a Protocol for Assessment of Beneficiary Eligibility and Needs, Infrastructure Planning, and Provider Qualifications to CMS no later than 90 days after approval of the HRSN expenditure authority. The protocol must include, as appropriate, a list of the HRSN services and service descriptions, the criteria for defining a medically appropriate population of focus for each service, the process by which those criteria will be applied including care plan requirements and/or other documented processes, and provider qualification criteria for each service. Any changes to the initial scope of clinical and social risk factors reflected in Attachment N must be effectuated through the process indicated in STC 26. The state must resubmit a revised protocol if required by CMS feedback on the initial submission. The state may not claim FFP for HRSN services until CMS approves the initial protocol. Once the initial protocol is approved, the state can claim FFP in expenditures for HRSN services retrospectively to the date of approval of the expenditure authority for HRSN services. The approved protocol will be appended to the STCs as Attachment K.

If the state adds new HRSN services beyond those specified in STC 20 through a demonstration amendment, the state must also submit revisions to the Protocol to CMS no later than 90 days after the approval of the amendment to the demonstration. The Protocol revisions must include a list of the new services and service descriptions provided through all delivery systems applicable, the criteria for defining a medically appropriate population of focus for each new service, the process by which those criteria will be applied including service plan requirements and/or other documented processes, and provider qualification criteria for each new service. This revised protocol must comply with applicable STCs.

Specifically, the protocol must include the following information:

- a. A list of the covered HRSN services (not to exceed those allowed under STC 20), with associated service descriptions and service-specific provider qualification requirements.
- b. A description of the process for identifying beneficiaries with health-related social needs, including outlining beneficiary qualifications, implementation settings, screening tool selection, and rescreening approach and frequency, as applicable.
- c. A description of the process by which clinical criteria will be applied, including a description of the documented process wherein a provider, using their professional judgment, may determine the service to be medically appropriate.
  - i. Plan to identify medical appropriateness based on clinical and social risk factors.
  - ii. Plan to publicly maintain these clinical and social risk criteria to ensure transparency for beneficiaries and other interested parties.

- d. A description of the process for developing care plans based on assessment of need.
  - i. Plan to initiate care plans and closed-loop referrals to social services and community providers based on the outcomes of screening.
  - ii. Description of how the state will ensure that HRSN screening and service delivery are provided to beneficiaries in ways that are culturally responsive and/or trauma informed, as appropriate.

# 26. Updates to the Protocol for Assessment of Beneficiary Eligibility and Needs and Provider Qualifications for HRSN Services.

- a. The state may choose to cover a subset of the HRSN services and/or beneficiary qualifying criteria specified in Attachments K and N. Certain changes to the state's service offerings and eligibility criteria, within what CMS has approved in Attachment K and N, do not require additional CMS approval. The state must follow the following process to notify CMS of any such HRSN service or qualifying criteria change.
  - i. The state must follow the same beneficiary notification procedures as apply in the case of changes to coverage and/or beneficiary service qualification criteria for state plan services, including with respect to beneficiaries who currently qualify for and/or are receiving services who may receive a lesser amount, duration, or scope of coverage as a result of the changes.
  - ii. The state must provide public notice.
  - iii. The state must submit a letter to CMS no less than 30 days prior to implementation describing the changes, which will be incorporated in the demonstration's administrative record.
- b. In addition to the requirements in a. above, if the state seeks to implement additional clinical and social risk factors than what were included in approved Attachment N, the state must follow the process below to update the protocol:
  - i. The state must provide a budget neutrality analysis demonstrating the state's expected cost for the additional population(s). The state may only add additional clinical and social risk factors through the protocol process described in this STC if CMS determines the criteria are allowable and doing so would not require an increase to the amount of the state's HRSN expenditure authority in Table 10.
  - ii. The state must receive CMS approval for the updated protocol prior to implementation of changes under this STC 26.b.
  - iii. The state is limited to submitting to CMS one update to its protocol per demonstration year as part of this process outlined in this STC. 26.

27. **HRSN Infrastructure Protocol**. The state must submit, for CMS approval, an HRSN Infrastructure Protocol to CMS no later than 90 days after approval of the expenditure authority for HRSN infrastructure expenditures. The protocol must include the state's proposed uses of HRSN infrastructure funds. The state must resubmit the revised protocol as may be required by CMS feedback on the initial submission. The protocol may be updated as details are changed or added. The state may not claim FFP for HRSN infrastructure expenditures until CMS approves the protocol. Once the protocol is approved, the state can claim FFP in HRSN infrastructure expenditures retrospectively to the date of approval of the expenditure authority for HRSN infrastructure. The approved protocol will be appended to the STCs as Attachment O: HRSN Infrastructure Protocol. If the state adds new HRSN services through a demonstration amendment, the state must submit revisions to the Protocol to CMS no later than 90 days after approval, if required based on changes to expenditures for HRSN infrastructure to support the newly added HRSN services. The revisions must include a list of proposed uses of HRSN infrastructure funds, if different than previously submitted.

Specifically, the protocol(s) must include the following information: Proposed uses of HRSN infrastructure expenditures, including the type of entities to receive funding, the intended purpose of the funding, the projected expenditure amounts, and an implementation timeline.

- **28.** Service Delivery. HRSN services will be provided in the managed care delivery system, and through FFS, and will be delivered by HRSN service providers. Terms applicable to all HRSN Services:
  - a. **FFS**. HRSN services will be paid on a FFS basis when those HRSN services are provided to beneficiaries through the Medicaid FFS.
    - i. In accordance with STC 29, CMS expects the state to have appropriate claims data associated with each HRSN service. This is necessary to ensure appropriate fiscal oversight for HRSN services as well as monitoring and evaluation. This is also critical to ensure appropriate documentation for claims payment. Therefore, CMS requires that, for HRSN services delivered in a FFS delivery system, the state must clearly document the name and definition of each HRSN service as well as the coding used on claims data. For example, the state must note specific Healthcare Common Procedure Coding System (HCPCS) or Current Procedural Terminology codes that identify each HRSN service. CMS will also consider this documentation necessary for approval of any rate methodologies per STC 36. The state must monitor and provide narrative updates through its Quarterly and Annual Monitoring Reports on the delivery of HRSN services through FFS.
  - b. **Managed Care**. When HRSN services are provided to beneficiaries enrolled in Medicaid managed care, the following terms will apply:

- i. HRSN services can be provided by managed care plans and paid on a non-risk basis and must be appropriately included in contracts. This can be accomplished by either a separate non-risk contract with a prepaid inpatient health plan (PIHP) or a prepaid ambulatory health plan (PAHP) (see the definition of "non-risk contract" at 42 CFR § 438.2) or as an amendment to a state's existing risk-based managed care plan contract to include a non-risk payment. The state must take measures to ensure there is no duplication of payments for either the delivery of such service or the administrative costs of delivering such services.
- ii. For a non-risk contract or a non-risk payment, the managed care plan is not at financial risk for changes in utilization or for costs incurred under the contract or payment that do not exceed the upper payment limits specified in 42 CFR 447.362 and may be reimbursed by the state at the end of the contract period on the basis of the incurred costs, subject to the specified limits. For the purposes of this demonstration, fee-for-service as defined in 42 CFR 447.362 is the fee-for-service authorized in this demonstration for HRSN services paid on a fee-for-service basis by the state. The managed care plan contracts must clearly document the process and methodology for non-risk payments.
- iii. When the state includes non-risk payments in a risk-based contract, the state must ensure all non-risk payments are separate and apart from risk-based payments and clearly define what services/populations are covered under non-risk payments versus included in risk-based capitation rates. All of the costs of delivering services under a non-risk payment must be excluded from the development of the risk-based capitation rates for the risk-based contracts. Specifically, the costs of delivery the services as well as any costs of administering the non-risk payment must be excluded from the development of the risk-based capitation rates.
- iv. Prior written CMS approval pursuant to STC 29 is required before the state moves to incorporate the HRSN services into the risk-based capitation rates in Medicaid managed care. When the state incorporates the HRSN services into the risk-based capitation rates in Medicaid managed care, the state must comply with all applicable federal requirements, including but not limited to 42 CFR 438.4, 438.5, 438.6, and 438.7, and may no longer utilize non-risk payments for the services included in risk-based capitation rates.
- v. Any applicable HRSN services that are delivered by managed care plans in a risk arrangement, must be included in the risk-based managed care contracts and rate certifications submitted to CMS for review and approval in accordance with 42 CFR 438.3(a) and 438.7(a).
- vi. The state must monitor and provide narrative updates through its Quarterly and Annual Monitoring Reports on the inclusion of HRSN services in managed care programs.

- vii. All expenditures for HRSN services delivered under non-risk contracts must be excluded from MLR reporting. When HRSN services (i.e., HRSN services defined in STC 20 for the covered populations defined in STC 24 are included in capitation rates paid to managed care plans under risk-based contracts, and only then, should HRSN services be reported in the medical loss ratio (MLR) reporting as incurred claims.
- viii. The state must develop an MLR monitoring and oversight process specific to HRSN services. This process must be submitted to CMS, for review and approval, no later than 6 months prior to the implementation of HRSN services in riskbased managed care contracts and capitation rates. The state should submit this process to CMS at DMCPMLR@cms.hhs.gov. This process must specify how HRSN services will be identified for inclusion in capitation rate setting and in the MLR numerator. The state's plan must indicate how expenditures for HRSN administrative costs and infrastructure will be identified and reported in the MLR as non-claims costs.
- c. CMS expects the state to have appropriate encounter data associated with each HRSN service. This is necessary to ensure appropriate fiscal oversight for HRSN services as well as monitoring and evaluation. This is also critical to ensure appropriate base data for Medicaid managed care rate development purposes as well as appropriate documentation for claims payment in managed care. Therefore, CMS requires that for HRSN services provided in a managed care delivery system, the state must include the name and definition of each HRSN service as well as the coding to be used on claims and encounter data in the managed care plan contracts. For example, the state must note specific Healthcare Common Procedure Coding System (HCPCS) or Current Procedural Terminology costs that identify each HRSN service. CMS will also consider this documentation necessary for approval of any rate methodologies per STC 36.
- **29.** Requirements for Services Prior to Being Delivered in Risk-Based Managed Care. The state's plan to incorporate HRSN into risk-based managed care contracts must be submitted to CMS, for review and approval, no later than 6 months prior to the implementation of HRSN services in risk-based managed care contracts and capitation rates. At least 6 months prior to moving HRSN services approved under these STCs into risk-based Medicaid managed care contracts, the state must submit to CMS, for review and written prior approval, documentation that details the following information:
  - a. Each HRSN service defined in STC 20 and each covered population that will receive each HRSN service defined in STC 24 where the state is seeking CMS written approval to deliver services to populations through one or more risk-based managed care program(s). The applicable managed care program(s) for each service and population should also be specified.

- b. If the HRSN service will be offered in all regions under each risk-based managed care program or if the offerings will be limited geographically.
- c. The first rating period the state is seeking to start offering the HRSN service(s) through risk-based managed care. If the HRSN services will be delivered through risk-based managed care on a rolling basis, provide the timeline for each service and/or population.
- d. The state's timeline to complete a readiness review pursuant to 438.66(d). Implementation may only begin when each managed care plan has been determined by the state to meet certain readiness and network requirements, including providing any documentation specified by CMS.
- e. A transition of care plan that provides continuity of care for beneficiaries transitioning from another delivery system (e.g. FFS) or non-risk contracts into risk-based contracts.
- f. A description of base data that the state and its actuary plan to use for capitation rate setting process to develop both the benefit and non-benefit costs, including the types of data used (FFS claims data, managed care encounter data, managed care plan financial data, etc.), and the data source(s) that will be used for capitation rate development. Consistent with Medicaid managed care rate development requirements under 42 CFR 438, CMS requires at least 3 years of encounter data or similar data (e.g. cost reports, claims data) for the HRSN services defined in STC 20 for the covered populations defined in STC 24 that will be incorporated into risk-based managed care. CMS will consider exceptions to the requirement for 3 years of base data for periods impacted by COVID-19.
- g. The methodology the state's actuary will use in the capitation rate setting process. This includes, but is not limited to, any trend factors and adjustments to the data the state and its actuary will apply to the base data in the capitation rate setting process. The methodology should also include information on the approach the actuary will take to incorporating the HRSN service(s) into capitation rate development (for example, if the actuary will create an add-on that will be applied to some or all existing rates cells, creating a separate rate cell, or some other method) and any changes to or new risk adjustments or acuity adjustments applied due to the inclusion of the HRSN services defined in STC 20 for the covered populations defined in STC 24.
- h. If the state is planning to delegate risk for the delivery of HRSN services to clinical providers, community organizations, and/or subcontractors for specific HRSN services, the capitation rate setting plan should include a description of these proposed delegated arrangements and/or sub-capitated payment arrangements that the state intends to use in the delivery of any HRSN services defined in STC 20 for covered populations defined in STC 24.

- i. Identification of any in-lieu of services (ILOS) the state currently offers through its managed care programs and if there will be changes to those ILOS as a result of the state moving these HRSN service(s) into risk-based managed care contracts.
- j. Because of the uncertainty associated with HRSN services and in alignment with past guidance about situations with high levels of uncertainty, CMS is requiring the state to implement a 2-sided risk mitigation strategy (such as a 2-sided risk corridor) to provide protection for state and federal governments, as well as managed care plans. The HRSN capitation rate setting plan should provide a description of the risk mitigation mechanism(s) that will be used in the transition of HRSN services to risk-based managed care. As part of plan to incorporate HRSN into risk-based managed care, the state will also need to develop an MLR monitoring and oversight process specific to HRSN services. This process must specify how HRSN services will be identified for inclusion in the MLR numerator. The state's plan must indicate how expenditures for HRSN administrative costs and infrastructure, as applicable, will be identified and reported by managed care plans as non-claims costs.
- k. All state directed payments the state plans to implement for any HRSN services defined in STC 20 for the covered populations defined in STC 24 that will be provided under risk-based contracts must comply with all applicable federal requirements, including but not limited to 438.6(c). The state should submit this information to establish compliance for any state-directed payments for HRSN services to CMS at statedirectedpayment@cms.hhs.gov.
- **30. Contracted Providers**. Managed care plan contracts must provide, applicable to all HRSN services:
  - a. Managed care plans will contract with providers to deliver the elected HRSN services authorized under the demonstration and included in the managed care contract.
  - b. Managed care plans must establish a network of providers and ensure the HRSN service providers have sufficient experience and training in the provision of the HRSN services being offered. HRSN service providers do not need to be licensed, however, staff offering services through HRSN service providers must be licensed when applicable (i.e., when the staff member is performing activities for which a licensure requirement applies in the state).
  - c. The managed care plan and contracted providers will use rates set by the state for the provision of applicable HRSN services, consistent with state guidance for these services, and in compliance with all related federal requirements. Any state direction of managed care plan expenditures under risk-based contract(s) and risk-based payments would be considered a state directed payment subject to the requirements in 42 CFR 438.6(c).

- **31. Provider Network Capacity**. Managed care plans must ensure the HRSN services authorized under the demonstration are provided to qualifying beneficiaries in a timely manner and shall develop policies and procedures outlining the managed care plan's approach to managing provider shortages or other barriers to timely provision of the HRSN services, in accordance with the managed care plan contracts and other state Medicaid/operating agency guidance.
- **32.** Compliance with Federal Requirements. The state shall ensure HRSN services are delivered in accordance with all applicable federal statutes and regulations.
- **33. Person Centered Service Plan**. The state shall ensure there is a person-centered service plan for each beneficiary receiving HRSN services that is person-centered, identifies the beneficiary's needs and individualized strategies and interventions for meeting those needs, and developed in consultation with the beneficiary and the beneficiary's chosen support network, as appropriate. The service plan is reviewed and revised at least every 12 months, when the beneficiary's circumstances or needs change significantly, or at the beneficiary's request.
- **34. Conflict of Interest**. The state shall ensure appropriate protections against conflicts of interest in HRSN service planning and delivery, including by ensuring that appropriate separation of service planning and service provision functions is incorporated into the state's conflict of interest policies.
- **35. CMS Approval of Managed Care Contracts**. As part of the state's submission of associated Medicaid managed care plan contracts to implement HRSN service through managed care, the state must include contract requirements including, but not limited to :
  - a. Beneficiary and plan protections, including but not limited to:
    - i. HRSN services must not be used to reduce, discourage, or jeopardize beneficiaries' access to covered services.
    - ii. Beneficiaries always retain their right to receive covered service on the same terms as would apply if HRSN services were not an option.
    - iii. Beneficiaries who are offered or utilized an HRSN service retain all rights and protections afforded under 42 CFR 438.
    - iv. Managed care plans are not permitted to deny a beneficiary a covered service on the basis that the beneficiary is currently receiving HRSN services, has requested those services, has previously qualified for or received those services, or currently qualifies or may qualify in the future for those services.
    - v. Managed care plans are prohibited from requiring a beneficiary to receive HRSN services.

- b. Managed care plans must timely submit data when requested by the state or CMS, including, but not limited to:
  - i. Data to evaluate the utilization and effectiveness of the HRSN services.
  - ii. Any data necessary to monitor health outcomes and quality of care metrics at the individual and aggregate level through encounter data and supplemental reporting on health outcomes and equity of care. When possible, metrics must be stratified by age, sex (including sexual orientation and gender identity), race, ethnicity, disability status, and language spoken to inform health quality improvement efforts, which may thereby mitigate health disparities.
  - iii. Any data necessary to monitor appeals and grievances for beneficiaries.
  - iv. Documentation to ensure appropriate clinical support for the medical appropriateness of HRSN services.
  - v. Any data determined necessary by the state or CMS to monitor and oversee the HRSN initiatives.
- c. All data and related documentation necessary to monitor and evaluate the HRSN services initiatives, including cost assessment, to include but not limited to:
  - i. The managed care plans must submit timely and accurate encounter data to the state for beneficiaries eligible for HRSN services. When possible, this encounter data must include data necessary for the state to stratify analyses by age, sex (including sexual orientation and gender identity), race, ethnicity, disability status and preferred language to inform health quality improvement efforts and subsequent efforts to mitigate health disparities undertaken by the state.
  - ii. Any additional information requested by CMS, the state, or another legally authorized oversight body to aid in ongoing evaluation of HRSN services initiative or any independent assessment or analysis conducted by the state, CMS, or a legally authorized independent entity.
  - iii. The state must monitor and provide narrative updates through its Quarterly and Annual Monitoring Reports its progress in building and sustaining its partnership with existing housing agencies and nutrition agencies to utilize their expertise and existing housing and nutrition resources to avoid duplication of efforts.
  - iv. Any additional information determined reasonable, appropriate and necessary by CMS.

36. **HRSN Rate Methodologies.** For FFS payment methodologies and/or rates, the state must comply with the payment rate-setting requirements in 42 CFR Part 447, as though a state plan amendment were required, to establish any payment rate and/or methodology for HRSN services as approved under demonstration expenditure authority 4. The state must conduct state-level public notice under 42 CFR 447.205 prior to the implementation of the applicable FFS payment rates or methodologies for HRSN and maintain documentation of these FFP payment rates or methodologies on its website described in 42 CFR 447.203. The state may receive FFP for HRSN service expenditures authorized under this demonstration upon implementation of the FFS payment rates and/or methodologies for which it has conducted prior public notice and may begin claiming for this FFP (for dates of service no earlier than the effective date of approval for the relevant expenditure authority) no earlier than the date of submission of the payment rates and/or methodology to CMS for approval. However, any FFS payments to providers or claims for FFP prior to CMS approval of the payment rate or methodology must be reconciled to the ultimately approved FFS payment rate and/or methodology within one year of CMS's approval. All requirements for timely filing of claims for FFP continue to apply.

For managed care payments and rates (including capitation rates, non-risk payments, and state directed payments), the state must comply with all federal requirements, including those in 42 CFR Part 438 and these STCs. As applicable, the state must also notify CMS at least 60 days prior to intended implementation if it intends to direct its managed care plans on how to pay for HRSN services (i.e., state directed payments).

All rates/payment methodologies for HRSN services, for both FFS and managed care delivery systems, must be submitted to CMS for review and approval, including but not limited to fee-for-service payments as well as managed care capitation rates, any state directed payments that require prior written approval, and non-risk payments, as outlined in the STCs. For all payment methodologies and/or rates, for both FFS and managed care delivery systems, in addition to submitting the payment rates and/or methodology, the state must also submit all supporting documentation requested by CMS, including but not limited to how the rates and/or methodology were developed, state responses to any public comments on the rates and/or methodology (when applicable), and information about Medicaid non-federal share financing.

**37. Maintenance of Effort** (**MOE**). The state must maintain a baseline level of state funding for ongoing social services related to housing transition supports for the duration of the demonstration, not including one time or non-recurring funding. Within 90 days of demonstration approval, the state will submit a plan to CMS as part of the HRSN Implementation Plan required by STC 39 that specifies how the state will determine baseline spending on these services throughout the state. The annual MOE will be reported and monitored as part of the Annual Monitoring Report described in STC 58, with any justifications, including declines in available state resources, necessary to describe the findings, if the level of state funding is less than the comparable amount of the predemonstration baseline.

38. Partnership with State and Local Entities. To ensure that expenditures for HRSN services under this demonstration do not supplant any other available funding sources available to the beneficiary through other local, state, or federal programs, the state must have in place partnerships with other state and local entities (e.g., HUD Continuum of Care Program, local housing authorities) to assist beneficiaries in obtaining non-Medicaid funded housing supports, if available, upon the conclusion of temporary demonstration payment for such supports, in alignment with beneficiary needs identified in the beneficiary's care plan, as appropriate. The state will submit a plan to CMS as part of the HRSN Implementation Plan that outlines how it will put into place the necessary arrangements with other state and local entities and also work with those entities to assist beneficiaries in obtaining available non-Medicaid funded housing and/or nutrition supports upon conclusion of temporary Medicaid payment as stated above. The plan must provide a timeline for the activities outlined. As part of the Monitoring Reports described in STC 58, the state will provide the status of the state's fulfillment of its plan and progress relative to the timeline, and whether and to what extent the non-Medicaid funded supports are being accessed by beneficiaries as planned. Once the state's plan is fully implemented, the state may conclude its status updates in the Monitoring Reports.

## **39.** HRSN Implementation Plan.

- a. The state is required to submit a HRSN Implementation Plan that will elaborate upon and further specify requirements for the provision of HRSN services and will be expected to provide additional details not captured in the STCs regarding implementation of demonstration policies that are outlined in the STCs. The state must submit the MOE information required by STC 37 no later than 90 calendar days after approval of demonstration expenditure authority for HRSN services. All other Implementation Plan requirements outlined in this STC must be submitted no later than 9 months after the approval of demonstration expenditure authority for HRSN services. The Implementation Plan shall be submitted to CMS but does not require CMS approval. CMS will ensure it is complete and contains sufficient detail for purposes of on-going monitoring. The state may update the implementation plan as initiatives are changed or added, with notification to CMS. The Implementation Plan will be appended as Attachment P.
- b. At a minimum, the Implementation Plan must provide a description of the state's strategic approach to implementing the policy, including timelines for meeting critical implementation stages or milestones, as applicable, to support successful implementation. The Implementation Plan does not need to repeat any information submitted to CMS under the Protocol for Assessment of Beneficiary Eligibility and Needs, and Provider Qualifications for HRSN services; however, as applicable, the information provided in the two deliverables must be aligned and consistent.
- c. The Implementation Plan must include information on, but not limited to, the following:
  - i. A plan for establishing and/or improving data sharing and partnerships with an array of health system and social services stakeholders interested parties to the

extent those entities are vital to provide needed administrative and HRSN-related data on screenings, referrals, and provision of services, which are critical for understanding program implementation and conducting demonstration monitoring and evaluation.

- ii. Information about key partnerships related to HRSN service delivery, including plans for capacity building for community partners and for soliciting and incorporating input from impacted groups (e.g., community partners, health care delivery system partners, and beneficiaries);
- iii. Plans for changes to IT infrastructure that will support HRSN-related data exchange, including development and implementation of data systems necessary to support program implementation, monitoring, and evaluation. These existing or new data systems should, at a minimum, collect data on beneficiary characteristics, qualification and consent to receive HRSN services, screening, referrals, and service provision;
- A plan for tracking and improving the share of Medicaid demonstration beneficiaries in the state who are eligible and enrolled in SNAP, the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), Temporary Assistance for Needy Families (TANF), and/or federal, state, and local housing and/or other nutrition assistance programs, relative to the number of total eligible demonstration beneficiaries in the state (including those who are eligible but unenrolled);
- v. An implementation timeline and considerations for demonstration evaluation that may be impacted by the timeline (e.g., in the case of a phased rollout of HRSN services), to facilitate robust evaluation designs;
- vi. Information as required per STC 37 (MOE); and
- vii. Information as required per STC 38 (Partnerships with State and Local Entities).

## VII. REENTRY DEMONSTRATION INITIATIVE

**40. 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 as specified in STC 42 who are inmates residing in state prisons or youth correctional facilities (hereinafter "correctional facilities"). To qualify for services covered under this demonstration, individuals residing in correctional facilities 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 as further specified in the STCs below.

**41.** 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, and health-related social needs;
- f. Reduce all-cause deaths in the near-term post-release;
- g. Reduce the number of emergency department visits, behavioral health crisis services, and inpatient hospitalizations among recently incarcerated Medicaid and CHIP individuals through increased receipt of preventive and routine physical and behavioral health care;
- 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.

- **42. 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 40;
  - b. Have been determined eligible for Medicaid or CHIP or be otherwise eligible for CHIP if not for their incarceration status;
  - c. Have an expected release date within 60 days.
- **43. 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 49.
  - a) The covered pre-release services are:
    - i. Case management to assess and address physical and behavioral health needs, and health-related social needs;
    - ii. MAT for all types of SUDs as clinically appropriate, including coverage for medications in combination with counseling/behavioral therapies; and
    - 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 prerelease 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 (e.g., EPSDT treatment services) benefit for qualifying Medicaid or CHIP individuals are not available to qualifying individuals through the reentry demonstration initiative.

44. 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 48/49. States must be mindful of and ensure the policies, procedures, and processes developed to support implementation of these provisions do not effectuate a delay of an individual's release or lead to increased involvement in the juvenile and adult justice systems. Correctional facilities that are also institutions for mental diseases (IMDs) are not allowed to participate in the reentry demonstration initiative.

### 45. 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.
- **46. Suspension of Coverage**. Upon entry of a Medicaid or CHIP enrolled 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.
- **47.** 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.

- **48. 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 42;
  - 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.
- **49. 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 <u>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.</u>

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 development of the Implementation Plan.

50. **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 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 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 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."

#### 51. 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 prerelease 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 51(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 51(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 89, 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 2. Annual Limits of Total Computable Expenditures for ReentryDemonstration Initiative Planning and Implementation Program

	DY 8	DY9	DY10	DY11	DY12	DY13
Total Computable						
Expenditures	\$2,328,750	\$1,293,750	\$258,750	\$258,750	\$258,750	\$0

- 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.

## VIII. DELIVERY SYSTEM

**52. Overview.** TEAMKY will utilize FFS, and 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.

### IX. MONITORING AND REPORTING REQUIREMENTS

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

The following process will be used: 1) 30 calendar days after the deliverable(s) were due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) 30 calendar 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(s) into alignment with CMS requirements:

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

- b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay, the steps the state has taken to address such issue(s), and the state's anticipated date of submission. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided. CMS may agree to a corrective action plan as an interim step before applying the deferral, if the state proposes a corrective action plan in the state's written extension request.
- c. If CMS agrees to an interim corrective process in accordance with subsection (b) above, and the state fails to comply with the corrective action plan or despite the corrective action plan, still fails to submit the overdue deliverable(s) that meet the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in (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.

- 54. Deferral of Federal Financial Participation (FFP) from IMD claiming for Insufficient Progress Toward Milestones. Up to \$5,000,000 in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones and goals as evidenced by reporting on the milestones in the Implementation Plan and the required performance measures in the Monitoring Protocol agreed upon by the state and CMS. Once CMS determines the state has not made adequate progress, up to \$5,000,000 will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made.
- **55. Submission of Post-Approval Deliverables.** The state must submit deliverables as stipulated by CMS and within the timeframes outlined within these STCs, unless CMS and the state mutually agree to another timeline.
- **56. Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional section 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 section 1115 demonstration, Transformed Medicaid Statistical Information System (T-MSIS), and other data elements that have been agreed to for reporting and analytics are provided by the state; and
- c. Submit deliverables to the appropriate system as directed by CMS.
- **57. 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.

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 58.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 58.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.

- 58. Monitoring Reports. The state must submit three Quarterly Monitoring Reports and one Annual Report each demonstration year (DY). The fourth-quarter information that would ordinarily be provided in a separate Quarterly Monitoring Report should be reported as distinct information within the Annual Monitoring Report. The Quarterly Monitoring Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The Annual Monitoring Report (including the fourth-quarter information) is due no later than ninety (90) calendar days following the end of the DY. The state must submit a revised monitoring report within 60 calendar days after receipt of CMS's comments, if any. The reports will include all required elements as per 42 CFR 431.428, and 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 Quarterly and Annual Monitoring Reports must follow the framework to be provided by CMS, which is subject to change as monitoring systems are developed/evolve, and will be provided in a structured manner that supports federal tracking and analysis.
  - a. <u>Operational Updates.</u> Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports must provide sufficient information to document key operational and other challenges, underlying causes of challenges, and how challenges are being addressed. The discussion should also include any issues or complaints identified by individuals; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. In addition, monitoring reports should describe key achievements, as well as the conditions and efforts to which these successes can be attributed. Monitoring reports should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
  - b. <u>Performance Metrics.</u> The demonstration's monitoring activities through quantitative data and narrative information must support tracking the state's progress toward meeting the applicable program-specific goals and milestones—including relative to their projected timelines—of the demonstration's program and policy implementation and infrastructure investments and transitional non-service expenditures, as applicable.

Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to individuals and the uninsured population, as well as on individuals' outcomes as well as outcomes of care, quality and cost of care, and access to care. This should also include the results of beneficiary satisfaction or experience of care surveys, if conducted, as well as grievances, and appeals. Specifically, the state must undertake standardized reporting on categories of metrics including, but not limited to: beneficiary participation in demonstration components, primary and specialist provider participation, utilization of services, quality of care, and health outcomes. The reporting of metrics focused on quality of care and health outcomes must be aligned with the demonstration's policies' and objectives' populations. Such reporting must also be 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 by demonstration components, to the extent feasible. Subpopulation reporting will support identifying any existing shortcomings or disparities in quality of care and health outcomes and help track whether the demonstration's initiatives help improve outcomes for the state's Medicaid population, including the narrowing of any identified disparities.

- c. 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 43, 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, nonservice expenditures, including enhancements in the data infrastructure and information technology.
- d. For the HRSN component, in addition to reporting on the metrics described above, the state must track beneficiary participation, screening, receipt of referrals and social services over time under the HRSN program component, as well as adoption of information technology infrastructure to support data sharing between the state or partner entities administering the administration of the demonstration and social services organizations.
- e. Common SUD metrics include, but are not limited to, those that measure alignment with assessment of need and qualification for SUD treatment services and the

demonstration's six milestones as outlined in the State Medicaid Director Letter (SMDL) dated November 1, 2017 (SMDL #17- 003).<sup>1</sup>

- f. Common SMI metrics include, but are not limited to, screening of beneficiaries admitted to psychiatric hospitals or residential treatment facilities, mental health services utilization (inpatient and outpatient), and average length of stay in IMDs and the demonstration's four milestones as outlines in the SMDL dated November 13, 2018 (SMDL #18—011).<sup>2</sup>
- g. Metrics for the RRSS component should include, but not be limited to rates of program enrollment among the SUD population, as well as measures pertaining to skills training, coaching, and overall case management furnished by the program.
- h. In addition, and pertaining to all components under the extension, the state must include the results of member satisfaction surveys, if conducted, and grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports and must follow the framework provided by CMS to support federal tracking and analysis.
- i. <u>Budget Neutrality and Financial Reporting Requirements.</u> 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 Form CMS-64.
- j. <u>Evaluation Activities and Interim Findings.</u> 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.
- <u>SUD and SMI Health IT</u>. The state will include a summary of progress made in regard to SUD and SMI Health IT requirements outlined in Attachment E and STC 118(d).

<sup>&</sup>lt;sup>1</sup> SMDL #17-003, Strategies to Address the Opioid Epidemic. Available at: https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf

<sup>&</sup>lt;sup>2</sup> SMDL #18—011, Opportunities to Design Innovative Service Delivery Systems for Adults with a Serious Mental Illness or Children with a Serious Emotional Disturbance. Available at: https://www.medicaid.gov/federal-policy-guidance/downloads/smd18011.pdf

**59. 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.

- **60. SUD and SMI Mid-Point Assessment.** For the SUD and SMI components, the state must contract with an independent entity to conduct an independent Mid-Point Assessment. This timeline will allow for the Mid-Point Assessment Report to capture approximately the first two-and-a-half years of demonstration program data, accounting for data run-out and data completeness. In addition, if applicable, the state should use the prior approval period experiences as context and conduct the Mid-Point Assessment in light of the data from any such prior approval period(s). In the design, planning and conduct of the Mid-Point Assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of MCOs, health care providers (including treatment providers), beneficiaries, community groups, and other key partners.
  - a. The state must require that the assessor provide a Mid-Point Assessment Report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than 60 calendar days after December 12, 2027. If requested, the state must brief CMS on the report. The state must submit a revised Mid-Point Assessment Report within 60 calendar days after receipt of CMS's comments, if any.
  - b. For milestones and measure targets at medium to high risk of not being achieved, the state must submit to CMS modifications to the relevant Implementation Plan and Monitoring Protocol for ameliorating these risks. Modifications to the Implementation, Financing Plan, and Monitoring Protocol are subject to CMS approval.
  - c. Elements of the Mid-Point Assessment must include:
  - i. An examination of progress toward meeting each milestone and timeframe approved in the Implementation Plans and toward meeting the targets for performance measures as approved in the Monitoring Protocol;
  - ii. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date;
  - iii. A determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets;
  - iv. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state's Implementation Plan, or to pertinent factors that the state can influence that will support improvement; and

- v. An assessment of whether the state is on track to meet the budget neutrality requirements in these STCs.
- 61. Corrective Action Plan Related to Monitoring. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A corrective action plan could include a temporary suspension of implementation of demonstration programs in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS will withdraw an authority, as described in STC 10, when metrics indicate substantial and sustained directional change inconsistent with the state's demonstration goals, and the state has not implemented corrective action. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.
- **62. Close Out Report.** Within 120 calendar days after the expiration of the demonstration, the state must submit a draft Close Out Report to CMS for comments.
  - a. The draft Close Out Report must comply with the most current guidance from CMS.
  - b. In consultation with CMS, and per guidance from CMS, the state will include an evaluation of the demonstration (or demonstration components) that are to phase out or expire without extension along with the Close-Out Report. Depending on the timeline of the phase-out during the demonstration approval period, in agreement with CMS, the evaluation requirement may be satisfied through the Interim and/or Summative Evaluation Reports stipulated in STCs 106 and 107, respectively.
  - c. The state will present to and participate in a discussion with CMS on the Close-Out report.
  - d. The state must take into consideration CMS's comments for incorporation into the final Close Out Report.
  - e. A revised Close Out Report is due to CMS no later than thirty (30) calendar days after receipt of CMS's comments.
  - f. A delay in submitting the draft or final version of the Close Out Report may subject the state to penalties described in STC 53.
- 63. Monitoring Calls. CMS will convene periodic conference calls with the state.
  - a. The purpose of these calls is to discuss ongoing demonstration operations, 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, enrollment and access, 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.
- 64. Post Award Forum. Pursuant to 42 CFR 431.420(c), within six months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 30 calendar days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its Medicaid website. The state must also post the most recent Annual Monitoring Report on its Medicaid website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the public comments in the Annual Monitoring Report associated with the year in which the forum was held.

## X. GENERAL FINANCIAL REQUIREMENTS

- **65. Allowable Expenditures.** This demonstration project is approved for authorized demonstration expenditures applicable to services rendered and for costs incurred during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.
- **66**. Standard Medicaid Funding Process. The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures under this Medicaid section 1115 demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state shall submit form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

- 67. Sources of Non-Federal Share. As a condition of demonstration approval, the state certifies that its funds that make up the non-federal share are obtained from permissible state and/or local funds that, unless permitted by law, are not other federal funds. The state further certifies that federal funds provided under this section 1115 demonstration must not be used as the non-federal share required under any other federal grant or contract, except as permitted by law. CMS approval of this demonstration does not constitute direct or indirect approval of any underlying source of non-federal share or associated funding mechanisms and all sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable implementing regulations. CMS reserves the right to deny FFP in expenditures for which it determines that the sources of non-federal share are impermissible.
  - a. If requested, the state must submit for CMS review and approval documentation of any sources of non-federal share that would be used to support payments under the demonstration.
  - b. If CMS determines that any funding sources are not consistent with applicable federal statutes or regulations, the state must address CMS's concerns within the time frames allotted by CMS.
  - c. Without limitation, CMS may request information about the non-federal share sources for any amendments that CMS determines may financially impact the demonstration.
- **68. State Certification of Funding Conditions**. As a condition of demonstration approval, the state certifies that the following conditions for non-federal share financing of demonstration expenditures have been met.
  - a. If units of state or local government, including health care providers that are units of state or local government, supply any funds used as non-federal share for expenditures under the demonstration, the state must certify that state or local monies have been expended as the non-federal share of funds under the demonstration in accordance with section 1903(w) of the Act and applicable implementing regulations.
  - b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the non-federal share of expenditures under the demonstration, the state must obtain CMS approval for a cost reimbursement methodology. This methodology must include a detailed explanation of the process, including any necessary cost reporting protocols, by which the state identifies those costs eligible for purposes of certifying public expenditures. The certifying unit of government that incurs costs authorized under the demonstration must certify to the state the amount of public funds allowable under 42 CFR 433.51 it has expended. The federal financial participation paid to match CPEs may not be used as the non-federal share to obtain additional federal funds, except as authorized by federal law, consistent with 42 CFR 433.51(c).

- c. The state may use intergovernmental transfers (IGT) to the extent that the transferred funds are public funds within the meaning of 42 CFR 433.51 and are transferred by units of government within the state. Any transfers from units of government to support the non-federal share of expenditures under the demonstration must be made in an amount not to exceed the non-federal share of the expenditures under the demonstration.
- d. Under all circumstances, health care providers must retain 100 percent of their payments for or in connection with furnishing covered services to beneficiaries. Moreover, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local governments, or third parties to return and/or redirect to the state any portion of the Medicaid payments in a manner inconsistent with the requirements in section 1903(w) of the Act and its implementing regulations. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.
- e. The State Medicaid Director or his/her designee certifies that all state and/or local funds used as the state's share of the allowable expenditures reported on the CMS-64 for this demonstration were in accordance with all applicable federal requirements and did not lead to the duplication of any other federal funds.
- **69. Financial Integrity for Managed Care Delivery Systems.** As a condition of demonstration approval, the state attests to the following, as applicable:
  - a. All risk-based managed care organization, prepaid inpatient health plan (PIHP), and prepaid ambulatory health plan (PAHP) payments, comply with the requirements on payments in 42 CFR 438.6(b)(2), 438.6(c), 438.6(d), 438.60, and 438.74.
- **70. Requirements for Health Care-Related Taxes and Provider Donations.** As a condition of demonstration approval, the state attests to the following, as applicable:
  - a. Except as provided in paragraph (c) of this STC, all health care-related taxes as defined by Section 1903(w)(3)(A) of the Act and 42 CFR 433.55 are broad-based as defined by Section 1903(w)(3)(B) of the Act and 42 CFR 433.68(c).
  - b. Except as provided in paragraph (c) of this STC, all health care-related taxes are uniform as defined by Section 1903(w)(3)(C) of the Act and 42 CFR 433.68(d).
  - c. If the health care-related tax is either not broad-based or not uniform, the state has applied for and received a waiver of the broad-based and/or uniformity requirements as specified by 1903(w)(3)(E)(i) of the Act and 42 CFR 433.72.

- d. The tax does not contain a hold harmless arrangement as described by Section 1903(w)(4) of the Act and 42 CFR 433.68(f).
- e. All provider-related donations as defined by 42 CFR 433.52 are bona fide as defined by Section 1903(w)(2)(B) of the Social Security Act, 42 CFR 433.66, and 42 CFR 433.54.
- **71. State Monitoring Federal Share.** If any payments under the demonstration are funded in whole or in part by a locality tax, then the state must provide a report to CMS regarding payments under the demonstration no later than 60 days after demonstration approval. This deliverable is subject to the deferral as described in STC 53. This report must include:
  - a. A detailed description of and a copy of (as applicable) any agreement, written or otherwise agreed upon, regarding any arrangement among the providers including those with counties, the state, or other entities relating to each locality tax or payments received that are funded by the locality tax;
  - b. Number of providers in each locality of the taxing entities for each locality tax;
  - c. Whether or not all providers in the locality will be paying the assessment for each locality tax;
  - d. The assessment rate that the providers will be paying for each locality tax;
  - e. Whether any providers that pay the assessment will not be receiving payments funded by the assessment;
  - f. Number of providers that receive at least the total assessment back in the form of Medicaid payments for each locality tax;
  - g. The monitoring plan for the taxing arrangement to ensure that the tax complies with section 1903(w)(4) of the Act and 42 CFR 433.68(f); and
  - h. Information on whether the state will be reporting the assessment on the CMS form 64.11A as required under section 1903(w) of the Act.
- **72.** Extent of Federal Financial Participation (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 following demonstration expenditures, subject to the budget neutrality expenditure limits described in the STCs in section XI:
  - a. Administrative costs, including those associated with the administration of the demonstration.

- b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved state plan, and
- c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability or CMS payment adjustments.
- 73. **Program Integrity.** The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.
- 74. Medicaid Expenditure Groups. Medicaid Expenditure Groups (MEG) are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The Master MEG Chart table provides a master list of MEGs defined for this demonstration.

		Table #3: N	Iaster MEG C	hart	
MEG	Which BN Test Applies?	Per WW		Brief Description	
SUD	Hypo 1	Х		Х	All expenditures for services provided to an individual while they are a patient in an IMD for SUD treatment, described in Section XIV.
RRSS	Нуро 2	х		Х	All expenditures for RRSS services, described in Section XIV.
SMI MCO	Нуро 3	х		х	All managed care expenditures for services provided to an individual while they are a patient in an IMD for SMI treatment described in of Section XV.
SMI FFS	Нуро 3	х		х	All FFS expenditures for services provided to an individual while they are a patient in an IMD for SMI treatment described in of Section XV
Reentry	Нуро 4	Х		Х	Expenditures for targeted services that are otherwise

	Table #3: Master MEG Chart									
MEG	Which BN Test Applies?	WOW Per Capita	WOW Aggregate	ww	Brief Description					
					covered under Medicaid provided to qualifying beneficiaries for up to 60 days immediately prior to release from participating facilities.					
Reentry Non- Service	Нуро 4		х		Expenditures for allowable planning and non-services for the reentry demonstration initiative.					
HRSN	SHAC		Х		Expenditures for HRSN services described in Section VII.					
HRSN Infrastructure	SHAC		Х		Expenditures for planning and supporting the HRSN initiative, as described in Section VII.					
ADM	N/A				All additional administrative costs that are directly attributable to the demonstration and not described elsewhere and are not subject to budget neutrality.					

- 75. Reporting Expenditures and Member Months. The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W--00306/4). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.
  - a. Cost Settlements. The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b (in lieu of lines 9 or 10c), or line 7. For any cost settlement not attributable to this demonstration, the adjustments should be

reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.

- b. **Premiums and Cost Sharing Collected by the State.** The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by demonstration year on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.
- c. **Pharmacy Rebates.** Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.
- d. Administrative Costs. The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise in the STCs in section XI, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.
- e. **Member Months.** As part of the Quarterly and Annual Monitoring Reports described in section IX, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. The term "eligible member months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months each contribute two eligible member months per person, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.
- f. **Budget Neutrality Specifications Manual.** The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state's Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications

Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

	Table 4:	MEG Detail f	or Expenditu	re and Men	nber Mon	th Reporting	ļ	
MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 or 64.10 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
SUD	Report all medical assistance expenditures for services provided to an individual while they are a patient in an IMD for SUD treatment.		Follow standard CMS 64.9 Category of Service Definitions	Date of service	MAP	Y	10/5/18	12/31/29
RRSS	Report all medical assistance expenditures for RRSS services.		Follow standard CMS 64.9 Category of Service Definitions	Date of service	MAP	Y	1/1/25	12/31/29
SMI MCO	Report all medical assistance expenditures for services provided to an individual while they are a patient in an IMD for SMI treatment under managed care.		Follow standard CMS 64.9 Category of Service Definitions	Date of service	MAP	Y	1/1/25	12/31/29
SMI FFS	Report all medical assistance expenditures for services provided to an individual while they are a patient in an IMD for SMI treatment under FFS		Follow standard CMS 64.9 Category of Service Definitions	Date of service	MAP	Y	1/1/25	12/31/29

<b>Reentry</b> Services	Report all expenditures for reentry services that are otherwise covered under Medicaid provided to qualifying beneficiaries for up to 60 days immediately prior to release from participating facilities.	Follow standard CMS 64.' Based Category of Servic Definition	Date of service	МАР	Y	7/2/24	12/31/29
Reentry Non- Services	Report all expenditures for allowable planning and non-services for the reentry demonstration initiative.	Follow CMS 64. Base Category of Servic Definition	Date of payment	ADM	N	7/2/24	12/31/29
HRSN	Report all expenditures for HRSN Services	Follow standard CMS 64. Category of Servic Definition	Date of service	МАР	Y	1/1/25	12/31/29
HRSN Infrastruct ure	Report all expenditures for HRSN infrastructure	Follow standard CMS 64. Category of Servic Definition	9 Date of payment	ADM	N	1/1/25	12/31/29
ADM	Report all additional administrative costs that are directly attributable to the demonstration and are not described elsewhere and are not subject	Follow standard CMS 64.1 Category of Servic Definition	0 Date of payment e	ADM	N	10/5/18	12/31/29

to budget neutrality				

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

	Table 5: Demonstration Years	
Demonstration Year 8	January 1, 2025 to September 30, 2025	9 months
Demonstration Year 9	October 1, 2025 to September 30, 2026	12 months
Demonstration Year 10	October 1, 2026 to September 30, 2027	12 months
Demonstration Year 11	October 1, 2027 to September 30, 2028	12 months
Demonstration Year 12	October 1, 2028 to September 30, 2029	12 months
Demonstration Year 13	October 1, 2029 to December 31, 2029	3 months

- 77. **Budget Neutrality Monitoring Tool.** The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the performance metrics database and analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing the demonstration's actual expenditures to the budget neutrality expenditure limits described in STC XI. CMS will provide technical assistance, upon request.<sup>3</sup>
- **78.** Claiming Period. The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.

<sup>&</sup>lt;sup>3</sup> Per 42 CFR 431.420(a)(2), states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and 431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS's current approach is to include language in STCs requiring, as a condition of demonstration approval, that states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget neutrality limit. CMS has obtained Office of Management and Budget (OMB) approval of the monitoring tool under the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and states agree to use the tool as a condition of demonstration approval.

- **79. Future Adjustments to Budget Neutrality.** CMS reserves the right to adjust the budget neutrality expenditure limit:
  - a. To be consistent with enforcement of laws and policy statements, including regulations and guidance, regarding impermissible provider payments, health care related taxes, or other payments. CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.
  - b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.
  - c. The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.
- **80. Budget Neutrality Mid-Course Correction Adjustment Request.** No more than once per demonstration year, the state may request that CMS make an adjustment to its budget neutrality agreement based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.
  - a. **Contents of Request and Process**. In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 80c. If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. Within 120 days of acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant

to STC 7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

- b. **Types of Allowable Changes.** Adjustments will be made only for actual costs as reported in expenditure data. CMS will not approve mid-demonstration adjustments for anticipated factors not yet reflected in such expenditure data. Examples of the types of mid-course adjustments that CMS might approve include the following:
  - i. Provider rate increases that are anticipated to further strengthen access to care;
  - ii. CMS or State technical errors in the original budget neutrality formulation applied retrospectively, including, but not limited to the following: mathematical errors, such as not aging data correctly; or unintended omission of certain applicable costs of services for individual MEGs;
  - iii. Changes in federal statute or regulations, not directly associated with Medicaid, which impact expenditures;
  - iv. State legislated or regulatory change to Medicaid that significantly affects the costs of medical assistance;
  - v. When not already accounted for under Emergency Medicaid 1115 demonstrations, cost impacts from public health emergencies;
  - vi. High-cost innovative medical treatments that states are required to cover; or,
  - vii. Corrections to coverage/service estimates where there is no prior state experience (e.g., SUD) or small populations where expenditures may vary widely.
- c. **Budget Neutrality Update.** The state must submit an updated budget neutrality analysis with its adjustment request, which includes the following elements:
  - i. Projected without waiver and with waiver expenditures, estimated member months, and annual limits for each DY through the end of the approval period; and
  - ii. Description of the rationale for the mid-course correction, including an explanation of why the request is based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or is due to a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

### XI. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

- **81.** Limit on Title XIX Funding. The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit consists of Hypothetical Budget Neutrality Tests, as described below. CMS's assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.
- 82. Risk. The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 3, Master MEG Chart and Table 4, MEG Detail for Expenditure and Member Month Reporting. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions, however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.
- **83.** Calculation of the Budget Neutrality Limits and How They Are Applied. To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.
- **84. Main Budget Neutrality Test**. This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests, including the "Supplemental HRSN Aggregate Ceiling." Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS.
- **85. Hypothetical Budget Neutrality**. When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), or when a WOW spending baseline for certain WW expenditures is difficult to estimate due to

variable and volatile cost data resulting in anomalous trend rates, CMS considers these expenditures to be "hypothetical," such that the expenditures are treated as if the state could have received FFP for them absent the demonstration. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the expenditures on those services. When evaluating budget neutrality, however, CMS does not offset nonhypothetical expenditures with projected or accrued savings from hypothetical expenditures; that is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state's WW hypothetical spending exceeds the Hypothetical Budget Neutrality Test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending through savings elsewhere in the demonstration or to refund the FFP to CMS.

86. Hypothetical Budget Neutrality Test 1: SUD. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test.

	Table 6: Hypothetical Budget Neutrality Test 1										
MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 8	DY 9	DY 10	DY 11	DY 12	DY 13		
SUD	PC	Both	6.2%	\$1,136.09	\$1,197.49	\$1,271.73	\$1,350.58	\$1,434.32	\$1,489.27		

87. Hypothetical Budget Neutrality Test 2: RRSS. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 2. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality

expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test 2 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 7: Hypothetical Budget Neutrality Test 2									
MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 8	DY 9	DY 10	DY 11	DY 12	DY 13
RRSS	RRSS    PC    Both    5.0%    \$18.18    \$18.97    \$19.92    \$20.92    \$21.97    \$22.6								

**88. Hypothetical Budget Neutrality Test 3: SMI**. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 3. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test 3 are counted as WW expenditures under the Main Budget Neutrality Test.

	Table 8: Hypothetical Budget Neutrality Test 3											
MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 8	DY 9	DY 10	DY 11	DY 12	DY 13			
SMI MCO	PC	Both	4.8%	\$1,497.67	\$1,560.39	\$1,635.29	\$1,713.78	\$1,796.04	\$1,849.45			
SMI FFS	PC	Both	4.8%	\$21,842.91	\$22,757.61	\$23,849.98	\$24,994.78	\$26,194.53	\$26,973.44			

**89.** Hypothetical Budget Neutrality Test 4: Reentry. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 4. 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

Table 9: Hypothetical Budget Neutrality Test 4									
MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 8	DY 9	DY 10	DY 11	DY 12	DY 13
Reentry Services	PC	Both	5.6%	\$1,591.32	\$1,669.03	\$1,762.50	\$1,861.20	\$1,965.43	\$2,033.52
Reentry Non- Services	PC	Both	N/A	\$2,328,750	\$1,293,750	\$258,750	\$258,750	\$258,750	\$0

neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test 4 are counted as WW expenditures under the Main Budget Neutrality Test.

90. Supplemental HRSN Aggregate Ceiling (SHAC) Hypothetical Budget Neutrality for Evidence-Based HRSN Initiatives. When expenditure authority is provided for specified HRSN initiatives in the demonstration (in this approval, as specified in section VII), CMS considers these expenditures to be "supplemental HRSN aggregate ceiling (SHAC)" expenditures; that is, the expenditures are eligible to receive FFP up to a specific aggregate spending cap per demonstration year, based on the state's expected expenditures. States can also receive FFP for capacity-building, infrastructure, and operational costs for the HRSN initiatives; this FFP is limited by a sub-cap of the aggregate spending cap and is determined by CMS based on the amount the state expects to spend. Like all hypothetical expenditures, SHAC expenditures do not need to be offset by savings, and cannot produce savings; however, unspent expenditure authority allocated for HRSN infrastructure in a given demonstration year can be applied to HRSN services in the same demonstration year. Any unspent HRSN services expenditure authority may not be used to fund HRSN infrastructure. To allow for SHAC expenditures and to prevent them from resulting in savings that would apply to the rest of the demonstration, CMS currently applies a separate, independent SHAC Budget Neutrality Test, which subjects SHAC expenditures to predetermined aggregate limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If actual HRSN initiative spending is less than the SHAC Budget Neutrality Test's expenditure limit for a given demonstration year, the difference is not considered demonstration savings. Unspent HRSN expenditure authority under the cap for each demonstration year can be carried, shifted, or transferred across future demonstration years. However, unspent HRSN expenditure authority cannot roll over to the next demonstration approval period. If the state's SHAC spending exceeds the SHAC Budget Neutrality Test's expenditure limit, the state agrees (as a condition of CMS

approval) to refund any FFP in excess of the cap to CMS. Demonstration savings from the Main Budget Neutrality Test cannot be used to offset excess spending for the SHAC.

91. SHAC Budget Neutrality Test: HRSN. The table below identifies the MEGs that are used for the SHAC Budget Neutrality Test. 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 SHAC 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 the SHAC Budget Neutrality Test cannot be offset by savings under the Main Budget Neutrality Test or the Hypothetical Budget Neutrality Tests.

Table 10: SHAC Budget Neutrality Test								
MEG	PC or Agg	WOW Only, WW Only, or Both	DY 8	DY 9	DY 10	DY 11	DY 12	DY 13
HRSN	Agg	Both	\$6,326,698	\$8,999,263	\$9,539,219	\$10,111,572	\$10,718,266	\$2,832,559
HRSN Infrastructure	Agg	Both	\$2,000,000	\$184,575	\$184,575	\$184,575	\$184,575	\$0

- **92.** Former Foster Care Youth (FFCY) Budget Neutrality. CMS has determined that the FFCY 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. The state will not be allowed to obtain budget neutrality "savings" from this demonstration population. The demonstration population will not include a budget neutrality expenditure limit. The state must report quarterly claims and report expenditures on the CMS-64 base form(s) for Medicaid State Plan populations in accordance with section 2500 of the State Medicaid Manual.
- **93. Composite Federal Share.** The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be

known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

- **94.** Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the demonstration period, which extends from 1/1/2025 to 12/31/2029. The Main Budget Neutrality Test for this demonstration period may incorporate carry-forward savings, that is, net savings from up to 10 years of the immediately prior demonstration approval period(s) (1/1/2025 to 12/31/2029). If at the end of the demonstration approval period the Main Budget Neutrality Test or a SHAC Budget Neutrality Test has been exceeded, the excess federal funds will be returned to CMS. If the Demonstration is terminated prior to the end of the budget neutrality agreement, the budget neutrality test shall be based on the time elapsed through the termination date.
- **95.** Corrective Action Plan. If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

Table 11: Budget Neutrality Test Corrective Action Plan Calculation				
DY 8	Cumulative budget	2.0%		
	neutrality limit plus:			
DY 8 through DY 9	Cumulative budget	1.5%		
	neutrality limit plus:			
DY 8 through DY 10	Cumulative budget	1.0%		
_	neutrality limit plus:			
DY 8 through DY 11	Cumulative budget	0.5%		
	neutrality limit plus:			
DY 8 through DY 12	Cumulative budget	0%		
	neutrality limit plus:			
DY 8 through DY 13	Cumulative budget	0%		
	neutrality limit plus:			

## XII. CHIP MONITORING ALLOTMENT NEUTRALITY

- **96. 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.
- **97. 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.
- **98. 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.

- **99.** 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.
- **100.** 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.

## XIII. EVALUATION OF THE DEMONSTRATION

- Cooperation with Federal Evaluators and Learning Collaborative. As required under 101. 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to: commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged; and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, a that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. This may also include the state's participation – including representation from the state's contractors, independent evaluators, and organizations associated with the demonstration operations, as applicable - in a federal learning collaborative aimed at cross state technical assistance, and identification of lessons learned and best practices for demonstration measurement, data development, implementation, monitoring and evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 54.
- **102. Independent Evaluator.** The state must use an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The independent party must sign an agreement to conduct the demonstration evaluation in an independent manner in accordance with the CMS-approved 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.

**103. 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.

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

- a. Attachment A (Developing the Evaluation Design) of these STCs, and
- b. Any applicable CMS evaluation guidance and technical assistance specific to the demonstration's policy components.
- c. The draft Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, such as quasi-experimental methods like difference-in-differences and interrupted time series, as well as establishing valid comparison groups and assuring causal inferences in demonstration evaluations. In addition to these requirements, if determined appropriate for the communities impacted by the demonstration, the state is encouraged to consider implementation approaches involving randomized control trials and staged rollout (for example, across geographic areas, by service setting, or by beneficiary characteristic), as these implementation strategies help create strong comparison groups and facilitate robust evaluation. The state is strongly encouraged to use the expertise of the independent party in the development of the draft Evaluation Design. The draft Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STCs 107 and 108.
- d. For any amendment to the demonstration, the state will be required to update the approved Evaluation Design to accommodate the amendment component. The amended Evaluation Design must be submitted to CMS for review no later than 180 calendar days after CMS's approval of the demonstration amendment. Depending on the scope and timing of the amendment, in consultation with CMS, the state may provide the details on necessary modifications to the approved Evaluation Design via the monitoring reports. The amended Evaluation Design must also be reflected in the state's Interim (as applicable) and Summative Evaluation Reports, described below.
- **104.** Evaluation Design Approval and Updates. The state must submit to CMS a revised draft Evaluation Design within 60 calendar days after receipt of CMS's comments, if any. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design to the state's Medicaid website within 30 calendar days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation progress in each of the Quarterly and Annual Monitoring Reports. Once CMS approves the Evaluation Design, if the state wishes to make changes, the state must submit a revised Evaluation Design to CMS for approval. if the changes are substantial in scope;

otherwise, in consultation with CMS, the state may include updates to the Evaluation Design in monitoring reports.

a. Evaluation Questions and Hypotheses. Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Reports) of these STCs, the evaluation deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS evaluation guidance and technical assistance, the evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact and its effectiveness in achieving the goals. The hypothesis testing should include, where possible, assessment of both process and outcome measures. The evaluation must study outcomes, such as likelihood of enrollment and enrollment continuity, and various measures of access, utilization, and health outcomes, as appropriate and in alignment with applicable CMS evaluation guidance and technical assistance, for the demonstration policy components. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) and the Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set), collectively referred to as the CMS Child and Adult Core Measure Sets for Medicaid and CHIP; Consumer Assessment of Health Care Providers and Systems (CAHPS); the Behavioral Risk Factor Surveillance System (BRFSS) survey; and/or measures endorsed by NQF.

CMS underscores the importance of the state undertaking a well-designed beneficiary survey and/or interviews to assess, for instance, beneficiary individual understanding of and experience with and experience the various demonstration policy components, including but not limited to, beneficiary experiences with access to and quality of care. In addition, the state is strongly encouraged to evaluate the implementation of the demonstration components in order to better understand whether implementation of certain key demonstration policies happened as envisioned during the demonstration design process and whether specific factors acted as facilitators of—or barriers to—successful implementation. Implementation research questions can also focus on beneficiary and provider experience with the demonstration. The implementation evaluation can inform the state's crafting and selection of testable hypotheses and research questions for the demonstration's outcome and impact evaluations and provide context for interpreting the findings.

b. 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.

c. Evaluation hypotheses for the HRSN initiatives in the demonstration must focus on assessing the effectiveness of the HRSN services in mitigating identified needs of beneficiaries. Such assessment is expected to use applicable demonstration monitoring and other data on the prevalence and severity of beneficiaries' HRSNs and the provision of and beneficiary utilization of HRSN services. Furthermore, the HRSN evaluation must include an analysis of how the initiatives (e.g., short-term preprocedure, and/or post-hospitalization housing (recuperative care) with room and board) affect utilization of preventive and routine care, utilization of and costs associated with potentially avoidable, high-acuity health care, and beneficiary physical and mental health outcomes. In alignment with the demonstration's objectives to improve outcomes for the state's overall beneficiary populations eligible for the HRSN initiatives, the state must also include research questions and hypotheses focused on understanding the impact of HRSN initiatives on advancing health quality, including through the reduction of health disparities, for example, by assessing the effects of the initiatives in reducing disparities in health care access, quality of care, or health outcomes at the individual, population, and/or community level.

The evaluation must also assess the effectiveness of the infrastructure investments authorized through the demonstration to support the development and implementation of the HRSN initiatives. The state must also examine whether and how local investments in housing, nutrition and any other type of allowable HRSN services change over time in concert with new Medicaid funding toward those services. In addition, in light of how demonstration HRSN expenditures are being treated for purposes of budget neutrality, the evaluation of the HRSN initiatives must include a cost analysis to support developing comprehensive and accurate cost estimates of providing such services. It is also required to include a robust assessment of potential improvements in the quality and effectiveness of downstream services that can be provided under the state plan authority, and associated cost implications.

In addition, in accordance with the approved Evaluation Design, the state must coordinate with its managed care plans to secure necessary data—for a representative beneficiary population eligible for the HRSN services—to conduct a robust evaluation of the effectiveness of the HRSN services in mitigating identified needs of beneficiaries. Such an assessment will require setting up a data infrastructure and/or data sharing arrangement to collect data on beneficiary screening and rescreening and prevalence and severity of beneficiaries' HRSNs, among others. If the data system is not operational to capture necessary data for a quantitative evaluation by the time the state's evaluation activities must be conducted, the state must provide applicable qualitative assessment to this effect leveraging suitable primary data collections efforts (e.g., beneficiary surveys).

- d. Evaluation hypotheses for the SUD component of the demonstration must support an assessment of the demonstration's success in achieving the core goals of the program through addressing, among other outcomes, initiation and compliance with treatment, utilization of health services in appropriate care settings, and reductions in key outcomes such as deaths due to overdose.
- e. Hypotheses for the SMI component must map to the SMI goals of the demonstration including reducing utilization and lengths of stay in EDs, reducing preventable readmissions to acute care hospitals and residential settings, improving the availability of crisis stabilization services, improving access to community-based services, and improving care coordination.
- f. Hypotheses for the RRSS program must align with the goals of the program to support SUD beneficiaries achieve independence in the community. Toward this end, the hypotheses should address whether the skills and coaching provided through the program result in greater community integration and better treatment outcomes for participants than would have occurred in the counterfactual scenario, i.e., no RRSS program.
- g. Finally, the state must accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, English language proficiency, primary language, disability status, and geography). Such stratified data analyses will provide a fuller understanding of existing disparities in access to and quality of care and health outcomes and help inform how the demonstration's various policies might support reducing such disparities.

- **105.** Evaluation Budget. A budget for the evaluation must be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluation such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.
- **106.** 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 extension of the demonstration, the Interim Evaluation Report should be posted to the state's Medicaid 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 of any components within the demonstration that expire prior to the overall demonstration's expiration date, and depending on the timeline of expiration/phase-out, the Interim Evaluation Report must include an evaluation of the authority, to be collaboratively determined by CMS and the state.
  - c. If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for the extension is submitted, or one year prior to the end of the demonstration, whichever is sooner. If the state made changes to the demonstration in its application for extension, the research questions and hypotheses, and a description of how the design was adapted should be included. If the state is not requesting an extension for a demonstration, an Interim Evaluation Report is due one (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 revised Interim Evaluation Report 60 calendar days after receiving CMS's comments on the draft Interim Evaluation Report, if any,
  - e. Once approved by CMS, the state must post the document to the state's Medicaid website within 30 calendar days.
  - f. The Interim Evaluation Report must comply with Attachment L (Preparing the Interim and Summative Evaluation Report) of these STCs.
- **107.** Summative Evaluation Report. The state must submit to CMS a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The draft Summative Evaluation Report must be developed in accordance with Attachment M (Preparing the Interim and

Summative Evaluation Reports) of these STCs, and in alignment with the approved Evaluation Design.

- a. Unless otherwise agreed upon in writing by CMS, the state must submit the revised Summative Evaluation Report within sixty (60) calendar days of receiving comments from CMS on the draft, if any.
- b. Once approved by CMS, the state must post the final Summative Evaluation Report to the state's Medicaid website within 30 calendar days.
- **108.** Corrective Action Plan Related to Evaluation Data. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of an extension process when associated with the state's Interim Evaluation Report or as part of the review of the Summative Evaluation Report. A corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 54. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.
- **109.** 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.
- **110. Public Access.** The state shall post the final documents (e.g., Implementation Plan, Monitoring Protocol, Monitoring Reports, Mid-Point Assessment, Close-Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 calendar days of approval by CMS.
- **111.** 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 30 calendar days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

## XIV. OPIOID USE DISORDER (OUD)/SUBSTANCE USE DISORDER (SUD)

**112. SUD Program Benefits.** Effective upon CMS's approval of the SUD Implementation Plan, in Attachment C, the demonstration benefit package for Medicaid beneficiaries will include SUD treatment services, including services provided in residential and inpatient treatment settings that qualify as an IMD, which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Medicaid beneficiaries who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance, including OUD/SUD services, that would otherwise be matchable if the beneficiary were not residing in an IMD once CMS approves the state's Implementation Plan. CMS approved the SUD Implementation Plan on July 10, 2018. The state will aim for a statewide average length of stay of 30 days or less in residential treatment settings, to be monitored pursuant to the Monitoring Protocol as outlined in STC 57, to ensure short-term residential stays.

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

- **113. Recovery Residence Support Services.** RRSS are non-clinical activities necessary to support beneficiaries recovering with SUD, which support their independence in the community through skills training and coaching. RRSS removes barriers to recovery of SUD and support continued engagement in the SUD recovery process.
  - a. **RRSS Eligibility**: Individuals eligible for RRSS must be individuals who are ages 18 or older, enrolled in Medicaid either through a Medicaid state plan eligibility group or through the FFCY demonstration population. Individuals must also meet the following eligibility criteria:
    - i. Be participating in a Behavioral Health Conditional Dismissal Program (BHCDP);
    - ii. Reside in a BHCDP-approved Recovery Residence;
    - iii. Meet American Society of Addiction Medicine (ASAM) Level of Care 2.7 or less, and
    - iv. Be experiencing homelessness, unemployment, or have a history of criminal justice involvement.
  - b. **RRSS Services**: Beneficiaries may receive RRSS for up to 90 days per rolling year. Activities and services included in RRSS are outlined in the RRSS Service Description Attachment J. Components of the RRSS Service Description include a list of the services covered under the RRSS program, and the associated service descriptions.

- c. **RRSS Providers**: Providers participating in the RRSS program must be a certified National Association of Recovery Residences (NARR) Level 2 or 3 recovery residence in accordance with the Kentucky Recovery Housing Network (KRHN) standards. Providers must be contracted with a Kentucky Medicaid MCO. In addition, Kentucky will require that RRSS be provided by:
  - i. Certified peer support specialists in accordance with 908 Kentucky Administrative Regulations (KAR) 2:220, with lived substance use experience and trained in recovery capital;
  - ii. Registered alcohol and drug peer support specialist in accordance with Kentucky Revised Statutes 309.080(12), with lived substance use experience and training in recovery capital, and may include;
  - iii. Targeted Case Managers certified in accordance with 908 KAR 2:260, with working experience in substance use disorder and training in recovery capital.
- d. Unallowable Expenditures Under the RRSS Expenditure Authority: The state may not claim or receive FFP under the RRSS expenditure authority for room and board costs for RRSS providers.
- **114. SUD Evaluation.** The SUD Evaluation will be subject to the same requirements as the overall demonstration evaluation, as described in Sections IX (Monitoring and Reporting Requirements) and XIII (Evaluation of the Demonstration) of these STCs.
- **115.** Unallowable Expenditures Under the SUD Expenditure Authority. In addition to the other unallowable costs and caveats already outlined in these STCs, the state may not receive FFP under any expenditure authority approved under this demonstration for any of the following:
  - a. Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

## XV. SERIOUS MENTAL ILLNESS (SMI) PROGRAM AND BENEFITS

**116. SMI Program Benefits.** Under this demonstration, beneficiaries will have access to, the full range of otherwise covered Medicaid services, including SMI treatment services. These SMI services will range in intensity from short-term acute care in inpatient settings for SMI, to ongoing chronic care for such conditions in cost-effective community-based settings. The state will work to improve care coordination and care for co-occurring physical and behavioral health conditions. The state must achieve a statewide average length of stay of no more than 30 days for beneficiaries receiving treatment in an IMD treatment setting through this demonstration's SMI Program, to be monitored pursuant to the SMI Monitoring Protocol as outlined in STC 57.

**117. SMI Program Eligibility**. Beneficiaries eligible to receive benefits under the SMI Program are 21 to 64 years of age, receiving a full Medicaid state plan benefit package, either through a Medicaid state plan eligibility group or the demonstration, with income up to 213 percent of the FPL. The state will not impose an income limit for state plan eligible former foster care children, demonstration eligible FFCY, and individuals determined aged, blind, or disabled. Individuals that receive limited Medicaid benefits or who are receiving long-term care services and supports (LTSS) are not eligible for the SMI program.

### **118.** SMI Implementation Plan.

- a. The state must submit the SMI Implementation Plan within 90 calendar days after approval of the demonstration extension for CMS review and comment. If applicable, the state must submit a revised SMI Implementation Plan within 60 calendar days after receipt of CMS's comments. The state may not claim FFP for services provided to beneficiaries residing in IMDs primarily to receive treatment for SMI under expenditure authority until CMS has approved the SMI Implementation Plan and the SMI financing plan described in STC 118(e). After approval of the required Implementation Plan and Financing Plan, FFP will be available prospectively, but not retrospectively.
- b. Once approved, the SMI Implementation Plan will be incorporated into the STCs as Attachment C, and once incorporated, may be altered only with CMS approval. Failure to submit an SMI Implementation Plan, within 90 calendar days after approval of the demonstration, 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 SMI program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral as described in STC 53.
- c. At a minimum, the SMI Implementation Plan must describe the strategic approach, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives for the program:
  - i. Ensuring Quality of Care in Psychiatric Hospitals and Residential Settings:
    - Hospitals that meet the definition of an IMD in which beneficiaries receiving demonstration services under the SMI program are residing must be licensed or approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals prior to the state claiming FFP for services provided to beneficiaries residing in a hospital that meets the definition of an IMD. In addition, hospitals must be in compliance with the conditions of participation set forth in 42 CFR Part 482 and either: a) be certified by the state agency as being in

compliance with those conditions through a state agency survey, or b) have deemed status to participate in Medicare as a hospital through accreditation by a national accrediting organization whose psychiatric hospital accreditation program or acute hospital accreditation program has been approved by CMS

- 2. Residential treatment providers that meet the definition of an IMD in which beneficiaries receiving demonstration services under the SMI program are residing must be licensed, or otherwise authorized, by the state to primarily provide treatment for mental illnesses. They must also be accredited by a nationally recognized accreditation entity prior to the state claiming FFP for services provided to beneficiaries residing in a residential facility that meets the definition of an IMD
- 3. Establishment of an oversight and auditing process that includes unannounced visits for ensuring participating hospitals and residential treatment settings in which beneficiaries receiving coverage pursuant to the demonstration are residing meet applicable state licensure or certification requirements as well as a national accrediting entity's accreditation requirements
- 4. Use of a utilization review entity (for example, a managed care organization or administrative service organization) to ensure beneficiaries have access to the appropriate levels and types of care and to provide oversight to ensure lengths of stay are limited to what is medically necessary and only those who have a clinical need to receive treatment in psychiatric hospitals and residential treatment settings are receiving treatment in those facilities
- 5. Establishment of a process for ensuring that participating psychiatric hospitals and residential treatment settings meet applicable federal program integrity requirements, and establishment of a state process to conduct risk-based screening of all newly enrolling providers, as well as revalidation of existing providers (specifically, under existing regulations, the state must screen all newly enrolling providers and reevaluate existing providers pursuant to the rules in 42 CFR Part 455 Subparts B and E, ensure providers have entered into Medicaid provider agreements pursuant to 42 CFR 431.107, and establish rigorous program integrity protocols to safeguard against fraudulent billing and other compliance issues)
- 6. Implementation of a state requirement that participating psychiatric hospitals and residential treatment settings screen beneficiaries for co-morbid physical health conditions and SUDs and demonstrate the

capacity to address co-morbid physical health conditions during short-term stays in residential or inpatient treatment settings (e.g., with on-site staff, telemedicine, and/or partnerships with local physical health providers).

- ii. Improving Care Coordination and Transitions to Community-Based Care:
  - 1. Implementation of a process to ensure that psychiatric hospitals and residential treatment facilities provide intensive pre-discharge, care coordination services to help beneficiaries transition out of those settings into appropriate community-based outpatient services, including requirements that facilitate participation of community-based providers in transition efforts (e.g., by allowing beneficiaries to receive initial services from a community-based provider while the beneficiary is still residing in these settings and/or by engaging peer support specialists to help beneficiaries make connections with available community-based providers and, where applicable, make plans for employment)
  - 2. Implementation of a process to assess the housing situation of a beneficiary transitioning to the community from psychiatric hospitals and residential treatment settings and to connect beneficiaries who have been experiencing or are likely to experience homelessness or who would be returning to unsuitable or unstable housing with community providers that coordinate housing services, where available;
  - 3. Implementation of a requirement that psychiatric hospitals and residential treatment settings that are discharging beneficiaries who have received coverage pursuant to this demonstration have protocols in place to ensure contact is made by the treatment setting with each discharged beneficiary and the community-based provider to which the beneficiary was referred within 72 hours of discharge to help ensure follow-up care is accessed by individuals after leaving those facilities by contacting the individuals directly and, as appropriate, by contacting the community-based provider the person was were referred to;
  - 4. Implementation of strategies to prevent or decrease the length of stay in emergency departments among beneficiaries with SMI (e.g., through the use of peer support specialists and psychiatric consultants in EDs to help with discharge and referral to treatment providers);

- 5. Implementation of strategies to develop and enhance interoperability and data sharing between physical, SUD, and mental health providers, with the goal of enhancing coordination so that disparate providers may better share clinical information to improve health outcomes for beneficiaries with SMI.
- iii. Increasing Access to Continuum of Care Including Crisis Stabilization Services:
  - 1. Establishment of a process to annually assess the availability of mental health services throughout the state, particularly crisis stabilization services, and updates on steps taken to increase availability (the state must provide updates on how it has increased the availability of mental health services in every Annual Monitoring Report)
  - 2. Commitment to implementation of the SMI financing plan described in STC 118(e). The state must maintain a level of state and local funding for outpatient community-based mental health services for Medicaid beneficiaries for the duration of the SMI program under the demonstration that is no less than the amount of funding provided at the beginning of the SMI program under the demonstration. The annual MOE will be reported and monitored as part of the Annual Monitoring Report described in STC X;
  - 3. Implementation of strategies to improve the state's capacity to track the availability of inpatient and crisis stabilization beds to help connect individuals in need with that level of care as soon as possible;
  - 4. Implementation of a requirement that providers, plans, and utilization review entities use an evidence-based, publicly available patient assessment tool, preferably endorsed by a mental health provider association [e.g., Level of Care Utilization System (LOCUS) or the Child and Adolescent Service Intensity Instrument (CASII)] to determine appropriate level of care and length of stay.
- iv. Earlier Identification and Engagement in Treatment and Increased Integration:
  - 1. Implementation of strategies for identifying and engaging individuals, particularly adolescents and young adults, with SMI in treatment sooner, including through supported employment and supported education programs;

- 2. Increasing integration of behavioral health care in non-specialty care settings, including schools and primary care practices, to improve identification of SMI conditions sooner and improve awareness of and linkages to specialty treatment providers;
- 3. Establishment of specialized settings and services, including crisis stabilization services, focused on the needs of young people experiencing SMI.
- d. SMI Health Information Technology (Health IT) Plan. The Health IT plan is intended to apply only to those State Health IT functionalities impacting beneficiaries within this demonstration and providers directly funded by this demonstration. 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. If the state is unable to provide such an assurance, it will submit to CMS a Health IT Plan, to be included as a section of the applicable Implementation Plan (see STC 118(c)), to develop the infrastructure/capabilities of the state's health IT infrastructure.
  - i. The Health IT Plan will detail the necessary Health IT capabilities in place to support beneficiary health outcomes to address the SMI goals of the demonstration. The plan(s) will also be used to identify areas of health IT ecosystem improvement. The Protocol must include implementation milestones and projected dates for achieving them (see Attachment D) and must be aligned with the state's broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state's Behavioral Health (BH) IT Health Plan.
  - ii. The state will include in its Monitoring Protocol (see STC 57e) an approach to monitoring its SMI Health IT Plan which will include performance metrics to be approved in advance by CMS.
  - iii. The state will monitor progress, each DY, on the implementation of its SMI Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS within its Annual Monitoring Report (see STC 58).
  - iv. 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 SMI Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.
  - v. Where there are opportunities at the state- and provider-level (up to and including usage in managed care organization (MCO) or Accountable Care

Organization (ACO) participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B "Standards and Implementation Specifications for HIT". If there is no relevant standard in 45 CFR 170 Subpart B, the state should review the Office of the National Coordinator for Health Information Technology's Interoperability Standards Advisory (https://www.healthit.gov/isa/) to locate other industry standards in the interest of efficient implementation of the state plan.

- vi. Components of the Health IT Plan include:
  - 1. The SMI 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 SMI care delivery. 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.
  - The Health IT Plan will describe the state's current and future capabilities to support providers implementing or expanding Health IT functionality in the following areas: (1) Referrals, (2) Electronic care plans and medical records, (3) Consent, (4) Interoperability, (5) Telehealth, (6) Alerting/analytics, and (7) Identity management.
  - 3. In developing the Health IT Plan, states should use the following resources.
    - States may use federal resources available on Health IT.Gov (https://www.healthit.gov/topic/behavioral-health) including but not limited to "Behavioral Health and Physical Health Integration" and "Section 34: Opioid Epidemic and Health IT" (https://www.healthit.gov/playbook/health-information-exchange/).
    - States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-andsystems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.
    - States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to electronic care plan sharing, care coordination, and behavioral healthphysical health integration, to meet the goals of the demonstration.

- e. SMI Financing Plan. As part of the SMI Implementation plan referred to in STC 118(d), the state must submit, within 90 calendar days after approval of the demonstration, a financing plan for approval by CMS. Once approved, the Financing Plan will be incorporated into the STCs as part of the Implementation Plan in Attachment C and, once incorporated, may only be altered with CMS approval. Failure to submit an SMI Financing Plan within 90 days of approval of the demonstration 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 SMI program under this demonstration. Components of the financing plan must include:
  - i. A plan to increase the availability of non-hospital, non-residential crisis stabilization services, including but not limited to the following: services made available through crisis call centers, mobile crisis units, coordinated community response services that includes law enforcement and other first responders, and observation/assessment centers; and
  - ii. A plan to increase availability of ongoing community-based services such as intensive outpatient services, assertive community treatment, and services delivered in integrated care settings.
- **119. Maintenance of Effort**. The state must maintain a level of state and local funding for outpatient community-based mental health services for Medicaid beneficiaries for the duration of the SMI program under the demonstration that is no less than the amount of funding provided at the beginning of the SMI program under the demonstration. The annual MOE will be reported and monitored as part of the Annual Monitoring Report described in STC 58.
- 120. Availability of FFP for the SMI Services Under Expenditure Authority #1. Federal Financial Participation is only available for services provided to beneficiaries who are residing in an IMD when the beneficiary is a short-term resident in the IMD primarily to receive treatment for mental illness. The state may claim FFP for services furnished to beneficiaries during IMD stays of up to 60 days, as long as the state shows at its Mid-Point Assessment that it is meeting the requirement of a 30-day average length of stay (ALOS) for beneficiaries residing in an IMD who are receiving covered services under the demonstration. Demonstration services furnished to beneficiaries whose stays in IMDs exceed 60 days are not eligible for FFP under this demonstration. If the state cannot show that it is meeting the 30 day or less ALOS requirement within one standard deviation at the Mid-Point Assessment, the state may only claim FFP for services furnished to beneficiaries during IMD stays of up to 45 days until such time that the state can demonstrate that it is meeting the 30 day or less ALOS requirement. The state will ensure that medically necessary services are provided to beneficiaries that have stays in excess of 60 days or 45 days, as relevant.

- **121.** Unallowable Expenditures Under the SMI Expenditure Authority. In addition to the other unallowable costs and caveats already outlined in these STCs, the state may not receive FFP under any expenditure authority approved under this demonstration for any of the following:
  - a) Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.
  - b) Costs for services furnished to beneficiaries who are residents in a nursing facility as defined in section 1919 of the Act that qualifies as an IMD.
  - c) Costs for services furnished to beneficiaries who are involuntarily residing in a psychiatric hospital or residential treatment facility by operation of criminal law.
  - d) Costs for services provided to beneficiaries under age 21 residing in an IMD unless the IMD meets the requirements for the "inpatient psychiatric services for individuals under age 21" benefit under 42 CFR 440.160, 441 Subpart D, and 483 Subpart G.

## XVI. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION PERIOD

Date	Deliverable	STC	
30 calendar days after demonstration approval	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter	
90 calendar days after demonstration approval	SUD/SMI Implementation Plan (including Health IT Plan)	STC 118	
60 calendar days after receipt of CMS comments	Revised SUD/SMI Implementation Plan (including Health IT Plan)	STC 118	
150 calendar days after demonstration approval	Monitoring Protocol	STC 57	
60 calendar days after receipt of CMS comments	Revised Monitoring Protocol	STC 57	
180 calendar days after demonstration approval	Draft Evaluation Design	STC 103	
60 days after receipt of CMS comments	Revised Evaluation Design	STC 103	
No later than 60 calendar days after December 12, 2027	Reentry Mid-Point Assessment	STC 59	
No later than 60 calendar days after December 12, 2027	SUD and SMI/SED Mid-Point Assessments	STC 60	
60 calendar days after receipt of CMS comments	Revised Reentry Mid-Point Assessment	STC 59	
60 calendar days after receipt of CMS comments	Revised SUD and SMI/SED Mid-Point Assessment	STC 60	
<i>December 31, 2028</i> , or with renewal application	Draft Interim Evaluation Report	STC 106	
60 calendar days after receipt of CMS comments	Revised Interim Evaluation Report	STC 106	
Within 18 months after December 31, 2029	Draft Summative Evaluation Report	STC 107	
60 calendar days after receipt of CMS comments	Revised Summative Evaluation Report	STC 107	
Monthly	Monitoring Calls	STC 63	
Quarterly monitoring reports due 60 calendar days after end of each	Quarterly Monitoring Reports, including implementation updates	STC 58	
quarter, except 4 <sup>th</sup> quarter.	Quarterly Expenditure Reports	STC 58	
Annual Deliverables - Due 90 calendar days after end of each 4 <sup>th</sup> quarter	Annual Monitoring Reports	STC 58	

### **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:
  - 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.
- a. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
- b. 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).
- c. 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

 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.

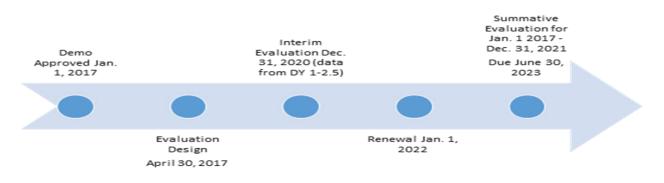
The format for the Interim and Summative Evaluation reports is as follows:

- 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/SMI Implementation Protocol

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

## ATTACHMENT E: SUD/SMI 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)<sup>4</sup> 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.<sup>5</sup>
- 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.<sup>6</sup> 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

<sup>&</sup>lt;sup>4</sup> Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance prescriptions in states. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the epidemic and facilitate a nimble and targeted response.

<sup>&</sup>lt;sup>6</sup> Ibid.

not inappropriately pay for opioids and that states implement effective controls to minimize the risk.  $^{7}$ 

- 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.

<sup>&</sup>lt;sup>7</sup> Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015.* MMWR Morb Mortal Wkly Rep 2017;66.

**Attachment F: Evaluation Design** 

# **Evaluation Plan**

# Commonwealth of Kentucky Section 1115 Substance Use Disorder Demonstration

February 18, 2020



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

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

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# A. GENERAL BACKGROUND INFORMATION

#### A.1.Purpose

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

Kentucky Medicaid proposed a Substance Use Disorder (SUD) demonstration project as part of its larger application for a Section 1115 demonstration project, "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. <u>increased access to SUD providers</u> by assessing Medicaid SUD provider capacity at critical levels of care and certifying residential treatment providers according to nationally-recognized standards for SUD treatment;
- 2. <u>waiver of the Medicaid Institutions for Mental Disease (IMD) exclusion</u>, allowing reimbursement for SUD treatment during short-term residential stays at certified IMD facilities with greater than 16 beds; and
- 3. 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].

Go	pal	Key	y Actions (Estimated Completion Date)
1.	improve access to critical levels of care for Opioid Use Disorder (OUD) and other	1a.	amend state plan to include coverage of SUD treatment planning (7/1/2019)
	SUDs for Medicaid beneficiaries	1b.	amend regulations to include partial
		10.	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-	2a.	amend state plan to require all SUD
	specific criteria for patient placement in		providers to incorporate ASAM's 6-
	outpatient and residential care, with the		dimensional assessment into their patient
	goal of improving SUD screening and patient care and retention		assessment in determining placement into treatment (7/1/2019)

## Table 1. Summary of Key Actions Associated with Demonstration Goals

	apply nationally-recognized SUD-specific program standards for the certification of residential treatment facilities	3b.	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) 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		conduct statewide survey of services, hours, staffing, and other characteristics of Medicaid-enrolled residential SUD providers (10/15/2018) 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		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) 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		amend state plan to include care coordination within the definition of residential SUD treatment (7/1/2019) 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:

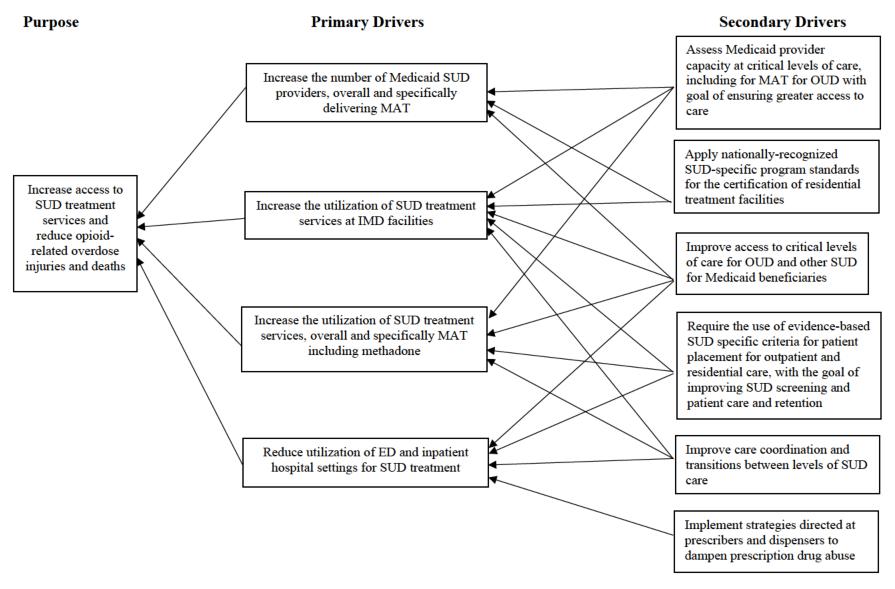
- 1. availability of provider services and capacity of treatment facilities available to Medicaid beneficiaries;
- 2. utilization of SUD services in residential facilities, particularly facilities affected by the IMD exclusion; and
- 3. utilization of SUD treatment services, especially medication-assisted 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
	Providers offering SUD services	N/A	Number of providers billing for SUD treatment services	Total number of beneficiaries	Claims data	Descriptive statistics
	Providers offering MAT	N/A	Number of providers prescribing any medication that is part of MAT	Total number of beneficiaries	Provider enrollment data	Interrupted time series without
Primary Driver (Increase the number of	Providers offering methadone as part of MAT	N/A	Number of providers prescribing methadone as part of MAT	Total number of beneficiaries		comparison group
Medicaid SUD providers, overall	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	
and specifically delivering MAT)	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	Provider enrollment data	Descriptive statistics
	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		

			residential treatment, especially r of SUD providers offering resi		cially IMDs.	
	Providers offering residential treatment for SUD	N/A	Number of providers billing for residential treatment for SUD	Total number of beneficiaries	Claims data	Descriptive statistics
Primary Driver (Increase the number of	IMD facilities offering treatment for SUD	N/A	Number of IMD facilities billing for treatment for SUD	Total number of beneficiaries	Provider enrollment data	Interrupted time series without comparison group
Medicaid SUD providers, overall and specifically delivering MAT)	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	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	enrollment data	
	I: Increased utilization of SUD		es. ion of SUD treatment services.			
	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		Descriptive statistics
Primary Driver (Increase the	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	Claims data	Interrupted time
utilization of SUD treatment services, overall and specifically	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		series without comparison group
MAT including methadone)	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 Goa improved access to	other continuum of care servic	es.	ital settings for treatment where femergency department visits an	-		
Primary Driver (Reduce utilization of ED	Emergency department visits for SUD (OUD) related diagnosis*	N/A	Number of ED visits for SUD (OUD) related diagnosis	Total number of beneficiaries		Descriptive statistics
and inpatient hospital settings for SUD treatment)	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	Claims data	Interrupted time series without comparison group

Evaluation Ouestion	n 2: Did beneficiaries receiving	2 SUD services e	xperience improved health outco	omes?		
			t services for SUD for beneficiar		<u>.</u>	
			D, the demonstration will decrea			r 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 Emergency department visits with primary SUD (OUD) related diagnosis for individuals receiving outpatient SUD (OUD) treatment	visits with primary SUD (OUD) related diagnosis for individuals receiving SUD (OUD) treatment Emergency department visits with primary SUD (OUD) related diagnosis for individuals receiving c(OUD) related diagnosis for individuals receiving outpatient SUD (OUD)		Number of beneficiaries who used SUD (OUD) services within 30 days Number of beneficiaries who used outpatient 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, 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 Goa	l: Fewer hospital readmissions	for SUD for ben				I
			D, the demonstration will reduce	e 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

Primary Driver	esis: Among beneficiaries recei Self-reported health in past	N/A	Rating on 5-point Likert-like	N/A		
(Increase the utilization of	6 months		scale of overall health			
SUD treatment services, overall and specifically MAT including	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		
methadone) Secondary Driver (Improve access	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	KTOS	Descriptive statistics
to critical levels of care for OUD and other SUD for Medicaid beneficiaries)	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	KORTOS	Interrupted time series without comparison group
Secondary Driver (Require the use of evidence-based criteria for patient placement in	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		
outpatient and residential care) Secondary Driver (Improve care	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		
coordination and transitions between levels of SUD care)	Self-reported continued substance use within past 6 months (KORTOS) / 12 months (KTOS)	N/A	Substance use within past 6 months	N/A		

Evaluation Questio	Evaluation Question 3: Did rates of opioid-related overdose deaths decrease?											
Demonstrated Goal	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 $\geq 15$	Claims data	Descriptive statistics Interrupted time series without comparison group						
Primary Driver (Increase the utilization of SUD treatment services, overall and specifically	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						
MAT including methadone)	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 opioidrelated 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."<sup>6</sup> 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:

 $Y_{m,c} = \beta_0 + \beta_1 time_m + \beta_2 I[post]_{m,c} + \beta_3 time_m \times I[post]_{m,c} + \beta' controls_{m,c} + \gamma'_c + \epsilon_{m,c}$ 

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);  $\gamma_c$  is a vector of county fixed effects;  $\varepsilon$  is the disturbance term; m indexes the month; and c indexes the county.

The coefficient  $\beta_2$  reflects the shift in outcome levels in the post-demonstration period (after accounting for secular time trends), while  $\beta_3$  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  $\alpha$ =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:

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

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);  $\varepsilon$  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  $\beta_2$ , which reflects the shift in spending in the post-demonstration period, and  $\beta_3$ , 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
	7/1/2019	7/1/2020	7/1/2021	7/1/2022	7/1/2023	7/1/2019
Category	6/30/2020	6/30/2021	6/30/2022	6/30/2023	6/30/2024	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													

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(Implementation Year 4) Data collection and analysis <sup>b</sup>							
Summative Evaluation Report completed (June 2024)							

<sup>a</sup> contingent on plan approval and data availability <sup>b</sup> contingent on data availability

## **E.4. References**

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Attachment G: Reentry Demonstration Initiative Implementation Plan

Attachment H: Reentry Demonstration Initiative Reinvestment Plan

# **Attachment I: Monitoring Protocol**

#### **Attachment J: RRSS Service Description**

# RECOVERY RESIDENCE SUPPORT SERVICE (RRSS) \*Does not include Room and Board

#### SERVICE COMPONENT DESCRIPTIONS

# *The following RRSS components will be <u>required</u> to be provided by RRSS providers for all beneficiaries:*

Service Intake	Purpose Admit participant to program utilizing intake protocols including orientation to the program, services to be provided and program	Person Responsible RRSS Staff	<b>Frequency</b> Upon admission
Assessment	expectations. Review of the assessment completed prior to admission including strengths, personal assets, supportive relationships, coping skills, resilience factors, cultural background, spirituality, and recovery capital to inform recovery management planning and leverage existing resources in the recovery process.	RRSS Staff	Within 72 hours of admission
Recovery Management Planning	Develop a person-centered Recovery Management Plan including an assessment of strengths and resources, addressing readiness to engage in recovery pathway and establishing goals for achieving recovery.	RRSS Staff	Within 72 hours of admission.
Recovery Management Plan Review	Engage participant in a review of their Recovery Management Plan including a review of progress toward identified goals, updates to the plan, addition of new goals and review of transition planning.	RRSS Staff	Monthly
Facilitate Health Care Needs	Recognize co-occurring medical conditions, ensure access to medications, promote health maintenance and prevention, assist with identification of primary health care provider and referral if needed.	RRSS Staff	Upon admission
Coordinate Treatment for Co-	Collaborate with community partners to coordinate care for co-occurring disorders including medication management,	RRSS Staff	Upon admission; 1-2 units per week.

Occurring Disorder	medication for SUD/OUD, follow-up appointments and coordination of care.		
Coordinate Health Care Related Issues	Coordinate services with community partners to address health care needs including medication assisted treatment, treatment of chronic conditions and treatment of alcohol and drug related illness (COPD, gastroenteritis, liver disease, etc.)	RRSS Staff	1-2 units per week as needed
Transition Planning	Addresses the individual's needs for continued recovery, personal growth, and community reintegration including housing, transportation, employment, and ongoing services and supports to maintain recovery.	RRSS Staff	Within 30 days of completion of the program

# The following RRSS components to be provided as needed by RRSS providers:

Service	Purpose	Person Responsible	Frequency
Individual	A personalized and collaborative service	Peer support	1-2 x week
Recovery	designed to assist individuals in initiating and	staff	
Coaching	maintaining their recovery. Recovery coaches		
	provide guidance, encouragement, and		
	practical assistance to help individuals		
	overcome obstacles and achieve their		
	recovery goals.		
Recovery	Provide mutual assistance, employing	Peer support	3-5 x week
Support Class	principles of empathy, accountability, and	staff	
	confidentiality to foster a sense of community		
	and promote sustained progress in achieving		
	and maintaining recovery goals. Participants		
	practice interpersonal and group living skills		
	receiving feedback from their peers.		
Life Skills	Education sessions address topics such as	Peer support	2-4 x week
Training	communication skills, decision-making,	staff/external	
	problem-solving, time management, stress	experts	
	management, financial literacy, goal setting,		
	job search and application, conflict resolution,		
	and interpersonal relationships. Participants		
	practice interpersonal and group living skills		
	within the context of the RH environment		
	(Services may include: "Contingence		

	Management" or SMART Recovery Life Skills		
Recovery Management Skills	<i>curriculum as a part of their RH program).</i> Sessions that focus on a curriculum that provides information on understanding addiction, its causes, effects on the brain, behavior and progression of the disorder, practical skills, techniques and coping mechanisms to manage cravings, triggers and stressors encountered during the recovery process, including relapse prevention strategies and healthy lifestyle practices.	Peer support staff/external experts with lived experience	2 x daily
Community/ House Meetings	A community/house meeting is a structured and collaborative gathering within a recovery setting where individuals come together to discuss issues, share experiences, provide support, and engage in therapeutic activities aimed at fostering personal growth, recovery, and community cohesion.	RRSS staff	1-5 x week
Mutual Aid Groups	Mutual aid groups are sessions onsite or in the community that assist individuals in addressing their SUD issues through a structured program based on guiding principles. These groups provide a safe and non-judgmental environment where members can share their experiences, receive support, and work together towards personal growth and recovery.	Peer Supports	3-7 x week
Peer Support Meetings	Peer support meetings focus on challenges and achievements in SUD recovery, normalizing experiences and reducing feelings of isolation and shame. They emphasize the value of sharing and connecting to like-minded individuals. They further assist participants in regulating emotions and practicing coping skills.	Peer Supports	1-5 x week
Continuing Care/Transition Planning	Planning for ongoing recovery needs including mutual help involvement, job search/placement, affordable housing, childcare, transportation, return to use prevention and intervention, leisure activities, family involvement, community involvement, etc.	RRSS Staff	Within 30 days of admission

Supporting Career Training and Education	Coordinate with community resources to provide support for ongoing training/education opportunities and work closely with KY Adult Education to schedule appointments, assure that appointments are kept and that opportunities for further education and training are available.	RRSS Staff	As needed
Coordinating Legal Services and Supports	Referrals to assist participants in addressing legal issues.	RRSS staff	As needed
Transitional Support Services	Support the individual with the ability to transition to housing and maintain housing once secured; this may include linkage to pre- tenancy supports for obtaining affordable and accessible housing, and developing a community integration plan based on functional needs assessment.	RRSS staff	Within 30 days of admission
Employment Supports	Link individuals to employment services such as vocational training for employment assessments, planning and job training, as well as job coaching and transportation arrangements.	RRSS staff	Within 30 days of admission
Family Support Services	Assist family members in understanding SUD and facilitate individual's participation in the family, if appropriate. Family Support Services provided to family or collaterals are for the direct benefit of the beneficiary, in accordance with their needs and goals in recovery.	RRSS staff	As needed

Attachment K: Protocol for Assessment of Beneficiary Eligibility and Needs, and Provider Qualifications for HRSN Services

# **Attachment L: Interim Evaluation Report**

Attachment M: Summative Evaluation Report

# **Attachment N: HRSN Service Matrix**

Service Category	Service	Population 1
	Case management for housing	
	Housing navigation and tenancy	
	support*	
	One-time transition and moving	
	costs <u>other than</u> rent	
Housing/Home Environment	Caregiver respite without room and	
interventions without room	board	
and board	Utility assistance	
	Day Habilitation Programs	
	Sobering centers (<24 hour stay)	
	Medically Necessary	
	Home Remediations	
	Home/environmental accessibility	
	modifications	
	Short-term pre-procedure housing	x
Housing interventions with	Short-term Recuperative care	
Room and Board	Short-term post-transition housing	x
(Episodic Interventions)	Caregiver respite with room and	
	board	
Housing interventions with Room and Board	First month's rent, as a transitional	
	service Short-term rental assistance	
(Rent Only Interventions)		
Nutrition interventions	Case management services for access to food/nutrition	
without food		
without loou	Nutrition counseling and instruction	
Nutrition interventions with	Home Delivered meals	
food	Pantry stocking	
	Medically Tailored Meals	
	Nutrition prescriptions	

	Service	Population	Social Risk Factor	Clinical Criteria for the pop
Housing interventions <u>with</u> Room and Board (Episodic	Short-term pre- procedure housing	All Kentucky beneficiaries eligible through mandatory, optional, or expansion eligibility groups, receiving full Medicaid coverage, ages 18 or older, with income up to 213 percent of the FPL, will be eligible for the HRSN service.	Individuals who are homeless, or at risk of homelessness who meet criteria based upon definitions in 24 CFR 91.5	Are at risk of hospitalization and/or readmission with a medical need, either: 1) Following discharge from acute care facility or Emergency Department, OR 2) Have a planned medical procedure requiring preparation care, OR 3) Have a planned medical treatment (i.e.: chemotherapy treatment) requiring care prior to or following the treatment. AND Must have a primary medical diagnosis
Interventions)	Short-term post- transition housing	All Kentucky beneficiaries eligible through mandatory, optional, or expansion eligibility groups, receiving full Medicaid coverage, ages 18 or older, with income up to 213 percent of the FPL, will be eligible for the HRSN service.	Individuals who are homeless, or	Are at risk of hospitalization and/or readmission with a medical need, either: 1) Following discharge from acute care facility or Emergency Department, OR 2) Have a planned medical procedure requiring preparation care, OR 3) Have a planned medical treatment (i.e.: chemotherapy treatment) requiring care prior to or following the treatment. AND Must have a primary medical diagnosis

<b>Clinical Risk Factor</b>	Clinical Criteria Detail
	Are at risk of hospitalization and/or readmission with a medical need: 1) following discharge from acute care facility or
Risk Factor 1	Emergency Department, or 2) Have a planned medical procedure requiring preparation care, or Have a planned medical
	treatment (i.e.: chemotherapy treatment) requiring care prior to or following the treatment
Risk Factor 2	Must have a primary medical diagnosis

Social Risk Factor	Social Criteria Detail
Risk Factor 1	Individuals who are homeless, or at risk of homelessness who meet criteria based upon definitions in 24 CFR 91.5

# **Attachment O: HRSN Infrastructure Protocol**