

Exhibit C



JAN 12 2018

Adam Meier
Deputy Chief of Staff
Office of Governor Matthew Bevin
700 Capital Avenue, Suite 100
Frankfort, KY 40601

Dear Mr. Meier,

I am pleased to transmit to you the approval package for the Commonwealth of Kentucky's section 1115 demonstration project, entitled "Kentucky Helping to Engage and Achieve Long Term Health (KY HEALTH) (Project Number 11-W-00306/4 and 21-W-00067/4). CMS recognizes your efforts and those of your dedicated team in designing this project, as well as Kentucky's ongoing commitment to improving the health and well-being of Medicaid beneficiaries living in the Commonwealth.

Your substantial work will help inform future state demonstrations seeking to draw on Kentucky's novel approaches to Medicaid reform, and CMS also looks forward to learning from the outcomes of your demonstration project. I appreciate the spirit of partnership we have shared over the course of the past year. It has been a pleasure to work with you and the entire Kentucky team.

Attached is the approval letter signed by Demetrios L. Kouzoukas, Principal Deputy Administrator, who is responsible for the disposition of all matters from which Administrator Verma is recused. Please let me know if you have any questions or if I can be of assistance in any way as the Commonwealth moves forward to implement KY HEALTH.

Sincerely,

A solid black rectangular box redacting the signature of the sender.

Brian Neale
Deputy Administrator

*Deputy Administrator*

Washington, DC 20201

Stephen P. Miller
Commissioner
Cabinet for Health and Family Services
275 East Main Street, 6 West A
Frankfort, KY 40621

Dear Mr. Miller:

The Centers for Medicare & Medicaid Services (CMS) is approving the Commonwealth of Kentucky's request for a new section 1115 demonstration project, entitled "Kentucky Helping to Engage and Achieve Long Term Health" (KY HEALTH) (Project Number 11-W-00306/4 and 21-W-00067/4). This statewide demonstration is approved under the authority of section 1115(a) of the Social Security Act (the Act), effective January 12, 2018, through September 30, 2023.

Extent and Scope of Demonstration

The KY HEALTH demonstration aims to transform the Kentucky Medicaid program to empower beneficiaries to improve their health. The KY HEALTH demonstration broadly encompasses several initiatives impacting a wide range of Kentucky Medicaid beneficiaries. Consistent with the Secretary's authority and with standard practice, the demonstration is being approved for a 5-year period, subject to the Special Terms and Conditions attached. Within KY HEALTH is a program called Kentucky HEALTH, into which Kentucky will enroll adult beneficiaries who do not qualify for Medicaid on the basis of a disability.

The Kentucky HEALTH program includes two consumer-driven tools, the *My Rewards Account* and the *Deductible Account*, which encourage beneficiaries to maintain and improve their health by providing incentives for healthy behavior. Beneficiaries will receive incentives in their *My Rewards Account* that can be used to obtain enhanced benefits. Kentucky will implement the *Deductible Account* as an educational tool to inform beneficiaries about the cost of healthcare.

In addition, Kentucky will implement a community engagement requirement as a condition of eligibility for adult beneficiaries ages 19 to 64 in the Kentucky HEALTH program, with exemptions for various groups, including: former foster care youth, pregnant women, primary caregivers of a dependent (limited to one caregiver per household), beneficiaries considered medically frail, beneficiaries diagnosed with an acute medical condition that would prevent them from complying with the requirements, and full time students. To remain eligible for coverage, non-exempt beneficiaries must complete 80 hours per month of community engagement activities, such as employment, education, job skills training, and community service. Beneficiaries will have their eligibility suspended for failure to demonstrate compliance with the community engagement requirement and will be able to reactivate their eligibility on the first day of the month after they complete 80 hours of community engagement in a 30-day period or a

state-approved health literacy or financial literacy course. Beneficiaries who are in an eligibility suspension for failure to meet the requirement on their redetermination date will have their enrollment terminated and will be required to submit a new application. Kentucky will provide good cause exemptions in certain circumstances for beneficiaries who cannot meet requirements.

CMS is also authorizing additional waivers and expenditure authorities for the Kentucky HEALTH program, including:

- Premiums for beneficiaries in the new adult group and section 1931 parents and other caretaker relatives (with exceptions for pregnant women, former foster care youth, and those determined medically frail);
- Consequences for beneficiaries who do not pay premiums after a 60 day payment period;
- Six month non-eligibility period for certain populations for failure to comply with the redetermination process;
- Disenrollment and six month non-eligibility period for certain populations for failure to report a change in circumstance that would affect Medicaid eligibility;
- Limiting managed care organization disenrollment without cause; and
- A waiver of retroactive eligibility for certain populations.

CMS is also approving the following additional waiver and expenditure authorities for the KY HEALTH demonstration as a whole:

- A waiver of non-emergency medical transportation (NEMT) for certain populations and services; and
- Alignment of a beneficiary's annual redetermination with their employer sponsored insurance (ESI) open enrollment period, including any children enrolled in Medicaid or CHIP and covered by a parent or caretaker's ESI.

The KY HEALTH demonstration will also include a substance use disorder (SUD) program available to all Kentucky Medicaid beneficiaries to ensure that a broad continuum of care is available to Kentuckians with SUD, which will help improve the quality, care, and health outcomes for Kentucky Medicaid beneficiaries.

Determination that the demonstration project is likely to assist in promoting Medicaid's objectives

Demonstration projects under section 1115 of the Act offer a way to give states more freedom to test and evaluate innovative solutions to improve quality, accessibility and health outcomes in a budget-neutral manner, provided that, in the judgment of the Secretary, the demonstrations are likely to assist in promoting the objectives of Medicaid.

While CMS believes that states are in the best position to design solutions that address the unique needs of their Medicaid-eligible populations, the agency has an obligation to ensure that proposed demonstration projects are likely to better enable states to serve their low-income populations, through measures designed to improve health and wellness and help individuals and families attain or retain capability for independence or self-care. Medicaid programs are complex and shaped by a diverse set of interconnected policies and components, including eligibility

standards, benefit designs, reimbursement and payment policies, IT systems, and more. Therefore, in making this determination, CMS considers the proposed demonstration as a whole.

In its consideration of the KY HEALTH proposal, CMS examined whether the demonstration was likely to assist in improving health outcomes; whether it would address behavioral and social factors that influence health outcomes; whether it would incentivize beneficiaries to engage in their own health care and achieve better health outcomes; and whether it would familiarize beneficiaries with a benefit design that is typical of what they may encounter in the commercial market and thereby facilitate smoother beneficiary transition to commercial coverage. CMS has determined that the KY HEALTH demonstration is likely to promote Medicaid objectives, and that the waivers and expenditure authorities sought are necessary and appropriate to carry out the demonstration.

1. The demonstration is likely to assist in improving health outcomes through strategies that promote preventive care and SUD services, and address certain health determinants.

Kentucky HEALTH is designed to address the unique challenges the Commonwealth is facing as it endeavors to maintain coverage and promote better health outcomes among its residents. For example, Kentucky HEALTH is designed to incentivize more individuals to seek preventive care through mechanisms like earning funds in the *My Rewards Account* for healthy behaviors. During the first year of Kentucky's Medicaid expansion, fewer than 10 percent of beneficiaries received an annual wellness or physical exam. Under Kentucky HEALTH, the *My Rewards Account* incentives for healthy behaviors are expected to incentivize uptake of preventive services, which we believe can help improve beneficiary health. In addition, the SUD program supports Medicaid's objectives by improving access to high-quality services, and is critical to addressing Kentucky's substance use epidemic.

Beyond promoting access to high-value health care services, the demonstration also supports coordinated strategies to address certain health determinants, as well as promote increased upward mobility, greater independence, and improved quality of life. Specifically, Kentucky HEALTH's community engagement requirement is designed to encourage beneficiaries to obtain employment and/or undertake other community engagement activities that research has shown to be correlated with improved health and wellness. Kentucky will incentivize participation in community engagement activities by making eligibility contingent on completion of certain requirements.

CMS has long supported policies that recognize meaningful work as essential to the economic self-sufficiency, self-esteem, well-being, and improved health of people with disabilities. However, CMS has not previously approved a community engagement requirement as a condition of eligibility. Given the potential benefits of work and community engagement, we believe that Medicaid programs should be able to support these activities and test incentives that are appropriate for this population and lead to improved health outcomes.

In the past, CMS has approved demonstrations which provided referrals to employment services or encouragement to seek employment. We understand from some states that these incentives

may not have been strong enough to influence individual beneficiary behavior. CMS and Kentucky believe that Kentucky HEALTH's community engagement incentive is likely to be more effective than other incentives or referrals to employment services, as it provides for the consequence of eligibility suspension for non-compliance. Kentucky HEALTH will also provide "on-ramps" to appropriately support individuals who have experienced a suspension or lapse of eligibility in regaining access to the program's benefits and resources. This is also likely to further incentivize individuals who have had their eligibility suspended to quickly satisfy the community engagement requirement and regain eligibility. The impact of this incentive, as well as other aspects of the demonstration, will be assessed through an evaluation designed to measure how the demonstration affects eligibility, behavior, and health outcomes over time for persons subject to the demonstration's policies.

We anticipate that the incentives provided under the demonstration for healthy behaviors and community engagement will promote Medicaid's objective of improving beneficiary health. Further, if improved uptake of preventive care and access to SUD services results in lower overall cost of care for Medicaid-eligible populations, the demonstration may also enable the state to stretch its Medicaid resources as far as possible. Kentucky leaders have expressed the importance of this demonstration as a means of preserving coverage for individuals.¹ Without fundamental, sustainable reforms, the Commonwealth expressed that it would be unable to maintain access for currently enrolled populations.

In addition to promoting improved health outcomes for Kentucky HEALTH beneficiaries by encouraging and supporting employment and other community engagement activities, the demonstration may also promote individual independence and reduce reliance on public assistance by creating incentives for individuals to obtain and maintain coverage through private, employer-sponsored insurance. This policy goal also aligns with the authorizing language in Section 1901 of the Social Security Act, which cites attaining or retaining independence as one of the program's purposes. The Commonwealth will connect beneficiaries with opportunities including education, job training, substance use disorder treatment, employment or volunteering. This statutory objective supports Medicaid program designs that enable and encourage enrolled individuals to seek economic self-sufficiency, which this demonstration proposes to do through employment and other community engagement activities.

2. The demonstration is likely to strengthen engagement by beneficiaries in their personal health care plan, and provide incentives for responsible decision-making.

Kentucky expects that the use of beneficiary-directed accounts, as well as redetermination and reporting requirements, will also strengthen beneficiary engagement in their personal health care plan and provide an incentive structure to support responsible consumer decision-making.

Prior evaluations of demonstration projects with beneficiary engagement components have shown promise that these strategies can have a positive impact on beneficiary behavior.² For example, evaluations have shown that financial incentives for specific health behaviors can

² https://www.in.gov/fssa/files/Lewin_IN%20HIP%202%200%20Interim%20Evaluation%20Report_FINAL.pdf

prompt beneficiaries to engage in those specific behaviors. Kentucky will include evaluation of the outcomes associated with these requirements in its Evaluation Design to further enrich the evidence regarding beneficiary engagement strategies.

Kentucky's use of beneficiary-directed services through the *Deductible Account* and *My Rewards Account* is also designed to incentivize appropriate and responsible utilization of health care services and to strengthen beneficiary engagement. The accounts are designed to encourage beneficiaries to engage in healthy behaviors.

The approval of the waiver of retroactive eligibility encourages beneficiaries to obtain and maintain health coverage, even when healthy. This is intended to increase continuity of care by reducing gaps in coverage when beneficiaries churn on and off Medicaid or sign up for Medicaid only when sick.

Imposition of a non-eligibility period for failing to complete timely redetermination of eligibility encourages individuals to maintain compliance with longstanding beneficiary responsibilities described in regulation that also protect program integrity.

Taken together, the evidence tying certain beneficiary behavior to improved health outcomes supports the rationale that these requirements promote the objectives of the Medicaid program. CMS has concluded that the demonstration will also meet several additional goals, including encouraging responsible utilization of services, promoting continuity of care by reducing gaps in coverage, and improving program integrity.

3. The demonstration will remove potential obstacles to a successful beneficiary transition to commercial coverage.

Kentucky HEALTH is designed to work more like insurance products sold on the commercial market. Kentucky's application noted the significant number of individuals estimated to move between Medicaid eligibility and Marketplace coverage. In order to ensure continuity of care, which is important for improving health outcomes, Kentucky HEALTH seeks to provide beneficiaries the tools to successfully utilize commercial market health insurance, thereby removing potential obstacles to a successful transition from Medicaid to commercial coverage.

The demonstration includes several features that align with common features of commercial market plans. For instance, Kentucky HEALTH includes premium payment requirements (with a non-eligibility period for certain beneficiaries for non-payment, similar to provisions CMS has approved in other states³), deductibles, and limited enrollment windows, all of which beneficiaries are likely to encounter should they transition off of Medicaid and into commercial coverage. Further, Kentucky HEALTH provides participants with an opportunity to use the *My Rewards Account*, which can be used to access certain additional benefits in a manner similar to a Health Savings Account available through many commercial plans.

The *Deductible Account* is also likely to prepare beneficiaries to manage their coverage in the commercial market, where plans often impose deductibles.

³ <https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/?entry=25478>

Similar to the standard commercial market policies, Kentucky HEALTH will require monthly premiums for certain populations, and benefits will start prospectively from the initial premium payment. Kentucky may adjust premium amounts incrementally over time as it evaluates the outcomes of the demonstration, not to exceed statutory limitations.

Also, Kentucky HEALTH will require beneficiaries to complete the annual redetermination process (with a non-eligibility period for non-compliance for certain populations), which will help educate beneficiaries on the need to timely complete enrollment requirements because of limited opportunities to enroll in coverage. While CMS previously did not approve a request from another state for a similar non-eligibility period for failure to complete redetermination, it believes that this policy should be evaluated and is likely to support the objectives of Medicaid to the extent that it prepares individuals for a smooth transition to commercial health insurance coverage and ensures that resources are preserved for individuals who meet eligibility requirements.

Similar to how commercial coverage operates, coverage eligibility under Kentucky HEALTH will be impacted for certain individuals for nonpayment of premiums, failure to report changes in circumstances that affect eligibility, or failure to complete redetermination. However, the state has provided for an “on-ramp” that enables these individuals to regain eligibility and successfully access all of the benefits, resources, and tools of the Kentucky HEALTH program, without waiting until the end of the non-eligibility period. CMS also notes that Kentucky has taken steps to protect beneficiaries by exempting certain vulnerable populations, such as pregnant women and individuals who are medically frail, from these policies, as well as by allowing temporary good cause exemptions in certain circumstances for beneficiaries who cannot meet the applicable requirement. Completion of timely redeterminations and reporting of changes in circumstances that affect eligibility are also fundamental safeguards for purposes of protecting program integrity.

Overall, CMS believes that Kentucky HEALTH has been designed to empower individuals to improve their health and well-being. If successful in its objectives, Kentucky HEALTH would improve health outcomes, promote increased upward mobility and improved quality of life, increase individual engagement in health care decisions, and prepare individuals who transition to commercial health insurance coverage to be successful in this transition. At the same time, Kentucky HEALTH would ensure vulnerable individuals like people with disabilities and pregnant women continue to receive medical assistance. By lessening dependence on government assistance and promoting individual self-sufficiency, Kentucky’s efforts should also help to promote the fiscal sustainability of the program to better protect services for the Commonwealth’s most vulnerable.

Consideration of Public Comments

Both Kentucky and CMS received a large volume of comments during the state and federal public comment periods. Consistent with federal transparency requirements, CMS reviewed all of the materials submitted by the Commonwealth, as well as all the public comments it received, when evaluating whether the demonstration project as a whole was likely to promote the

objectives of the Medicaid program, and whether the waiver and expenditure authorities sought were necessary and appropriate to implement the demonstration. In addition, CMS took public comments submitted during the federal comment period into account as it worked with the Commonwealth to develop the special terms and conditions (STCs) that accompany this approval, and that will bolster beneficiary protections, including specific state assurances around these protections to further support beneficiaries.

Comments in support of the application noted its efforts to promote beneficiary responsibility and accountability and enhance sustainability of the program in the long-term. Supporters noted that beneficiary engagement provisions, such as the cost-sharing and premium requirements, aligned with aspects of the private insurance market. Supporters also noted their agreement with the principle that working-age able-bodied adults meet community engagement activities as a condition of eligibility. Others supported the Commonwealth's efforts to expand services for substance use disorder by lifting the IMD exclusion for substance use treatment.

Opposing commenters expressed general disagreement with efforts to modify the Commonwealth's Medicaid expansion program. Some offered more specific feedback regarding individual elements of the demonstration or the impact of certain provisions on distinct populations. Some commenters expressed the desire to see greater detail regarding how the program would be operationalized, particularly with respect to provisions like the community engagement requirements. Other comments expressed concerns that these requirements would be burdensome on families or create barriers to coverage.

Many commenters who opposed the community engagement requirement emphasized that CMS has rejected similar proposals in the past. Commenters reported that most non-disabled adult Medicaid beneficiaries are already employed and that imposing this requirement would create significant barriers to access for vulnerable individuals who are not able to work or otherwise meet the requirements. To address these concerns, Kentucky has agreed to important protections for vulnerable individuals, including maintaining a system that identifies, validates and provides reasonable accommodations for those who may not be able to meet the requirements, or who need assistance to do so, due to disability. Kentucky will also deem SNAP or TANF participants who are exempt from SNAP or TANF work requirements to satisfy the Kentucky HEALTH community engagement requirement. CMS also acknowledges comments from those concerned that the majority of individuals who will be subject to the community engagement requirement may already be working. CMS notes that beneficiaries who work at least 120 hours per month are deemed to satisfy the community engagement reporting requirements. Moreover, CMS believes that there would still be a significant number of individuals for whom the incentives under this demonstration may spur new community engagement activity. Some commenters cited evidence that, since an individual needs to be healthy to be able to work or look for a job, a work requirement can prevent an individual from getting the health care they need to be able to work. CMS and Kentucky acknowledged these concerns and Kentucky will be exempting from the requirement those individuals who are medically frail, as well as those whom a medical professional has determined are unable to work due to illness or injury. Finally, some commenters questioned the efficacy of work requirements in other public programs. CMS has considered those comments and decided to allow states to test the implementation of community

engagement requirements in Medicaid, subject to the parameters set out in the January X state Medicaid directors letter.

Several commenters noted that the 10-day requirement for reporting changes in circumstances would present a substantial burden on beneficiaries and that the proposed period of non-eligibility for beneficiaries who fail to report any change would have the potential to harm individuals who would lose eligibility. CMS and the state have responded to those comments and the state will impose a period of non-eligibility only where the unreported change in circumstances would have resulted in loss of eligibility for Medicaid, had it been reported. In addition, where an individual experiences a period of non-eligibility, Kentucky is providing opportunities to return to eligibility.

Several commenters noted that the state's Medicaid offices, where many beneficiaries must go to report those changes, and the phone lines used to call to report changes are already busy and the calls and visits are time consuming. We understand that the state has made improvements in its call center operations and beneficiaries are able to report changes both over the phone and electronically. This is expected to reduce the burden of reporting and increase beneficiaries' likelihood for success in meeting the requirements. CMS also will track beneficiary success in meeting these requirements as part of ongoing demonstration monitoring. Additionally, Kentucky will allow good cause exemptions in certain circumstances for beneficiaries who cannot meet their requirement. Kentucky also will be required to provide reasonable modifications for beneficiaries with disabilities.

CMS recognizes that Kentucky was responsive to many concerns raised through the public notice and comment process by making several key changes to its demonstration application. Kentucky exempted primary caregivers of a dependent from work and community engagement requirements (one primary caregiver per household), and removed a proposed amendment to eliminate allergy testing and private duty nursing as covered services, after public comments indicated concern from consumers, beneficiaries, and others.

To help determine whether the demonstration is meeting its goals of improving quality, accessibility, and health outcomes, Kentucky will submit, for CMS comment and approval, a draft evaluation design with implementation timeline, no later than one hundred eighty (180) days after demonstration approval. CMS will work with Kentucky to ensure that the comments received also inform the monitoring and evaluation design and the necessary oversight is in place to provide for program adjustments when necessary.

CMS' approval of this demonstration is conditioned upon compliance with the enclosed list of waiver and expenditure authorities and the STCs defining the nature, character and extent of anticipated federal involvement in the project. The award is subject to our receiving your written acknowledgement of the award and acceptance of these STCs within 30 days of the date of this letter. Your project officer for this demonstration is Ms. Andrea Casart. She is available to answer any questions concerning your demonstration project under section 1115 of the Act. Ms. Casart's contact information is as follows:

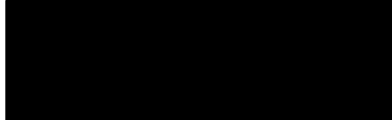
Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-03-17
7500 Security Boulevard
Baltimore, MD 21244-1850
Email: Andrea.Casart@cms.hhs.gov

Official communications regarding program matters should be sent simultaneously to Ms. Casart and Ms. Shantrina Roberts, Acting Associate Regional Administrator, in our Atlanta Regional Office. Ms. Roberts' contact information is as follows:

Centers for Medicare & Medicaid Services
Atlanta Federal Center
61 Forsyth Street, SW, Suite 4T20
Atlanta, Georgia 30303-8909
E-mail: Shantrina.Roberts@cms.hhs.gov

If you have questions regarding this approval, please contact Ms. Judith Cash, Acting Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (410) 786-9886. Thank you for all your work with us, as well as stakeholders in Kentucky, over the past months on this new demonstration.

Sincerely,



Demetrios L. Kouzoukas
Principal Deputy Administrator

Enclosures

cc: Shantrina Roberts, Acting Associate Regional Administrator, CMS Atlanta Regional Office

**CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY**

NUMBER: 11-W-00306/4 and 21-W-00067/4
TITLE: KY HEALTH Section 1115 Demonstration
AWARDEE: Kentucky Cabinet for Health and Family Services

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

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

The following expenditure authorities shall enable Kentucky to implement the KY HEALTH section 1115 demonstration:

1. Expenditures to the extent necessary to enable Kentucky to align a beneficiary's annual redetermination with their employer sponsored insurance (ESI) open enrollment period, including any children enrolled in Medicaid and covered by a parent or caretaker's ESI, in a manner inconsistent with requirements under section 1943 of the Act as implemented in 42 CFR 435.916(a).
2. Expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental disease (IMD).

The following expenditure authorities shall enable Kentucky to implement the Kentucky HEALTH program within the KY HEALTH section 1115 demonstration:

3. Expenditures under contracts with managed care entities that do not meet the requirements in section 1903(m)(2)(A)(vi) of the Act insofar as that provision requires compliance with requirements in section 1932(a)(4) of the Act, including as it is implemented and interpreted in 42 CFR 438.56(c)(2)(i) that enrollees be permitted an initial period to disenroll without cause, in order to permit the state to restrict this right except in situations that are described in these STCs.

4. Expenditures for My Rewards Account incentives, which are limited to vision services, dental services, over-the-counter medications, and limited fitness-related services, to the extent that they are not included for beneficiaries receiving benefits under the alternative benefit plan for Kentucky HEALTH program beneficiaries and/or in the Medicaid state plan (state plan), and which are either determined by the Secretary to fall within the definition of “medical assistance” at section 1905(a) of the Act, or are found by the Secretary to be necessary for the proper and efficient administration of the state plan, to be federally matched at the applicable matching rate under section 1903(a)(1) or 1903(a)(7) of the Act.

**CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER LIST**

NUMBER: 11-W-00306/4 and 21-W-00067/4
TITLE: KY HEALTH Section 1115 Demonstration
AWARDEE: Kentucky Cabinet for Health and Family Services

Title XIX Waiver Authority

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

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

1. Methods of Administration

**Section 1902(a)(4) insofar
as it incorporates 42 CFR
431.53**

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

2. Provision of Medical Assistance

**Section 1902(a)(8)
and 1902(a)(10)**

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

The following waivers of state plan requirements contained in section 1902 of the Act are granted for the Kentucky HEALTH program within the KY HEALTH demonstration, subject to these STCs.

3. Retroactive Eligibility **Section 1902(a)(34)**

To enable the state not to provide three months of retroactive eligibility for beneficiaries receiving coverage through the Kentucky HEALTH program, except for pregnant women and former foster care youth.

4. Premiums **Section 1902(a)(14) insofar as it incorporates Sections 1916 and 1916A**

To the extent necessary to enable Kentucky to require monthly premium payments, as described in these STCs.

5. Comparability **Sections 1902(a)(10)(B) and 1902(a)(17)**

To the extent necessary to enable Kentucky to vary premium requirements for different Kentucky HEALTH program beneficiaries based on income and/or length of time enrolled in Medicaid, and on other factors consistent with how premiums are permitted to vary in the commercial insurance market in Kentucky, and in a manner consistent with all otherwise applicable law, except that all beneficiaries, unless excepted, will be required to contribute, at a minimum, a monthly \$1 premium contribution as described in these STCs.

To enable the state to exempt Kentucky HEALTH program beneficiaries who pay premiums from the cost sharing described in the state plan, and to enable the state to require Kentucky HEALTH program beneficiaries with income under 100 percent of the federal poverty level (FPL) to incur state plan cost sharing in lieu of paying premiums if they do not pay premiums, (except former foster care youth, the medically frail, and pregnant women), as described in these STCs.

To enable the state to offer different state plan benefits for different Kentucky HEALTH program beneficiaries as described in these STCs.

6. Reasonable Promptness **Section 1902(a)(8)**

To the extent necessary to enable Kentucky to start enrollment in the Kentucky HEALTH program on the first day of the month in which a beneficiary makes his or her initial premium payment, or, for beneficiaries at or below 100 percent of the FPL who fail to make an initial premium payment within sixty (60) days following the date of invoice, the first day of the month in which the sixty (60) day payment period expires, except for pregnant women, beneficiaries determined medically frail, former foster care youth, and beneficiaries found eligible through presumptive eligibility, as described in these STCs.

7. Provision of Medical Assistance

**Section 1902(a)(8)
and 1902(a)(10)**

To the extent necessary to enable Kentucky to suspend eligibility for, and not make medical assistance available to, Kentucky HEALTH beneficiaries who fail to comply with community engagement requirements, as described in these STCs, unless the beneficiary is exempted as described in STCs 44 or 47(a).

8. Eligibility

**Section 1902(a)(10)
and (a)(52)**

To the extent necessary to enable Kentucky to require community engagement as described in these STCs.

To the extent necessary to enable Kentucky to prohibit re-enrollment, and deny eligibility, for up to six months for Kentucky HEALTH program beneficiaries with income above 100 percent of the FPL who are disenrolled for failure to make their required premium contributions within sixty (60) days of the date of invoice, subject to the exceptions and qualifying events described in these STCs.

To the extent necessary to enable Kentucky to prohibit re-enrollment, and deny eligibility, for up to six months following the end of the ninety (90) day reconsideration period for Kentucky HEALTH program beneficiaries who are disenrolled for failure to provide the necessary information for the state to complete an annual redetermination, subject to the exceptions and qualifying events described in these STCs.

To the extent necessary to enable Kentucky to prohibit re-enrollment, and deny eligibility, for up to six months for Kentucky HEALTH program beneficiaries who are disenrolled for failure to timely and accurately report a change in circumstance affecting eligibility only in such circumstances where a beneficiary would no longer be eligible for Medicaid under any MAGI or Non-MAGI categories, subject to the exceptions and qualifying events described in these STCs.

9. Methods of Administration

**Section 1902(a)(4) insofar
as it incorporates 42 CFR
431.53**

To the extent necessary to relieve Kentucky of the requirement to assure non-emergency medical transportation to and from providers for the new adult group, as defined in 42 CFR 435.119, except that the state must provide non-emergency medical transportation for beneficiaries who are medically frail; who are 19 or 20 years old and entitled to early and period screening, diagnostic, and treatment (EPSDT); who are former foster care youth; or who are pregnant women.

**CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER LIST**

NUMBER: 11-W-00306/4 and 21-W-00067/4
TITLE: KY HEALTH Section 1115 Demonstration
AWARDEE: Kentucky Cabinet for Health and Family Services

Title XXI Waiver Authority

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

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

1. Continuous Eligibility

Section 2107(e)(1)(R)

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

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

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

TITLE: KY HEALTH 1115 Demonstration

AWARDEE: Kentucky Cabinet for Health and Family Services

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the “KY Helping to Engage and Achieve Long Term Health” (KY HEALTH) demonstration under section 1115(a) of the Social Security Act (hereinafter “demonstration”) to enable Kentucky to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authorities and waivers of requirements under section 1902(a) and section 2107 of the Social Security Act (the Act). These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state’s obligations to CMS during the life of the demonstration. The KY HEALTH demonstration will be statewide and is approved from January 12, 2018 through September 30, 2023. The demonstration includes a program entitled Kentucky HEALTH, which will begin July 1, 2018, although roll out for portions of the Kentucky HEALTH program, including the ability to earn credit for My Rewards activities, will begin April 1, 2018.

The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description and Objectives
- III. General Program Requirements
- IV. Kentucky HEALTH Populations Affected
- V. Benefits
- VI. Beneficiary-Managed Healthcare Accounts
- VII. Beneficiary-Required Contributions
- VIII. Community Engagement Initiative
- IX. Delivery System
- X. General Reporting Requirements
- XI. General Financial Requirements
- XII. Budget Neutrality
- XIII. Evaluation
- XIV. Opioid Use Disorder (OUD)/Substance Use Disorder (SUD)

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

- Attachment A: Developing the Evaluation Design

- Attachment B: Preparing the Interim and Summative Evaluation Reports
- Attachment C: SUD Implementation Protocol
- Attachment D: SUD Monitoring Protocol
- Attachment E: SUD Health Information Technology (Health IT)

At the state's option, additional supplemental protocols describing various operational details of the Kentucky HEALTH program may be submitted to CMS for approval and incorporation by reference into these STCs.

II. PROGRAM DESCRIPTION AND OBJECTIVES

This section 1115(a) demonstration, KY HEALTH, aims to transform the Kentucky Medicaid program to empower beneficiaries to improve their health. "KY HEALTH" refers to the demonstration collectively, and includes components of the demonstration that may impact additional Kentucky Medicaid beneficiaries along with the eligibility groups specified in STC 17, Table 1. This includes beneficiaries impacted by the SUD program, the waiver of NEMT for methadone treatment, and the alignment of a beneficiary's annual redetermination with their employer sponsored insurance (ESI) open enrollment period (including for any children enrolled in Medicaid or CHIP and covered by a parent or caretaker's ESI). "Kentucky HEALTH" refers specifically to program components detailed in Sections IV through IX of these STCs, which apply to the eligibility groups outlined in STC 17, Table 1.

The Kentucky HEALTH program includes two consumer-driven tools, the My Rewards Account and the Deductible Account, which encourage beneficiaries to maintain and improve their health by providing incentives for healthy behavior. Beneficiaries will receive incentives in their My Rewards Account that can be used to obtain enhanced benefits. Kentucky will implement the Deductible Account as an educational tool to inform beneficiaries about the cost of healthcare.

In addition, Kentucky will implement a community engagement requirement as a condition of eligibility for adult beneficiaries ages 19 to 64 in the Kentucky HEALTH program, with exemptions for various groups, including: former foster care youth, pregnant women, primary caregivers of a dependent (limited to one caregiver per household), beneficiaries considered medically frail, and full time students. To remain eligible for coverage, non-exempt beneficiaries must complete 80 hours per month of community engagement activities, such as employment, education, job skills training, and community service. Beneficiaries will have their eligibility suspended for failure to demonstrate compliance with the community engagement requirement, but will be able to reactivate their eligibility on the first day of the month after they complete 80 hours of community engagement in a 30-day period, or a state-approved health literacy or financial literacy course. Beneficiaries who are in an eligibility suspension for failure to meet the requirement on their redetermination date will have their enrollment terminated, and will be required to submit a new application, unless they can show they meet the requirement or qualify for an exemption in the month of redetermination. Kentucky will provide good cause exemptions in certain circumstances for beneficiaries who cannot meet requirements.

CMS is also authorizing additional waivers and expenditure authorities for the Kentucky HEALTH program, including:

- Premiums for beneficiaries in the new adult group and section 1931 parents and other caretaker relatives (with exceptions for pregnant women, former foster care youth, and those determined medically frail);
- Consequences for beneficiaries who do not pay premiums after a 60 day payment period;
- Six month non-eligibility period for certain populations for failure to comply with the redetermination process;
- Disenrollment and six month non-eligibility period for certain populations for failure to report a change in circumstance affecting eligibility;
- Limit to managed care organization disenrollment without cause; and
- A waiver of retroactive eligibility for certain populations;

CMS is also approving the following additional waiver and expenditure authorities for the KY HEALTH demonstration as a whole:

- A waiver of non-emergency medical transportation (NEMT) for certain populations and services;
- Alignment of a beneficiary's annual redetermination with their employer sponsored insurance (ESI) open enrollment period, including any children enrolled in Medicaid or CHIP and covered by a parent or caretaker's ESI; and
- Extension of coverage to former foster care youth who were the responsibility of another state.

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

Over the demonstration period, the state seeks to demonstrate several demonstration goals. The state's goals will inform the state's evaluation design hypotheses, subject to CMS approval, as described in these STCs. The state's goals include, and are not limited to the following:

- The Kentucky HEALTH program will strengthen beneficiary engagement in their personal health care, and will provide incentives for responsible decision making;
- A monthly premium contribution will result in more efficient use of health care services;
- The incentives established in this demonstration for Kentucky HEALTH program beneficiaries to engage in their communities and healthy behaviors will result in better health outcomes, lower overall health care costs, and improved socio-economic conditions for beneficiaries;
- The community engagement requirement will assist Kentucky HEALTH program beneficiaries in obtaining employment and transitioning to commercial health insurance and thereby improve health outcomes; and

- Increased access to certain SUD services through a comprehensive opioid/substance abuse strategy including an expenditure authority covered services provided to Medicaid eligible adults ages 21 through 64 will result in:
 - Increased and improved SUD treatment outcomes and establishment of best practices in treatment and accreditation processes.
 - A reduction of overdose deaths
 - A reduction of overall healthcare utilization (hospitals, urgent, etc.)
 - A reduction of co-morbidities associated with Substance Use Disorder (NAS, HIV, Hepatitis C, Hepatitis, Endocarditis) commodities associated with Substance use disorder

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state shall comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, and section 1557 of the Affordable Care Act.
2. **Compliance with Medicaid and Children’s Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid program and CHIP, expressed in law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.
3. **Changes in Federal Law, Regulation, and Policy.** The state shall, within the timeframes specified in the applicable federal law, regulation, or policy, come into compliance with changes in federal law, regulation or policy affecting the Medicaid or CHIP program that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable as described in these STCs. In addition, these STCs may be amended at the request of either CMS or the state to reflect such changes and/or changes that the Secretary determines to be of an operational nature without requiring the submission of an amendment to the demonstration under STC 7. The requesting entity will notify the other 30 calendar days in advance of the expected approval date of the amended STCs to allow for comment.
4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
 - a. To the extent that a change in federal law, regulation, or policy requires a change in federal financial participation (FFP) for expenditures made under this demonstration, the state shall adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration, as well as a modified allotment neutrality worksheet as necessary to comply with such change. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
 - b. If mandated changes in federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the day

such state legislation becomes effective, or on the day such legislation was required to be in effect under federal law, whichever is sooner.

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

As outlined in CMS' November 21, 2016 CMCS Informational Bulletin, *Section 1115 Demonstration Opportunity to Allow Medicaid Coverage to Former Foster Care Youth Who Have Moved to a Different State*, the state shall submit a conforming amendment to the state plan for the former foster care youth from another state affected by the implementation of this demonstration indicating that the proposed effective date of the SPA will be the effective date of this section 1115 demonstration project. After the associated Medicaid SPA is effectuated, the state will not be required to submit any additional title XIX SPAs for changes affecting this former foster care youth population made eligible solely through this demonstration.

6. **Changes Subject to the Amendment Process.** If not otherwise specified in these STCs, changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, and budget neutrality that are specifically authorized under the demonstration project shall 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 shall 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 FFP will not be available for 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 shall 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 reports and other deliverables in a timely fashion according to the deadlines specified herein. Amendment requests shall 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 14, prior to submission of the requested amendment;
 - b. A data analysis worksheet which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using

- the most recent actual expenditures, as well as summary and detail projections of the change in the “with waiver” expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
- c. An up-to-date CHIP allotment neutrality worksheet, if necessary;
 - d. A detailed description of the amendment including impact on beneficiaries, with sufficient supporting documentation and data supporting the evaluation hypotheses as detailed in the evaluation design in STC 82; and
 - e. If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.

8. Extension of the Demonstration. No later than twelve (12) months prior to the expiration date of the demonstration, the Governor of the state must submit to CMS either a demonstration extension request that meets federal requirements at 42 CFR 431.412(c) or a phase out plan consistent with the requirements of STC 9.

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

- a. **Notification of Suspension or Termination.** The state shall 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 shall submit a notification letter and a draft plan to CMS. The state shall submit the notification letter and a draft plan to CMS no less than six months before the effective date of the demonstration’s suspension or termination. Prior to submitting the draft plan to CMS, the state shall publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state shall conduct tribal consultation in accordance with STC 14, if applicable. Once the 30-day public comment period has ended, the state shall provide a summary of the public comments received, the state’s response to the comment and the extent to which the state incorporated the received comment into the revised plan.
- b. **Prior CMS Approval.** The state shall obtain CMS approval of the transition and phase-out plan prior to the implementation of the phase-out activities. Implementation of activities shall be no sooner than 14 calendar days after CMS approval of the plan.
- c. **Transition and Phase-out Plan Requirements.** The state shall include, at a minimum, in its plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary’s appeal rights, if any), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the program for the affected beneficiaries, and ensure ongoing coverage for those beneficiaries determined eligible, as well as any community outreach activities including community resources that are available.
- d. **Phase-out Procedures.** The state shall comply with all applicable notice requirements found in 42 CFR 431.206, 431.210, and 431.213. In addition, the state shall assure all applicable appeal and hearing rights afforded to demonstration beneficiaries as outlined in 42 CFR 431.220 and 431.221. If a

demonstration beneficiary is entitled to and requests a hearing before the date of action, the state shall maintain benefits as required in 42 CFR 431.230. In addition, the state shall conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category.

- e. **Exemption from Public Notice Procedures 42 CFR 431.416(g).** CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
 - f. **Federal Financial Participation (FFP).** If the demonstration is terminated or any relevant waivers suspended by the state, FFP shall be limited to normal closeout costs associated with terminating the demonstration including services, continued benefits as a result of beneficiaries' appeals and administrative costs of disenrolling beneficiaries.
- 10. Post Award Forum.** Pursuant to 42 CFR 431.420(c), within six months of the demonstration's implementation, and annually thereafter, the state shall afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 30 calendar days prior to the date of the planned public forum, the state shall publish the date, time and location of the forum in a prominent location on its website. The state can either use its Medical Care Advisory Committee, or another meeting that is open to the public and where an interested party can learn about the progress of the demonstration to meet the requirements of this STC. Pursuant to 42 CFR 431.420(c), the state shall include a summary of the comments in the quarterly report associated with the quarter in which the forum was held. The state shall also include the summary in its annual report.
- 11. Expiring Demonstration Authority.** For demonstration authority that expires prior to the demonstration's expiration date, the state shall submit a transition plan to CMS no later than six months prior to the applicable demonstration authority's expiration date, consistent with the following requirements:
- a. **Expiration Requirements.** The state shall include, at a minimum, in its demonstration expiration plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights, if any), the process by which the state shall conduct administrative reviews of Medicaid or CHIP eligibility for the affected beneficiaries, and ensure ongoing coverage for eligible individuals, as well as any community outreach activities.
 - b. **Expiration Procedures.** The state shall comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, 431.211, and 431.213. In addition, the state shall assure all applicable appeal and hearing rights afforded to demonstration participants as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a demonstration participant requests and is entitled to a hearing before the date of action, the state shall maintain benefits as required in 42 CFR section 431.230. In addition, the state shall conduct administrative renewals for all beneficiaries in

Kentucky HEALTH in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to termination as discussed in October 1, 2010, State Health Official Letter #10-008 and required under 42 C.F.R. 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

- c. **Federal Public Notice.** CMS will conduct a 30-day federal public comment period consistent with the process outlined in 42 CFR Section 431.416 in order to solicit public input on the state's demonstration expiration plan. CMS will consider comments received during the 30-day period during its review and approval of the state's demonstration expiration plan. The state shall obtain CMS approval of the demonstration expiration plan prior to the implementation of the expiration activities. Implementation of expiration activities shall be no sooner than 14 calendar days after CMS approval of the plan.
 - d. **Federal Financial Participation (FFP).** FFP shall be limited to normal closeout costs associated with the expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals and administrative costs of dis-enrolling participants.
- 12. Withdrawal of Waiver Authority.** CMS reserves the right to amend and withdraw waivers 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 amendment and 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 or amended, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiaries' appeals and administrative costs of disenrolling participants.
- 13. Adequacy of Infrastructure.** The state shall 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.
- 14. Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request.

The state must also comply with tribal and Indian Health Program/Urban Indian Health Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR §431.408(b), State Medicaid Director Letter #01-024, and/or contained in the state's approved state plan, when any program changes to the demonstration, either through amendment as set out in STC 6 or extension, are proposed by the state.

The state must also comply with the public notice procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

15. **Federal Financial Participation (FFP).** No federal matching for service expenditures for this demonstration will take effect until the effective date identified in the demonstration approval letter or, if later, as expressly stated within these STCs.
16. **Common Rule Exemption.** The state shall ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. The Secretary has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.101(b)(5).

IV. KENTUCKY HEALTH PROGRAM POPULATIONS AFFECTED

17. **Eligible Populations.** Only individuals eligible for Medicaid under an eligibility group listed in Table 1 are subject to the provisions of the Kentucky HEALTH program within this demonstration.

Table 1. Medicaid Eligibility Groups Affected by the Kentucky HEALTH	
Eligibility Group	Citations
New adult group	1902(a)(10)(A)(i)(VIII) 42 CFR 435.119
Parents and other caretaker relatives	1902(a)(10)(A)(i)(I) 1931(b) and (d) 42 CFR 435.110
Transitional medical assistance	408(a)(11)(A) 1931(c)(2) 1925 1902(a)(52)
Pregnant women	42 CFR 435.116
Former Foster Care Youth	42 CFR 435.150 42 CFR 435.218 1902(a)(10)(A)(i)(IX) 1902(a)(10)(A)(ii)(XX)

18. **Effective Date of Coverage.** All beneficiaries in the Kentucky HEALTH program, with the exception of beneficiaries who are medically frail (under 42 CFR 440.315(f) and as defined in the alternative benefit plan in the state plan), former foster care youth, and

pregnant women, are required to make monthly premium payments as described in STC 34. Individuals determined eligible for Kentucky HEALTH who are not otherwise exempt from premiums will be required to make their first premium payment prior to the start of coverage, except for beneficiaries found eligible through presumptive eligibility who will transition directly to Kentucky HEALTH effective the first day of the month of the state's eligibility determination, with no gap in coverage, as described in STC 21. Individuals will have sixty (60) days from the date of their premium invoice to pay the premium payment. Once an individual pays the premium, coverage will begin the first day of the month in which the payment was received.

- a. Individuals with income above 100 percent of the FPL who do not make an initial premium payment will not be enrolled in Kentucky HEALTH and will be required to reapply should they wish to participate.
- b. Individuals at or below 100 percent of the FPL who do not make an initial premium payment will be enrolled in Kentucky HEALTH effective the first day of the month in which the sixty (60) day payment period expired; however, once enrolled, these beneficiaries will be subject to the requirements and conditions outlined in STC 39(b).

As noted above, beneficiaries who are medically frail, former foster care youth, and pregnant women are not required to make premium payments. As a result, pregnant women and former foster care youth will be enrolled in the Kentucky HEALTH program with effective dates consistent with Medicaid regulations. Beneficiaries who are known to be medically frail at the time of application will be enrolled in Kentucky HEALTH effective the first day of the month in which the beneficiary applied for coverage.

- 19. Expedited Coverage.** Individuals not yet determined eligible for the Kentucky HEALTH program will be permitted to make an initial pre-determined premium pre-payment to expedite coverage on the electronic application or through the member self-service portal. This pre-payment amount shall not exceed the highest monthly premium that could be required under these STCs (for an individual at 133 percent FPL). Once the individual is determined eligible, coverage will begin the first day of the month in which the initial premium pre-payment was made. Once a premium pre-payment has been received, the beneficiary may not change managed care organization (MCOs) except for cause prior to their annual open enrollment opportunity, as specified in STC 51(b). The pre-determined premium pre-payment amount shall be determined by the state, and may be modified in accordance with STC 34(a).

The premium pre-payment is optional and fully refundable if the individual is determined not to be eligible for the Kentucky HEALTH program or if the individual is determined to be in a group for whom premiums are optional and subsequently requests a refund. Beneficiaries will remain responsible for the full amount of the monthly premium payment, as described in STC 34, during the first month of coverage and such amount will be included on the subsequent month invoice. If the beneficiary's monthly premium payment is less than the pre-payment, the remaining pre-payment amount must be credited against the monthly premium due until the full amount of the premium pre-

payment is exhausted. If the premium pre-payment is not exhausted after being credited to the remainder of the benefit period, the beneficiary will be refunded the remainder. If a beneficiary is determined presumptively eligible, s/he will not have the option to obtain expedited coverage through a premium pre-payment, because the beneficiary would receive expedited coverage through the state's presumptive eligibility processes.

20. **Retroactive Eligibility.** The state is not obligated to provide retroactive eligibility in accordance with Section 1902(a)(34) for beneficiaries enrolled in Kentucky HEALTH, except for pregnant women and former foster care youth.
21. **Presumptive Eligibility.** Individuals found eligible through presumptive eligibility will transition directly to the Kentucky HEALTH program copayment plan effective the first day of the month of the state's eligibility determination, with no gap in coverage under which they may be required to make copayments for all services equal to the copayment schedule in the Kentucky Medicaid state plan. Beneficiaries will have sixty (60) days from the date of their premium invoice to pay the premium payment. Beneficiaries who do not pay a premium at the end of the sixty (60) day payment period will be subject to the penalties described in STC 39.
22. **Failure to Complete a Redetermination.** Consistent with Medicaid regulations, beneficiaries failing to provide necessary information or documentation to complete the annual redetermination process will be disenrolled from Kentucky HEALTH. Beneficiaries will be granted an additional ninety (90) day reconsideration period in which to submit their redetermination paperwork to be reenrolled in Kentucky HEALTH. Upon the expiration of the ninety (90) day reconsideration period, Kentucky HEALTH beneficiaries, except those described in this STC 22(d), will be prohibited from re-enrollment in the demonstration for up to six months, unless the individual meets a good cause exception described in STC 23(d).

The state must provide reasonable modifications to the annual redetermination process to beneficiaries with disabilities protected by the ADA, Section 504 of the Rehabilitation Act, and Section 1557 of the Patient Protection and Affordable Care Act to enable and assist them in completing the annual redetermination process.

- a. The state may not terminate eligibility if the beneficiary has provided documentation that the state has not processed yet, provided the beneficiary returned the required documentation no later than the last day of the redetermination period.
- b. The state may not apply the six-month non-eligibility period if the beneficiary has provided documentation that the state has not processed yet, provided the beneficiary returned the required documentation no later than the last day of the ninety (90) day reconsideration period.
- c. Following the ninety (90) day reconsideration period, disenrolled beneficiaries subject to the non-eligibility period will be eligible for early re-enrollment at any time prior to the end of the six month non-eligibility period consistent with STC 41.

- d. Pregnant women, former foster care youth, and beneficiaries determined medically frail are exempt from this non-eligibility period. Any beneficiary who becomes pregnant, is determined to be medically frail or otherwise becomes eligible for Medicaid under an eligibility group not subject to the provisions of this non-eligibility period can reactivate their eligibility with an effective date consistent with the beneficiary's eligibility category.
- e. Beneficiaries who experienced a good cause exception that prevented the completion of the annual redetermination requirements, as described in STC 23(d), will be permitted to re-enroll prior to the expiration of the six-month non-eligibility period by providing verification of the exception.
- f. The state may not terminate eligibility of any individual with a disability under the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act for failure to submit redetermination paperwork if the individual needed and was not provided with reasonable modifications necessary to complete the process.

23. Failure to Complete Redetermination: State Assurances. The state shall:

- a. Maintain an annual renewal process, including ex parte renewals and use of pre-populated forms, consistent with all applicable Medicaid requirements, except that, with respect to individuals receiving premium assistance, (including any children enrolled in Medicaid or CHIP and covered by a parent or caretaker's ESI) Medicaid and CHIP eligibility re-determinations will be aligned with the individual's ESI open enrollment period.
- b. Maintain systems to complete ex parte renewals based on available information for all beneficiaries, achieving successful ex parte renewal for at least 75 percent of their Kentucky HEALTH beneficiaries, not including beneficiaries in a non-eligibility period or suspension at the time of the redetermination.
- c. Maintain timely processing of applications to avoid further delays in accessing benefits once the non-eligibility period is over.
- d. Include good cause exceptions to the non-eligibility period that would allow beneficiaries to re-enroll under certain conditions without completion of early re-enrollment requirements as described in STC 41 or waiting six months, including, at a minimum, the following verified conditions:
 - i. The beneficiary is hospitalized, otherwise incapacitated, or has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act and as a result was unable to provide information necessary to complete the redetermination during the entire redetermination and/or reconsideration reporting period, or is a person with a disability who was not provided with reasonable modifications needed to complete the process, or is a person with a disability and there were no reasonable modifications that would have enabled the individual to complete the process;
 - ii. A member of the beneficiary's immediate family who was living in the home with the beneficiary was institutionalized or died during the redetermination reporting period or the immediate family member has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the

- Patient Protection and Affordable Care Act and caretaking or other disability-related responsibilities resulted in an inability to complete redetermination;
- iii. The beneficiary obtained or lost private insurance coverage during the redetermination reporting period;
 - iv. The beneficiary was evicted from home or experienced homelessness during the redetermination reporting period;
 - v. The beneficiary was the victim of a declared natural disaster, such as a flood, storm, earthquake, or serious fire that occurred during the redetermination reporting period; or
 - vi. The beneficiary was a victim of domestic violence during the redetermination reporting period.
- e. Provide beneficiaries written notice of specific activities as described in STC 41 that would qualify them for early re-enrollment during a non-eligibility period and assures that these activities are available during a range of times and through a variety of means (e.g. online, in person) at no cost to the beneficiary.
 - f. Provide written notice to beneficiaries of any non-eligibility period exemptions and good cause exceptions, as described in STC 22(d) and (e), that would allow them to re-enroll during a non-eligibility period without completing early re-enrollment requirements. Such notice must include an explanation of the availability of good cause exceptions, as indicated in this STC.
 - g. Provide notice to beneficiaries, prior to adverse action, regarding the non-eligibility period, and explaining what this status means, including but not limited to: their right to appeal, their right to apply for Medicaid on a basis not affected by this status, what this status means with respect to their ability to access other coverage (such as coverage in a qualified health plan through the Exchange, or access to premium tax credits through the Exchange), what they should do if their circumstances change such that they may be eligible for coverage in another Medicaid category, as well as any implications with respect to whether they have minimum essential coverage.
 - h. Provide beneficiary education and outreach that supports compliance with redetermination requirements, such as through communications or coordination with state-sanctioned assistors, providers, MCOs, or other stakeholders.
 - i. Provide full appeal rights prior to disenrollment and observe all requirements for due process for beneficiaries who will be disenrolled for failing to provide the necessary information to the state to complete their redeterminations to allow beneficiaries the opportunity to raise additional issues in a hearing, including whether the beneficiary should be subject to the non-eligibility period and/or provide additional documentation through the appeals process.
 - j. Provide beneficiaries with written notice of the rights of people with disabilities to receive reasonable modifications that will assist them in meeting redetermination requirements
 - k. Provide reasonable modifications to the annual redetermination process to beneficiaries with disabilities protected by the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Patient Protection and Affordable Care Act to enable and assist them in completing the annual redetermination process.

- 24. Failure to Report a Change in Circumstance.** Beneficiaries who fail to report changes in circumstance in the required reporting period for changes affecting eligibility for Medicaid under any modified adjusted gross income (MAGI) or non-MAGI rules will be disenrolled. Disenrollment from Medicaid may only occur after the state conducts an administrative renewal for the beneficiary and determines the beneficiary ineligible for all other bases of Medicaid eligibility and reviews him/her for eligibility for other insurance affordability programs in accordance with 42 CFR 435.916(f). Disenrollment will be limited to circumstances in which the failure to report a change affected eligibility; specifically if it led to additional month(s) of Medicaid eligibility during which the member was not otherwise eligible. After disenrollment, the individual will be prohibited from re-enrollment in the demonstration for up to six months.
- a. Pregnant women, former foster care youth, and beneficiaries who are medically frail are exempt from this six-month non-eligibility period. Any beneficiary who becomes pregnant, is determined to be medically frail or otherwise becomes eligible for Medicaid under an eligibility group not subject to the provisions of this non-eligibility period can reactivate their eligibility with an effective date consistent with the beneficiary's eligibility category.
 - b. Disenrolled individuals will be eligible for early re-enrollment at any time prior to the end of the non-eligibility period consistent with STC 25(b) and STC 41.
 - c. The state must provide reasonable modifications to the obligation to report a change in circumstance for beneficiaries with disabilities protected by the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Patient Protection and Affordable Care Act.
- 25. Failure to Report a Change in Circumstance: State Assurances.** The state shall:
- a. Assure that beneficiaries identified as failing to have reported a change in circumstance affecting eligibility for Medicaid under any MAGI or Non-MAGI rules as outlined in STC 24 will have the opportunity to provide additional clarifying information indicating the beneficiary did report the change in circumstance or to support a good cause exception pursuant to 42 CFR 435.916(d)(1)(i) and further assures that it will observe all requirements for due process, including adequate notice and appeal rights, in connection with any non-eligibility period.
 - b. Include good cause exceptions that would allow beneficiaries to re-enroll under certain conditions without completion of early re-enrollment requirements as described in STC 41 or waiting six months, including, at a minimum, the following verified circumstances:
 - i. The beneficiary is out of town, hospitalized, otherwise incapacitated, or has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act, and as a result is unable to report the change during the entire change in circumstance reporting period as defined in the state plan, or is a person with a disability who was not provided with reasonable modifications needed to complete the process, or is a person with a disability and there

- were no reasonable modifications that would have enabled the individual to report the required changes in circumstances;
- ii. A member of the beneficiary’s immediate family who was living in the home with the beneficiary was institutionalized or died during the change in circumstance reporting period or the immediate family member has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act, and caretaking or other disability-related responsibilities resulted in an inability to report the change in circumstance;
 - iii. The beneficiary was the victim of a declared natural disaster, such as a flood, storm, earthquake, or serious fire that occurred during the change in circumstance reporting period as defined in the state plan;
 - iv. The beneficiary obtained or lost private insurance coverage during the change in circumstance reporting period as defined in the state plan;
 - v. The beneficiary was evicted from home or experienced homelessness during the change in circumstance reporting period as defined in the state plan; or
 - vi. The beneficiary was a victim of domestic violence during the change in circumstance reporting period as defined in the state plan.
- c. Assure that the non-eligibility period would only apply to beneficiaries where the unreported change in circumstance would affect eligibility as outlined in STC 24.
 - d. Provide written notice to beneficiaries of specific activities as described in STC 41 that would qualify them for early re-enrollment during a non-eligibility period and assure that these activities are available during a range of times and through a variety of means (e.g. online, in person) at no cost to the beneficiary.
 - e. Provide written notice to beneficiaries of any non-eligibility period exemptions and good cause exceptions, as described in STC 24(a) and 25(b), that would allow them to re-enroll during a non-eligibility period without completing early re-enrollment requirements. Such notice must include an explanation of the availability of good cause exceptions, as indicated in this STC.
 - f. Provide notice to beneficiaries, prior to adverse action, about the non-eligibility period, and explaining what this status means, including but not limited to: their right to appeal, their right to apply for Medicaid on a basis not affected by this status, what this status means with respect to their ability to access other coverage (such as coverage in a qualified health plan through the Exchange, or access to premium tax credits through the Exchange), what they should do if their circumstances change such that they may be eligible for coverage in another Medicaid category, as well as any implications with respect to whether they have minimum essential coverage.
 - g. Provide beneficiary education and outreach that supports compliance with change in circumstance reporting requirements, such as through communications or coordination with state-sanctioned assistors, providers, MCOs, or other stakeholders.
 - h. Assure that disenrollment from Medicaid will only occur after an individual has been screened and determined ineligible for all other bases of Medicaid eligibility

and reviewed for eligibility for insurance affordability programs in accordance with 42 CFR 435.916(f).

- i. Provide beneficiaries with written notice of the rights of people with disabilities to receive reasonable modifications related to reporting a change in circumstance.
- j. Maintain a system that identifies, validates, and provides reasonable modifications related to the obligation to report a change in circumstance to beneficiaries with disabilities protected by the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Patient Protection and Affordable Care Act.

V. BENEFITS

26. Kentucky HEALTH Program Benefits. Beneficiaries in the new adult group enrolled in Kentucky HEALTH will receive benefits through an Alternative Benefit Plan (ABP) that will be defined in the state plan. Benefits will remain consistent with the existing state plan for all pregnant women, former foster care youth, beneficiaries who are medically frail, and other traditional low-income (i.e., not in the new adult group) Medicaid populations transitioning to Kentucky HEALTH. In these STCs, references to a beneficiary's "base benefit plan" refer either to the ABP or to state plan benefits, depending on the beneficiary's eligibility category. Beneficiaries receiving state plan benefits will continue to receive covered vision services, dental services, and over-the-counter-medications in accordance with the state plan rather than through the My Rewards Account. In addition, all beneficiaries under 21 years of age receiving services through the demonstration will continue to receive all early and periodic screening, diagnostic, and treatment (EPSDT) services.

27. Non-Emergency Medical Transportation (NEMT).

- a. The state is not obligated to provide NEMT for any services provided to beneficiaries enrolled in the new adult group as defined in 42 CFR 435.119 except for beneficiaries who are medically frail, 19 or 20 year old beneficiaries entitled to EPSDT services, former foster care youth, and pregnant women. Most beneficiaries receiving state plan benefits will continue to receive non-emergency transportation for all services, except for methadone treatment. However, children under age 21 who are subject to EPSDT, former foster care youth, and pregnant women will continue to receive NEMT for all services, including methadone treatment, as specified in STC 92.
- b. Offering methadone through the state plan is contingent upon the waiver of NEMT.

VI. BENEFICIARY-MANAGED HEALTHCARE ACCOUNTS

28. General Description. Beneficiaries enrolled in the Kentucky HEALTH program will be provided with two member-managed health care accounts, one of which is a deductible account, and the other of which is a My Rewards Account through which beneficiaries accrue incentives that have a dollar value equivalent that can be used to access certain approved additional items and services.

- 29. Deductible Account.** All Kentucky HEALTH program beneficiaries (except pregnant women, and beneficiaries receiving premium assistance) will have a deductible account. At the beginning of each benefit year, the deductible account will reflect an initial dollar-value equivalent of \$1,000 which is available to cover a \$1,000 value plan deductible that is applicable to all non-preventive healthcare services. The deductible account acts as an educational tool to encourage appropriate health care utilization. Beneficiaries will receive monthly deductible account statements detailing the costs of utilized services and including an account balance. If funds in the deductible account are exhausted before the end of a beneficiary's 12-month benefit period, the beneficiary will still be able to access covered services without unreasonable delay.
- a. **Balance Transfer Incentive.** Beneficiaries with funds remaining in their deductible account at the end of their 12 month benefit period may, at the end of their 12 month benefit period, transfer up to 50 percent of the prorated balance of their deductible account to their My Rewards Account. The amount will be prorated based on the beneficiary's number of active member months (months in which a beneficiary is not disenrolled or in a suspension status) during the 12 month benefit period.
- 30. My Rewards Account.** All adult Kentucky HEALTH beneficiaries, including beneficiaries receiving premium assistance, will be provided with a My Rewards Account to access items and services not covered in a beneficiary's corresponding Kentucky HEALTH base benefit plan, as described in STC 26. The My Rewards Account acts as a mechanism to encourage healthy behaviors and community engagement which earn incentives that have a dollar-value equivalent that can be used to access certain approved additional items and services.
- a. **Eligibility.** My Rewards Accounts are available only to beneficiaries who remain enrolled in Kentucky HEALTH and who continue to make required monthly premium contributions consistent with STC 31 and 39, if applicable. Except for pregnant women, in no event may a Kentucky HEALTH beneficiary have an active My Rewards Account unless they are making monthly premium payments of no less than \$1.00.
- b. **Enhanced Benefits.** Kentucky will assist beneficiaries with an active My Rewards Account by covering benefits not included in the beneficiary's corresponding Kentucky HEALTH base benefits plan with amounts that have accrued in the My Rewards Account. Items and services available through the My Rewards Account will include only the following: vision services, dental services, over-the-counter medications, and limited fitness-related services, such as a gym membership. To help ensure that they have an opportunity to earn My Rewards Account credits to access vision services, dental services, over-the-counter medications, and limited fitness-related services, beneficiaries will be able to accumulate dollars in their My Rewards Account prior to the implementation of the Kentucky HEALTH program. Vision services, dental services, and over-the-counter medications will be covered through the My Rewards Account at the rate in the Medicaid fee-for-service fee schedule. Coverage of vision services, dental

services, and over-the-counter medications through the My Rewards account will be limited in scope to the services that would be covered under the Kentucky state plan if the beneficiary was not receiving the Alternative Benefit Plan.

- i. **State Plan Benefit Exception.** Kentucky HEALTH beneficiaries receiving state plan benefits (i.e. pregnant women, former foster care youth, beneficiaries who are medically frail, and adults who are not in the new adult group) will continue to receive state plan vision, dental, and over-the-counter medication covered under the state plan through their MCO rather than through the beneficiary's My Rewards Account.
- c. **Healthy Behaviors.** The state will provide earned incentives for certain state-specified healthy behaviors.
- d. **Community Engagement Activities.** Completion of community engagement activities will qualify for earned incentives only to the extent the activities exceed the 80 hour per month minimum requirements established for the Kentucky HEALTH community engagement initiative as detailed in STC 46.
- e. **Appropriate Healthcare Utilization.** Beneficiaries will be eligible for an annual contribution to their My Rewards Account for not having a non-emergent visit to the emergency department (including for non-use of the emergency department) during the 12 month benefit period.
- f. **Balance Accrual.** My Rewards Account balances accrue continuously when the account is active and the beneficiary is not otherwise suspended or disenrolled. The My Rewards Account is not subject to any annual limits.
- g. **Balance Deduction.** Deductions from the My Rewards Account will not apply when a beneficiary's My Rewards account is suspended. The My Rewards Account may reflect a negative balance of up to negative \$150 to reflect cumulative deductions. A beneficiary's My Rewards Account balance will be reduced for the following:
 - i. Non-payment of Premiums. Beneficiaries will have dollars deducted from their My Rewards Account each time a beneficiary fails to meet their premium payment obligation outlined in STC 39.
 - ii. Non-emergent Use of the Emergency Department. My Rewards Account dollars will be reduced for each non-emergent visit to the emergency department, and the amount of the reduction may increase for each subsequent non-emergent use. As the My Rewards Account deduction is not a copayment, the amount is not subject to the limitations in 42 CFR 447.54(b). This reduction will be waived for any beneficiary who contacts their MCO's 24-hour nurse hotline prior to utilizing the hospital emergency department. The beneficiary must receive an appropriate medical screening examination under section 1867—the Emergency Medical Treatment and Labor Act, or EMTALA, provision of the Act, before their My Rewards dollars can be deducted. Notwithstanding the fact that the My Rewards Account deduction is not a co-payment, the state will ensure that hospitals comply with the requirements described in 42 CFR 447.54(d)(2) related to educating beneficiaries about appropriate

- alternative settings before the state deducts amounts from the My Rewards Account for non-emergent use of the emergency department.
- iii. Missed Appointments. The state may evaluate whether, as a general matter, beneficiaries participating in Kentucky HEALTH are missing health care appointments. Based on that evaluation, the state may permit beneficiaries to earn incentives for keeping all scheduled appointments in the 12-month benefit period, or may deduct dollars from the My Rewards Account for each healthcare appointment missed without adequate notice of cancellation or good cause.
 - iv. No Actual Charges to Beneficiaries. The state assures that at no time would a beneficiary be required to make a monetary payment to the state as a result of having a negative dollar balance in his or her My Rewards Account.
- h. **Provider Reimbursement from My Rewards Account.** When beneficiaries seek to access benefits or services using the My Rewards Account, a Medicaid-enrolled provider should follow a prior authorization process before providing the benefit or service in order to assess whether the My Rewards Account contains an amount sufficient to cover the cost of the benefit or service. If the provider provides the benefit or service without checking available My Rewards Account funds, the provider will be at risk that the benefit or service is not reimbursable due to insufficient funds. Only if the My Rewards Account contains an amount sufficient to cover the cost of the benefit or service may the provider receive reimbursement under the demonstration. Notwithstanding the foregoing, in limited circumstances where prior authorized benefits or services changed after the hold on the My Rewards Account balance, the account balance will be permitted to go negative in order to reimburse the provider in full for the benefits or services rendered. All payments for My Rewards Account services will also reduce the beneficiary's My Rewards Account by the appropriate published state plan reimbursement rate for the eligible service provided. For items or services for which there is a state plan rate, reimbursement may not exceed the Medicaid fee-for-service rate. For items or services for which there is not a state plan rate, CMS must determine that reimbursement for the items and services is cost effective and efficient. Nothing in this provision would prevent the beneficiary from opting to self-pay the full cost of the benefit or service.

VII. BENEFICIARY-REQUIRED CONTRIBUTIONS

31. **Premiums.** All beneficiaries enrolled in the Kentucky HEALTH program, except pregnant women, former foster care youth, and beneficiaries who are medically frail, are required to pay monthly premiums of no less than one dollar per month, subject to exemptions and limitations in STCs 34, 39, and 42.
32. **Notice.** The state must notify Kentucky HEALTH beneficiaries of premium payment requirements upon eligibility determination. The state must determine the amount of a beneficiary's monthly premium based on the beneficiary's modified adjusted gross income and will notify the beneficiary and MCO of this amount. The MCO must bill for

and collect the premium from beneficiaries. Monthly invoices must include information about how to report any change in income; the time period over which income is calculated (e.g., monthly income); the deadline for reporting changes in circumstances; the consequences of non-payment and failure to report changes in circumstance that could affect eligibility; and that once the payment is made the individual may only change MCOs for cause, except during the beneficiary's annual enrollment opportunity.

33. Beneficiary-Required Contributions: State Assurances. The state shall:

- a. Permit the MCO to attempt to collect the unpaid premiums from the beneficiary, but the MCO may not report the premium amount owed to credit reporting agencies, place a lien on a beneficiary's home, refer the case to debt collectors, file a lawsuit, or seek a court order to seize a portion of the beneficiary's earnings for enrollees at any income level. The state will not "sell" the obligation for collection by a third-party. Further, while the amount is collectible by the state, re-enrollment is not conditioned upon repayment, except in the event of early re-enrollment described in STC 41.
- b. Monitor that beneficiaries do not incur household cost sharing and premiums that, combined, exceed 5 percent of the aggregate household income, in accordance with 42 CFR 447.56(f), without regard to MCO enrollment of members in the household. Once a household reaches the cap, the state assures that no further copayments can be charged to beneficiaries, and the premium amount will be reduced to \$1.00 per month for the remainder of the quarter to retain access to the My Rewards Account, except as outlined in STC 39.
- c. Charge copayment amounts, if applicable, that do not exceed Medicaid cost sharing permitted by federal law and regulation and the terms of this demonstration.
- d. Ensure that the state, or its designee, does not pass along the cost of any surcharge associated with processing payments to the beneficiary. Any surcharges or other fees associated with payment processing are considered an administrative expense by the state.
- e. Ensure that all payments from the beneficiary, or on behalf of the beneficiary, are accurately credited toward unpaid premiums in a timely manner, and provide the beneficiary an opportunity to review and seek correction of the payment history.
- f. Ensure that the state has a process to refund any premiums paid for a month in which the beneficiary is ineligible for Medicaid services for that month.
- g. Ensure that a beneficiary will not be charged a higher premium the following month due to nonpayment or underpayment of a premium in the previous month/s, except that amounts outstanding and due from the previous month/s may be reflected separately on subsequent invoices.
- h. Ensure the state suspends monthly invoices of premiums to beneficiaries whose eligibility has been suspended for failure to meet the community engagement requirement, and provide written notice to prevent overpayment of premiums.
- i. Conduct outreach and education to beneficiaries to ensure that they understand the program policies regarding premiums and associated consequences for nonpayment. Beneficiaries must be informed of how premium payments should

be made; the potential impact of a change in income on premium payments owed; the consequences of failure to report a change in income or circumstances that affect eligibility; the time period over which income is calculated (e.g., monthly income); the deadline for reporting changes in circumstances; and how to re-enroll if disenrolled for non-payment of premiums.

- j. Provide good cause exceptions to the consequences for failure to pay premiums described in STC 39 that would allow beneficiaries to re-enroll under certain conditions without completion of early re-enrollment requirements or waiting the full six (6) months, including, at a minimum, the following:
 - i. The beneficiary was hospitalized, otherwise incapacitated, or has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act and as a result is unable to pay premiums during the entire sixty (60) day payment period, or is a person with a disability who was not provided with reasonable modifications needed to pay the premium, or is a person with a disability and there were no reasonable modifications that would have enabled the individual to pay premiums during the entire sixty (60) day payment period;
 - ii. A member of the beneficiary's immediate family who was living in the home with the beneficiary was institutionalized or died during the sixty (60) day payment period, or the immediate family member has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act and caretaking or other disability-related responsibilities resulted in an inability to pay the premiums;
 - iii. The beneficiary was evicted from their home or experienced homelessness during the sixty (60) day payment period,
 - iv. The beneficiary was the victim of a declared natural disaster, such as a flood, storm, earthquake, or serious fire that occurred during the sixty (60) day payment period; or
 - v. The beneficiary was a victim of domestic violence during the sixty (60) day payment period.
- k. Provide all applicants and beneficiaries with timely and adequate written notices of any decision affecting their eligibility, including an approval, denial, termination, or suspension of eligibility or a denial or change in benefits and services pursuant to 42 CFR 435.917. The state will also provide availability and accessibility resources to program information in accordance with 42 CFR 435.901 and 435.905. The state will provide beneficiaries with 10 days advance notice for any adverse action prior to the date of action pursuant to 42 CFR 431.211.
- l. Provide beneficiaries written notice of specific activities that would qualify them for early re-enrollment during a non-eligibility period, as described in STC 41, and assure that these activities are available during a range of times and through a variety of means (e.g. online, in person) at no cost to the beneficiary.
- m. Provide notice to beneficiaries, prior to adverse action, about the non-eligibility period, and explaining what this status means, including but not limited to: their

right to appeal, their right to apply for Medicaid on a basis not affected by this status, what this status means with respect to their ability to access other coverage (such as coverage in a qualified health plan through the Exchange, or access to premium tax credits through the Exchange), what they should do if their circumstances change such that they may be eligible for coverage in another Medicaid category, as well as any implications with respect to whether they have minimum essential coverage.

- n. Provide beneficiaries with written notice of the rights of people with disabilities to receive reasonable modifications related to premium payment.
- o. Maintain a system that identifies, validates, and provides reasonable modifications related to the obligation to pay premiums to beneficiaries with disabilities protected by the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Patient Protection and Affordable Care Act.

34. Premium Amounts. All Kentucky HEALTH beneficiaries, including beneficiaries receiving premium assistance, with the exception of beneficiaries who are medically frail, former foster care youth, and pregnant women, as described in STC 18 and 31, are required to make premium payments at an amount established by the state. A premium amount shall not exceed four (4) percent of household income, except that all beneficiaries will be required to contribute, at a minimum, a monthly \$1 premium payment, unless exempt as described in STC 31. The state may vary premium amounts for beneficiaries, including (but not limited to) based on household income or the length of time a beneficiary is enrolled in Kentucky HEALTH, subject to the 4 percent of household income limit on premiums. Other bases for varying premiums shall be consistent with how premium requirements vary in the commercial insurance market in Kentucky and with all otherwise applicable law. Beneficiaries who meet the 5 percent aggregate household cap on premiums and cost sharing will pay a \$1 premium (the minimum) per month for the remainder of the calendar quarter, unless exempt as described in STC 31.

- a. **Changes in Premium Amount.** The state may reduce a premium amount at any time. The state will annually evaluate the premium rates and amounts, and reserves the right to increase a premium amount within the limitations set forth in these STCs in response to evaluation results on an annual basis. The state will notify CMS of upcoming premium changes through the Annual Report described in these STCs. The state will notify beneficiaries at least 60 days prior to implementing a premium change.

35. Household Limits. Premium payments apply towards all Kentucky HEALTH beneficiaries, as described in STC 31, in the MAGI household enrolled with the same MCO, such that premiums will not be collected on a per person basis, but rather on a per MCO basis and will be applicable to all Kentucky HEALTH members enrolled in the MCO.

36. Recalculation of Premium Payments. At a minimum, at annual redetermination or any time the state is made aware that a beneficiary's household income has changed during

the current eligibility period, the state must determine whether an adjustment to the member's monthly premium payment is necessary. Recalculated premium payments are effective the first day of the month following the recalculation. When a beneficiary has a change in circumstance, including household income, any overpayments made by the member shall reduce the premium contribution obligation for the next month(s).

- 37. Third Party Contributions.** Third parties, except contracted MCOs, are permitted to pay premiums on behalf of Kentucky HEALTH beneficiaries. There are no limits on the amounts third parties can contribute. Such third party contributions offset required beneficiary premium obligations only, and may not be used for any other purpose. Payments that exceed such obligations will be returned to the contributing third party. The payment must be used to offset the beneficiary's required premium payment obligation only, not the state's share. Healthcare providers or provider-related entities making premium payments on beneficiaries' behalf must have criteria for providing assistance that do not distinguish between beneficiaries based on whether or not they receive or will receive services from the contributing provider(s) or class of providers. Providers may not include the cost of such payments in the cost of care for purposes of Medicare and Medicaid cost reporting and such payments cannot be included as part of a Medicaid shortfall or uncompensated care.
- 38. Payment Period.** Kentucky HEALTH beneficiaries will have at least sixty (60) calendar days from the date of the payment invoice to make the required monthly premium payment to avoid non-payment penalties described in STC 39.
- 39. Non-Payment.**
- a. **Beneficiaries with Income Above 100 percent of FPL.**
 - i. Following the sixty (60) day payment period, currently enrolled Kentucky HEALTH members with income above 100 percent FPL who do not make their premium payment will be disenrolled from Kentucky HEALTH and will be prohibited from re-enrollment in the demonstration for up to six months, unless the beneficiary completes the requirements for early re-enrollment as described in STC 41. The state will provide beneficiaries with 10 days advance notice for any adverse action prior to the date of the eligibility action pursuant to 42 CFR 431.211.
 - ii. Beneficiaries who re-enter Kentucky HEALTH after the six month period will not be required to pay past premium debt as a condition of eligibility.
 - iii. Beneficiaries will have dollars deducted from their My Rewards Account pursuant to STC 30(g)(i).
 - iv. Beneficiaries who meet the requirements for good cause exceptions identified in STC 33(j) will be eligible to re-enter Kentucky HEALTH before the end of the six month period without completing the early re-enrollment requirements described in STC 41.
 - b. **Beneficiaries with Income At or Below 100 percent of FPL.**
 - i. Beneficiaries with income at or below 100 percent of the FPL who fail to make premium payments will not be disenrolled.

- ii. Beneficiaries who do not make their premium payment within the sixty (60) day payment period will be required to make copayments for all services equal to the copayments schedule in the Kentucky Medicaid state plan.
 - iii. Beneficiaries will have dollars deducted from their My Rewards Account pursuant to STC 30(g)(i).
 - iv. Beneficiaries will have their My Rewards Account suspended (i.e., may not use or accrue incentive amounts) for up to six months.
 - v. Beneficiaries may complete the requirements as described in STC 41 to end the copayment requirement and reactivate their My Rewards Account prior to the end of the six month period.
 - vi. Beneficiaries whose My Rewards Accounts are reactivated after the six month period will not be required to pay past premium(s) owed to reactivate their account.
 - vii. Beneficiaries who meet the requirements for good cause exceptions identified in STC 33(j) will be eligible to resume premium payments instead of copayments and access their My Rewards Account in the next administratively feasible month without completing the requirements described in STC 41.
- c. **Former Foster Care Youth and Beneficiaries Determined Medically Frail.**
- i. Former foster care youth and Kentucky HEALTH beneficiaries who have been identified as medically frail will have the option to pay premiums.
 - ii. Former foster care youth and beneficiaries who are medically frail will not be subject to copayments for services, and will not be subject to disenrollment for nonpayment.
 - iii. Beneficiaries who choose not to pay premiums (or who do not make a premium payment within the sixty (60) day payment period) will have their My Rewards Account suspended (i.e., may not use or accrue incentive amounts) for up to six months.
 - iv. Former foster care youth and beneficiaries who are medically frail may reactivate their My Rewards Accounts by attending an early re-enrollment educational course as described in STC 41(a)(ii). Former foster care youth and beneficiaries who are medically frail will not be required to pay past premiums owed to reactivate their My Rewards Account.
 - v. Beneficiaries who meet the requirements for good cause exceptions identified in STC 33(j) will be eligible to resume premium payments to access their My Rewards Account in the next administratively feasible month without having to attend an early re-enrollment educational course described in STC 41(a)(ii).

40. Eligibility Review. For each Kentucky HEALTH beneficiary subject to disenrollment for non-payment under STC 39, the state must review that beneficiary's eligibility for all other eligibility categories under the state's Title XIX program including notifying the beneficiary of the option of requesting a medically frail status review, pursuant to 42 CFR 435.916(f). The beneficiary's Medicaid MCO must also provide at least two written notices advising the beneficiary of the delinquent payment, the date by which the

payment must be made to prevent disenrollment, and the option for medical frailty screening. The first notice must be sent to the beneficiary on or before the seventh day of the month of coverage for which the premium payment was to be applied and must describe the consequences of nonpayment of required premiums. Notices must include information about reporting any changes in circumstances, including household income.

41. Early Re-Enrollment or Early Re-Activation of My Rewards Account. Kentucky HEALTH beneficiaries subject to consequences for non-payment of premiums as described in STC 39(a) or (b), for failure to complete a redetermination as described in STC 22, or for failure to report change in circumstance as described in STC 24, will have the opportunity to re-enter the program with full access to their MCO and My Rewards Account benefits, or (in the case of beneficiaries described in STC 39(b)) the opportunity to re-activate their My Rewards Account benefits, prior to the expiration of the applicable six-month period. The early re-enrollment or My Rewards reactivation opportunity is only available one time per 12 month benefit period per consequence type.

a. Beneficiaries seeking early re-enrollment following non-payment of premiums as described in STC 39(a), early re-activation of their My Rewards Account as described in STC 39(b), early re-enrollment following failure to complete a redetermination as described in STC 22, or early re-enrollment following failure to report change in circumstance as described in STC 24, must complete both of the following:

- i. Pay the premium payment required for the first month of coverage to restart benefits. Additionally, if the applicable six-month period is due to premium non-payment, beneficiaries seeking early re-enrollment, or (in the case of beneficiaries described in STC 39(b)) early re-activation of the My Rewards Account, must pay a one-time payment equaling premium payments owed for each month in which the member received healthcare coverage during the sixty (60)-day payment period prior to the effective date of the applicable six-month period.
- ii. Attend an early re-enrollment educational course. The course providers will be certified by the state and offer members course options for early re-enrollment on: (1) health literacy, and (2) financial literacy.

42. Exemptions. Pregnant women will be exempt from all Kentucky HEALTH premiums. Kentucky HEALTH beneficiaries who are medically frail or former foster care youth will not be required to pay premium payments as a condition of participation; however, these beneficiaries must make premium payments in order to access the beneficiary's My Rewards Account, as described in STC 39(c). Kentucky HEALTH beneficiaries with incomes at or below 100 percent FPL will not be disenrolled for non-payment of premiums, but will be required to make copayments and will be subject to the additional actions described in STC 39(b). Beneficiaries who are disenrolled and subject to a non-eligibility period as a result of non-payment of premiums but during that period become pregnant, are determined to be medically frail or otherwise become eligible for Medicaid under an eligibility group not subject to the provisions of this non-eligibility period can reactivate their eligibility with an effective date consistent with the beneficiary's

eligibility category. These beneficiaries may access their My Rewards Account if they otherwise meet the requirements in STC 30.

VIII. COMMUNITY ENGAGEMENT INITIATIVE

43. Overview. Kentucky will implement a community engagement requirement as a condition of eligibility for adult beneficiaries in the Kentucky HEALTH program who are not otherwise subject to an exemption described in STC 44 or 47(a). To maintain program eligibility, non-exempt beneficiaries will be required to participate in specified activities that may include employment, education, or community service.

44. Exempt Populations. The following Kentucky HEALTH beneficiaries are exempt from the community engagement initiative:

- Former Foster Care Youth;
- Pregnant women;
- Primary caregivers of a dependent, including either a dependent minor child or an adult who is disabled (limited to only one exempt beneficiary per household);
- Beneficiaries identified as medically frail (under 42 CFR 440.315(f) and as defined in the alternative benefit plan in the state plan);
- Beneficiaries diagnosed with an acute medical condition that would prevent them from complying with the requirements (as validated by a medical professional);
- Full time students, as determined by the state; and
- Beneficiaries under the age of 19 or over the age of 64.

Beneficiaries meeting one or more of the above listed exemptions will not be required to complete community engagement related activities to maintain eligibility.

45. Qualifying Activities. Kentucky HEALTH beneficiaries may satisfy their community engagement requirements through a variety of activities, including but not limited to:

- Job skills training;
- Job search activities;
- Education related to employment (e.g. management training);
- General education (e.g., high school, GED, college or graduate education, English as a second language, etc.)
- Vocational education and training;
- Self-employment;
- Subsidized or unsubsidized employment;
- Community work experience;
- Community service/ public service;
- Caregiving services for a non-dependent relative or other person with a disabling medical condition; and
- Participation in substance use disorder treatment.

Beneficiaries without an exemption must document their participation in any one or combination of qualifying activities on at least a monthly basis.

Notwithstanding the foregoing, some beneficiaries will be deemed to satisfy community engagement requirements by virtue of their verified participation in the following specified activities: (i) the beneficiary meets the requirements of the Supplemental Nutrition Assistance Program (SNAP) and/or Temporary Assistance for Needy Families (TANF) employment initiatives or is exempt from having to meet those requirements, (ii) the beneficiary is enrolled in the state's Medicaid employer premium assistance program (a spouse or dependent of the beneficiary enrolled in the premium assistance program is also exempt), or (iii) the beneficiary is employed at least 120 hours per calendar month. Beneficiaries who are deemed to satisfy the community engagement requirements will not be required to actively document their participation in qualifying activities, although, like all beneficiaries, they will be required to timely report changes in eligibility to the state consistent with the reporting rules under the Kentucky HEALTH Program.

- 46. Hour Requirements.** The community engagement initiative will require beneficiaries to participate in 80 hours of community engagement activities per calendar month. The community engagement requirement will be implemented on a regional basis following implementation of Kentucky HEALTH. Kentucky HEALTH beneficiaries who have not been subject to the Kentucky HEALTH community engagement requirement in the past five years, will be given a three month period before being required to meet the community engagement requirement. All other beneficiaries will be subject to the consequences described in STC 47. Beneficiaries can demonstrate that they meet the requirement, in a manner consistent with 42 CFR 435.945.
- a. **Reasonable modifications:** Kentucky must provide reasonable accommodations related to meeting the community engagement requirement for beneficiaries with disabilities protected by the ADA, Section 504 of the Rehabilitation Act, and Section 1557 of the Patient Protection and Affordable Care Act, when necessary, to enable them to have an equal opportunity to participate in and benefit from the program. The state must also provide reasonable modifications for program protections and procedures, including but not limited to assistance with demonstrating eligibility for good cause exemptions; appealing suspensions; documenting community engagement activities and other documentation requirements; understanding notices and program rules related to community engagement requirements; and other types of reasonable modifications.
 - i. Reasonable modifications must include exemptions from participation where an individual is unable to participate for disability-related reasons, modification in the number of hours of participation required where an individual is unable to participate for the required number of hours, and provision of support services necessary to participate, where participation is possible with supports. In addition, the state must evaluate individuals' ability to participate and the types of reasonable modifications and supports needed.
- 47. Non-Compliance.** Eligibility will be suspended, effective under the time frame described in this STC 47(d), for beneficiaries who fail to meet required community engagement hours for a month, unless the beneficiary requests and meets a good-cause

exemption within the allotted time period or appeals the suspension prior to its effective date, and will remain suspended until the first day of the month after the beneficiary completes 80 hours of community engagement in a 30-day period or completes a state-approved re-enrollment health literacy or financial literacy course. If a Kentucky HEALTH beneficiary is in a suspension for failure to meet the requirement on his or her redetermination date, and does not meet the requirement or qualify for an exemption under STC 44 or 47(a) in the month of redetermination, Kentucky will deny that beneficiary's eligibility and terminate his or her enrollment at that time.

- a. **Good Cause Exemption.** The state will waive the suspension for beneficiaries who failed to meet the community engagement hours due to a good cause exemption for a circumstance that occurred in the month in which the beneficiary failed to meet their required community engagement hours. Beneficiaries may seek a good cause exemption up to 10 days prior to suspension. The recognized good cause exemptions include, but are not limited to, at a minimum, the following verified circumstances:
 - i. The beneficiary has a disability as defined by the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act and was unable to meet the requirement for reasons related to that disability; or has an immediate family member in the home with a disability under federal disability rights laws and was unable to meet the requirement for reasons related to the disability of that family member; or the beneficiary or an immediate family member who was living in the home with the beneficiary experiences a hospitalization or serious illness;
 - ii. The beneficiary experiences the birth, or death, of a family member living with the beneficiary;
 - iii. The beneficiary experiences severe inclement weather (including natural disaster) and therefore was unable to meet the requirement; or
 - iv. The beneficiary has a family emergency or other life-changing event (e.g. divorce or domestic violence).
- b. **Opportunity to Cure.** In the month immediately following the month in which a beneficiary fails to meet the hours requirement, beneficiaries will have the opportunity to avoid Kentucky HEALTH suspension for community engagement non-compliance by being current on all hours for the current month, and, either: (1) making up all deficit hours not completed in the prior month, or (2) completing a state approved re-enrollment health literacy or financial literacy course. The option to take a re-enrollment course to avoid suspension or re-enter from suspension is only available one time per 12-month benefit period.
- c. **Extra Hours.** Unless a beneficiary is completing hours in accordance with paragraph (b) above, beneficiaries who engage in more qualifying activities than required in a month do not have the ability to apply the excess hours to any month other than the current month.
- d. **Suspension Effective Date.** Suspensions for non-compliance with community engagement requirements are effective the first day of the month following the one month opportunity to cure.

- e. **Re-activation Following Non-Compliance.** Following suspension for community engagement non-compliance, beneficiaries can re-activate eligibility at any time during their 12-month benefit period by completing 80 hours of community engagement in a 30-day period or completing a state approved re-enrollment health literacy or financial literacy course. The re-enrollment course to avoid suspension or for reactivation is only available one time per 12-month benefit period. Benefits will be effective the first day of the month following completion of the required hours or health literacy or financial literacy course. During a suspension period, any beneficiary who becomes pregnant; is determined to be medically frail; becomes the primary caregiver of a dependent including either a dependent minor child or adult who is disabled (limited to only one exempt beneficiary per household); becomes a full-time student; becomes diagnosed with an acute medical condition that would prevent them from complying with the requirements (as validated by a medical professional); or otherwise becomes eligible for Medicaid under an eligibility group not subject to the provisions of the community engagement suspension can reactivate their eligibility with an effective date consistent with the beneficiary's new eligibility category or status.

48. Community Engagement: State Assurances. Prior to implementation of the community engagement requirements as a condition of eligibility, the state shall:

- a. Maintain system capabilities to operationalize the suspension and/or denial of eligibility and the lifting of suspensions of eligibility once community engagement requirements are met.
- b. Maintain mechanisms to stop capitation payments to an MCO when a beneficiary's eligibility is suspended and to trigger payment once the suspension is lifted.
- c. Ensure that there are processes and procedures in place to seek data from other sources including SNAP and TANF, and systems to permit beneficiaries to efficiently report community engagement hours, and to permit Kentucky to monitor compliance.
- d. Ensure that there are timely and adequate beneficiary notices provided in writing, including but not limited to:
 - i. When the community engagement requirement will commence for that specific beneficiary;
 - ii. Whether a beneficiary is exempt, and under what conditions the exemption would end;
 - iii. A list of the specific activities that may be used to satisfy community engagement requirements and a list of the specific activities that beneficiaries can engage in to cure an impending suspension, as described in STC 47(b);
 - iv. Information about resources that help connect beneficiaries to opportunities for activities that would meet the community engagement requirement, and information about the community supports that are

- available to assist beneficiaries in meeting community engagement requirements;
 - v. Information about how community engagement hours will be counted and documented;
 - vi. What gives rise to a suspension, what a suspension would mean for the beneficiary, including how it could affect redetermination, and how to avoid a suspension, including how to apply for a good cause exemption and what kinds of circumstances might give rise to good cause;
 - vii. If a beneficiary is not in compliance for a particular month, that the beneficiary is out of compliance, and how the beneficiary can cure the non-compliance in the immediately following month;
 - viii. If a beneficiary has eligibility suspended, how to appeal a suspension, and how to have the suspension lifted, including the number of community engagement hours that must be performed within a 30 day period by the specific beneficiary to have the suspension lifted, and information on the option to take a re-enrollment course to have the suspension lifted; and
 - ix. If a beneficiary has requested a good cause exemption, that the good cause exemption has been approved or denied, with an explanation of the basis for the decision and how to appeal a denial.
- e. Ensure that specific activities that may be used to satisfy community engagement requirements and specific activities that would allow beneficiaries to cure an impending community engagement suspension (as described in STC 47(b)) are available during a range of times and through a variety of means (e.g. online, in person) at no cost to the beneficiary.
 - f. Provide full appeal rights as required under 42 CFR, Part 431, subpart E prior to suspension and observe all requirements for due process for beneficiaries whose eligibility will be suspended, denied, or terminated for failing to meet the community engagement requirement, including allowing beneficiaries the opportunity to raise additional issues in a hearing, including whether the beneficiary should be subject to the suspension, and provide additional documentation through the appeals process.
 - g. Assure that disenrollment or denial of eligibility will only occur after an individual has been screened and determined ineligible for all other bases of Medicaid eligibility and reviewed for eligibility for insurance affordability programs in accordance with 42 CFR 435.916(f).
 - h. Establish beneficiary protections, including assuring that Kentucky HEALTH beneficiaries do not have to duplicate requirements to maintain access to all public assistance programs that require community engagement and employment.
 - i. Make good faith efforts to connect Kentucky HEALTH beneficiaries to existing community supports that are available to assist beneficiaries in meeting community engagement requirements, including available non-Medicaid assistance with transportation, child care, language access services and other supports; and make good faith efforts to connect beneficiaries with disabilities as defined in the ADA, section 504 of the Rehabilitation Act, or section 1557 of the

- Patient Protection and Affordable Care Act with services and supports necessary to enable them to meet community engagement requirements.
- j. Ensure the state will assess areas within the state that experience high rates of unemployment, areas with limited economies and/or educational opportunities, and areas with lack of public transportation to determine whether there should be further exemptions from the community engagement requirements and/or additional mitigation strategies, so that the community engagement requirements will not be impossible or unreasonably burdensome for beneficiaries to meet.
 - k. Ensure that the state will assess whether people with disabilities have limited job or other opportunities for reasons related to their disabilities. If these barriers exist for people with disabilities, the state must address these barriers.
 - l. Provide beneficiaries with written notice of the rights of people with disabilities to receive reasonable modifications related to meeting community engagement requirements.
 - m. Maintain a system that provides reasonable modifications related to meeting the community engagement requirement to beneficiaries with disabilities as defined in the ADA, section 504 of the Rehabilitation Act, or section 1557 of the Patient Protection and Affordable Care Act.

IX. DELIVERY SYSTEM

- 49. Overview.** Kentucky HEALTH will utilize the current statewide mandatory managed care delivery system for all covered populations under the authority of the Kentucky Managed Care Organization Program 1915(b) waiver. Only eligible members participating in the employer premium assistance program will be exempt from mandatory managed care enrollment.
- 50. Managed Care Organizations (MCO).** Beneficiaries shall be enrolled to receive services through an MCO under contract to the state. The MCOs are subject to the federal laws and regulations as specified in 42 CFR Part 438, unless specified otherwise herein. Beneficiaries will be given an opportunity to select an MCO at the time of application. A beneficiary who does not make an MCO selection at the time of application may be auto-assigned to a MCO by the state.
- 51. Beneficiary’s Right to Change MCOs.**
- a. A beneficiary may change MCOs without cause if the change is requested prior to (i) the date the beneficiary pays their initial premium, or (ii) the date the beneficiary has enrolled in Kentucky HEALTH after the sixty (60) day initial payment period has expired. This does not apply to pregnant women and former foster care youth who will be permitted to change MCOs without cause for 90 days after enrollment.
 - b. **For Cause.** A beneficiary may change MCOs for cause at any time and the state will include this information in all communications about beneficiary contributions. “Cause” is defined in 42 CFR 438.56(d)(2).

- c. The beneficiary must submit his or her request for change either orally or in writing. The beneficiary shall still have access to the state's normal grievance and appeals process required under the managed care regulations.
- d. If the state fails to make a determination by the first day of the second month following the month in which the beneficiary files the request, the request for change will be considered approved and the beneficiary will be transferred into the new MCO.
- e. If a beneficiary is transferred from the MCO, the MCO must refund any balance of the beneficiary's premium (if applicable) to the beneficiary within 30 days of the last date of participation with the MCO.
- f. The deductible account balance will transfer with the beneficiary to the new MCO. The deductible account is a virtual account, and no funds are transferred due to an MCO change. The transferring MCO shall provide the individual's current deductible account balance to the new MCO with the information needed to properly track the beneficiary's account balance for the remainder of the benefit period.
- g. The state shall ensure that all transferring beneficiaries receive coverage from their new MCO promptly, and without any interruption in care
- h. **Excluded Services.** Consistent with the state's Kentucky Managed Care Organization (MCO) Program §1915(b) waiver (KY.0007.R01.00), MCOs will not be responsible for Kentucky HEALTH beneficiary nursing facility costs during the first 30 calendar days the beneficiary is enrolled in the MCO; however, if a member is admitted to a nursing facility, the MCO will be required to cover the costs of any non-nursing facility covered health services provided to the beneficiary while the beneficiary resides in the nursing facility, for up to 30 calendar days, after which, the MCO will not be responsible for the costs of the beneficiary's care for so long as the beneficiary is residing in the nursing facility or enrolled in the MCO..

52. Public Contracts. Payments under contracts with public agencies, that are not competitively bid in a process involving multiple bidders, must not exceed the documented costs incurred in furnishing covered services to eligible beneficiaries (or a reasonable estimate with an adjustment factor no greater than the annual change in the consumer price index).

X. GENERAL REPORTING REQUIREMENTS

53. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in the amount of \$5,000,000 (federal share) per deliverable when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter singly or collectively referred to as "deliverable(s)")) are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. Similarly, deferrals of \$5,000,000 per deliverable may be issued when the state does not demonstrate sufficient progress on milestones in the SUD Implementation Protocol, as described in STC 93. Specifically:

- a. Thirty (30) days after the deliverable was due, CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverables.
- b. For each deliverable, the state may submit a written request for an extension to submit the required deliverable. Extension requests that extend beyond the fiscal quarter in which the deliverable was due must include a Corrective Action Plan (CAP).
 - i. CMS may decline the extension request.
 - ii. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided.
 - iii. If the state's request for an extension includes a CAP, CMS may agree to or further negotiate the CAP as an interim step before applying the deferral.
- c. The deferral would be issued against the next quarterly expenditure report following the written deferral notification.
- d. When the state submits the overdue deliverable(s) that are accepted by CMS, the deferral(s) will be released.
- e. As the purpose of a section 1115 demonstration is to test new methods of operation or services, and timely and complete submission of required deliverables is necessary for effective testing, the state's failure to submit all required deliverables may preclude the state from renewing a demonstration or obtaining a new demonstration.
- f. CMS will consider with the state an alternative set of operational steps for implementing the intended deferral to align the process with the state's existing deferral process, for example which quarter the deferral applies to, and how the deferral is released.

54. Submission of Post-Approval Deliverables. The state will submit all deliverables using the process stipulated by CMS and within the timeframes outlined within these STCs.

55. General Financial Requirements. The state shall comply with all general financial requirements under Title XIX, including reporting requirements related to monitoring budget neutrality, set forth in Section XI of these STCs.

56. Reporting Requirements Related to Budget Neutrality. The state shall comply with all reporting requirements for monitoring budget neutrality set forth in Section XII of these STCs.

57. Periodic Monitoring Calls. CMS will convene periodic conference calls with the state. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to) any significant actual or anticipated developments affecting the demonstration; including planning for future changes in the program or intent to further Kentucky HEALTH beyond September 30, 2023. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration. The state and CMS will jointly develop the agenda for the calls.

- 58. Monitoring Reports.** The state will submit to CMS a draft of proposed metrics for quarterly and annual monitoring reports within 120 days after implementation of the demonstration. CMS will then work with the state to jointly identify required metrics for quarterly and annual reports. These metrics will reflect the major elements of the demonstration, including but not limited to data that applies to the waiver and expenditure authorities, and may include (but are not limited to): beneficiary engagement through My Rewards Accounts, community engagement initiatives, and coverage of substance use disorder services. Metrics may be identified through a variety of sources, including but not limited to, the CMS Child and Adult Core Measure sets, HEDIS measures, and NCQA measures, as well as proposed CMS metrics. CMS will combine these programmatic metrics with general metrics aimed at monitoring beneficiary enrollment, access to services, and the overall functioning of the demonstration.

The resulting performance metric set is one part of the quarterly and annual monitoring report framework specified later in this STC. The state will submit three (3) quarterly reports and one (1) compiled annual report each demonstration year (DY). The quarterly reports are due no later than sixty (60) days following the end of each demonstration quarter. The annual report is due no later than ninety (90) days following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the report may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and must be provided in a structured manner that supports federal tracking and analysis.

- a. **Operational Updates.** Per 42 CFR 431.428, the monitoring reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges and how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The monitoring reports should also include any lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held.
- b. **Performance Metrics.** Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis. The performance metrics should be included in the first quarterly report following CMS approval of the metrics.
- c. **Budget Neutrality and Financial Reporting Requirements.** Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state will provide an updated budget neutrality workbook that

includes established baseline and member months data with every Monitoring Report. The budget neutrality workbook will meet all the reporting requirements for monitoring budget neutrality set forth in Section XI. General Financial Requirements of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state will report quarterly expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately.

- d. **Evaluation Activities and Interim Findings.** Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

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

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

60. Close Out Report. Within 120 days prior to the expiration of the demonstration, the state must submit a draft Close Out Report to CMS for comments.

- a. The draft report must comply with the most current guidance from CMS.
- b. The state will present to and participate in a discussion with CMS on the Close-Out report.
- c. The state must take into consideration CMS' comments for incorporation into the final Close Out Report.
- d. The final Close Out Report is due to CMS no later than thirty (30) days after receipt of CMS' comments.
- e. A delay in submitting the draft or final version of the Close Out Report may subject the state to penalties described in STC 6.

XI. GENERAL FINANCIAL REQUIREMENTS

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

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

- 62. Reporting Expenditures under the Demonstration.** The following describes the reporting of expenditures subject to the budget neutrality agreement:
- a. **Tracking Expenditures.** In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and state Children’s Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in sections 2500 and 2115 of the state Medicaid Manual. All demonstration expenditures subject to the budget neutrality limit must be reported each quarter on separate Forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (including the project number extension, which indicates the DY in which services were rendered or for which capitation payments were made).
 - b. **Cost Settlements.** For monitoring purposes, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (Form CMS-64.9P Waiver) for the Summary Sheet Line 10B, in lieu of Lines 9 or 10C. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual.
 - c. **Kentucky HEALTH Premiums.** Premiums from beneficiaries that are collected by the MCO on behalf of the state from beneficiaries under the demonstration must be reported to CMS each quarter on Form CMS-64 summary sheet line 9.D, columns A and B. In order to assure that these collections are properly credited to the demonstration, premium collections (both total computable and federal share) should also be reported separately by DY on the form CMS-64 narrative. In the calculation of expenditures subject to the budget neutrality expenditure limit, premium collections applicable to demonstration populations will be offset against expenditures. These section 1115 premium collections will be included as a manual adjustment (decrease) to the demonstration’s actual expenditures on a quarterly basis.
 - d. **Use of Waiver Forms.** For each DY, separate Forms CMS-64.9 Waiver and/or 64.9P Waiver must be submitted reporting expenditures for beneficiaries enrolled in the demonstration, subject to the budget neutrality limit. The state will complete separate waiver forms for the following benefits/ waiver names:
 - i. “SUD” expenditures
 - ii. “My Rewards” expenditures
- 63. Administrative Costs.** Administrative costs will not be included in the budget neutrality limit, but the state shall separately track and report additional administrative costs that are directly attributable to the demonstration, using Forms CMS-64.10 Waiver and/or 64.10P Waiver, with waiver name State and Local Administration Costs (“ADM”).

- 64. Claiming Period.** All claims for expenditures subject to the budget neutrality limit (including any cost settlements) shall be made within 2 years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including any cost settlements) shall be made within 2 years after the conclusion or termination of the demonstration. During the latter 2-year period, the state shall continue to identify separately net expenditures related to dates of services during the operation of the demonstration on the Form CMS-64 and Form CMS-21 in order to properly account for these expenditures in determining budget neutrality.
- 65. Reporting of Member Months.** The following describes the reporting of member months for the demonstration populations:
- a. For the purpose of calculating the budget neutrality expenditure cap and for other purposes, the state will provide to CMS, as part of the quarterly report required under STC 58, the actual number of eligible member months for the demonstration populations. The state will submit a statement accompanying the quarterly report, which certifies the accuracy of this information.
 - b. To permit full recognition of “in-process” eligibility, reported counts of member months may be subject to revisions after the end of each quarter. Member month counts may be revised retrospectively as needed.
 - c. The term "eligible member months" refers to the number of months in which persons are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months each contribute two eligible member months to the total, for a total of four eligible member months.
- 66. Standard Medicaid Funding Process.** The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure cap and separately report these expenditures by quarter for each federal fiscal year on the Form CMS-37 for both the Medical Assistance Payments (MAP) and State and Local Administration Costs (ADM). CMS will make federal funds available based upon the state's estimate, as approved by CMS. Within 30 calendar days after the end of each quarter, the state must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter just ended. CMS will reconcile expenditures reported on the Form CMS-64 quarterly with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.
- 67. Extent of FFP for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole as outlined below:
- a. Administrative costs, including those associated with the administration of the demonstration. With respect to expenditures for items and services covered through the My Rewards account, only those items and services that the Secretary

has found to be necessary for the proper and efficient administration of the state plan may be claimed as administrative costs.

- b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved state plan.
- c. Medical Assistance expenditures made under section 1115 demonstration authority, including those made in conjunction with the demonstration, cost sharing, pharmacy rebates, and all other types of third party liability or CMS payment adjustments. With respect to expenditures for items and services covered through the My Rewards account, only those items and services that the Secretary has determined meet the definition of medical assistance in section 1905(a) of the Act may be claimed as medical assistance expenditures.

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

- a. CMS may review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS must be addressed within the time frames set by CMS.
- b. Any amendments that impact the financial status of the demonstration shall require the state to provide information to CMS regarding all sources of the non-federal share of funding.
- c. The state assures that all health care-related taxes comport with section 1903(w) of the Act and all other applicable federal statutory and regulatory provisions, as well as the approved Medicaid state plan.

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

- a. Units of government, including governmentally operated health care providers, may certify that state or local tax dollars have been expended as the non-federal share of funds under the demonstration.
- b. To the extent the state utilizes certified public expenditures (CPEs) as the funding mechanism for Title XIX (or under section 1115 authority) payments, CMS shall approve a cost reimbursement methodology. This methodology shall include a detailed explanation of the process by which the state would identify those costs eligible under Title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
- c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for payments under the demonstration, governmental entities to which general revenue funds are appropriated shall certify to the state the amount of such tax revenue (state or local) used to fund the non-federal share of

demonstration expenditures. The entities that incurred the cost shall also provide cost documentation to support the state's claim for federal match.

- d. The state may use intergovernmental transfers to the extent that such funds are derived from state or local tax revenues and are transferred by units of government within the state. Any transfers from governmentally operated health care providers shall be made in an amount not to exceed the non-federal share of Title XIX payments.
- e. Under all circumstances, health care providers must retain 100 percent of the reimbursement amounts claimed by the state as demonstration expenditures. Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state and/or local government to return and/or redirect any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business (such as payments related to taxes (including health care provider-related taxes), fees, and business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments) are not considered returning and/or redirecting a Medicaid payment.

XII. BUDGET NEUTRALITY

- 70. Limit on Title XIX Funding.** The state is subject to a limit on the amount of federal Title XIX funding that the state may receive on selected Medicaid expenditures during the period of approval of the demonstration. The limit is determined by using the per capita cost method described in STC 71. The budget neutrality expenditure limits are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. The data supplied by the state to CMS to set the annual caps is subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit. CMS' assessment of the state's compliance with these annual limits will be done using the Schedule C reports from the CMS-64.
- 71. Risk.** The state will be at risk for exceeding the limits on per capita cost (as determined by the method described below) for the demonstration expenditures, as described in STC 72 and STC 73, and shall not be at risk for costs pertaining to the number of enrollees in the demonstration population. By providing FFP without regard to enrollment in the demonstration populations, CMS will not place the state at risk for changing economic conditions that impact enrollment levels. However, by placing the state at risk for the per capita costs of current eligibles, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration.
- 72. Calculation of the Budget Neutrality Limit.** For the purpose of calculating the overall budget neutrality limit for the demonstration, separate annual budget limits will be calculated for each DY on a total computable basis, as described in this STC 72(b). The annual limits will then be added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of

demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality limit by the Composite Federal Share, which is defined in STC 75. The demonstration expenditures subject to the budget neutrality limit are those reported under the waiver names “My Rewards Expenditures” and “SUD Expenditures”.

- a. The Medicaid Eligibility Group (MEGs) listed in the table below are included in the calculation of the budget neutrality limit for the Kentucky HEALTH demonstration.
- b. The budget neutrality cap is calculated by taking the per member per month (PMPM) cost projection for the below groups in each DY, times the number of eligible member months for that group and DY, and adding the products together across DYs. The federal share of the budget neutrality cap is obtained by multiplying total computable budget neutrality cap by the federal share.
- c. The state will not be allowed to obtain budget neutrality “savings” from these populations.

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

- a. The SUD MEG listed in the table below is included in SUD budget neutrality test.
- b. SUD expenditures cap are calculated by multiplying the projected PMPM for each SUD MEG, each DY, by the number of actual eligible SUD member months for the same MEG/DY—and summing the products together across all DYs. The federal share of the SUD expenditure cap is obtained by multiplying those caps by the Composite Federal Share (see STC 75).
- c. SUD budget neutrality test is a comparison between the federal share of SUD expenditure cap and total FFP reported by the state for the SUD MEG.

Eligibility group	Trend Rate	DY 1	DY 2	DY 3	DY 4	DY 5	DY 6
SUD PMPM	5.0%	\$1,430.18	\$1,501.69	\$1,576.77	\$1,655.61	\$1,738.39	\$1,759.72
My Rewards PMPM	5.0%	\$10.26	\$10.77	\$11.31	\$11.88	\$12.47	\$12.62

74. Former Foster Care Youth. CMS has determined that the provision of benefits and services to this demonstration population is budget neutral based on CMS’ assessment that the waiver authorities granted for this demonstration population are unlikely to result in any increase in federal Medicaid expenditures, and that no expenditure authorities are

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

- 75. Composite Federal Share Ratio.** The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period, as reported through the MBES/CBES and summarized on Schedule C (with consideration of additional allowable demonstration offsets such as, but not limited to, premium collections) by total computable demonstration expenditures for the same period as reported on the same forms. Should the demonstration be terminated prior to the end of the extension approval period (see STC 9 and STC 11), the Composite Federal Share will be determined based on actual expenditures for the period in which the demonstration was active. For the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed upon method.
- 76. Enforcement of Budget Neutrality.** CMS must enforce budget neutrality over the life of the demonstration rather than on an annual basis. However, if the state’s expenditures exceed the calculated cumulative budget neutrality expenditure cap by the percentage identified below for any of the demonstration years, the state shall submit a corrective action plan to CMS for approval. The state will subsequently implement the approved corrective action plan.

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

DY6 July 1, 2022- September 30, 2023	Cumulative budget neutrality expenditure cap plus:	0%
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77. **Exceeding Budget Neutrality.** If at the end of the demonstration period the cumulative budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the budget neutrality agreement, an evaluation of this provision will be based on the time elapsed through the termination date.
78. **Impermissible DSH, Taxes or Donations.** The CMS reserves the right to adjust the budget neutrality expenditure limit in order to be consistent with enforcement of impermissible provider payments, health care related taxes, new federal statutes, or with policy interpretations implemented through letters, memoranda, or regulations. CMS reserves the right to make adjustments to the budget neutrality expenditure limit if CMS determines that any health care-related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is in violation of the provider donation and health care related tax provisions of Section 1903(w) of the Act. Adjustments to the budget neutrality agreement will reflect the phase-out of impermissible provider payments by law or regulation, where applicable.

XIII. EVALUATION

79. **Independent Evaluator.** Upon approval of the demonstration, the state must begin to arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The independent party must sign an agreement to conduct the demonstration evaluation in accord with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology in the evaluation design, but the state may request, and CMS may agree to, changes in the methodology in the appropriate circumstances.
80. **Draft Evaluation Design.** The draft evaluation design must be developed in accordance with Attachment A of these STCs. The state will submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after demonstration approval. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state may choose to use the expertise of the independent party in the development of the draft Evaluation Design.
81. **Evaluation Design Approval and Updates.** The state will submit a revised draft Evaluation Design within sixty (60) days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state will implement the evaluation

design and submit evaluation implementation progress in each of the Monitoring Reports, including any required Rapid Cycle Assessments. Rapid cycle assessments should include any early or interim findings the evaluators have prior to evaluation reports being due. 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.

- 82. Evaluation Questions and Hypotheses.** Consistent with Attachments A and B of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS’s Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
- 83. Evaluation Design Elements.** The following items must be specified for each hypothesis:
- a. Quantitative and qualitative research methodologies;
 - b. Proposed baseline and comparison groups;
 - c. Proposed process and outcome measures and specifications;
 - d. Data sources and collection frequency;
 - e. Cost estimates; and
 - f. Timelines for deliverables.
- 84. Evaluation Data Sources.** The Evaluation Design will incorporate multiple stakeholder perspectives, including (but not limited to), surveys of beneficiaries (both enrolled and those no longer enrolled), claims data, and national survey data (such as CAHPS).
- 85. Evaluation Budget.** A budget for the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluation such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the Evaluation Design, if CMS finds that the Evaluation Design is not sufficiently developed, or if the estimates appear to be excessive.
- 86. State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the final Evaluation Design, post approval, in conjunction with these STCs. The state will present on its interim evaluation in conjunction with these STCs. The state will present on its summative evaluation in conjunction with these STCs.
- 87. Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), should CMS undertake a federal evaluation of the demonstration or any component of the

demonstration, the state will cooperate fully and timely with CMS and its contractors' evaluation activities. 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 will include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required by the state under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 53.

- 88. Interim Evaluation Report.** The state will submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Interim Evaluation Report should be posted to the state's website with the application for public comment. Also refer to Attachment B for additional information on the Interim Evaluation Report.
- a. The Interim Evaluation Report will discuss evaluation progress and present findings to date as per the approved Evaluation Design.
 - b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
 - c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration, the research questions, hypotheses and how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
 - d. The state will submit the final Interim Evaluation Report sixty (60) days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.
 - e. The Interim Evaluation Report must comply with Attachment B of these STCs.
- 89. Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with Attachment B of these STCs. The state will submit 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 Summative Evaluation Report must include the information in the approved Evaluation Design. Refer to Attachment B for additional information on the Summative evaluation report.
- a. Unless otherwise agreed upon in writing by CMS, the state will submit the final Summative Evaluation Report within sixty (60) days of receiving comments from CMS.

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

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

91. Additional Publications and Presentations. For a period of twenty-four 24 months following CMS approval of the final reports, CMS will be notified prior to the public release or presentation of these reports and related publications (including, for example, journal articles), by the state, contractor, or any other third party (an entity which is not the state or contractor) over which the state Medicaid agency has control. Prior to release of these reports, articles and other publications, CMS will be provided a copy including any associated press materials. CMS will be given thirty (30) 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.

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

Effective upon CMS’ approval of the SUD Implementation Protocol, as described in STC 93, the demonstration benefit package for all Medicaid beneficiaries as authorized by this demonstration will include OUD/SUD residential treatment, crisis stabilization and withdrawal management services provided in IMDs, which are not otherwise matchable expenditures under section 1903 of the Act. Medicaid beneficiaries residing in IMDs under the terms of this demonstration will have coverage of all benefits that would otherwise be covered if the beneficiary were not residing in an IMD. Effective upon CMS’ approval of this demonstration, methadone treatment services will be a covered service under the state plan for Medicaid beneficiaries.

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

Table 2: Kentucky SUD Benefits Coverage with Expenditure Authority

SUD Benefit	Medicaid Authority	Costs Not Otherwise Matchable
Early Intervention (Screening, Brief Intervention and Referral to Treatment)	State plan (Individual services covered)	
Outpatient Therapy (Individual; Group; Family; Collateral)	State plan (Individual	

	services covered)	
Intensive Outpatient Program	State plan (Individual services covered)	
Partial Hospitalization Treatment (including Day Treatment for children/youth under the age of 21)	State plan (Individual services covered)	
Residential Treatment	State plan (Individual services covered)	Services provided to individuals in IMDs
Medically Supervised Withdrawal Management	State plan	Services provided to individuals in IMDs
Medication-Assisted Treatment (MAT)	State plan	Services provided to individuals in IMDs
Methadone treatment for opioid dependence	State Plan (contingent on this 1115 demonstration waiver of NEMT)	Services provided to individuals in IMDs
Peer Support (including Parent/Family Peer Support)	State plan	Services provided to individuals in IMDs
Crisis Intervention (including Mobile Crisis)	State plan (Individual services covered)	
Residential Crisis Stabilization	State plan (Individual services covered)	Services provided to individuals in IMDs

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

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

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

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

- a. **Access to Critical Levels of Care for OUD and other SUDs:** Service delivery for new benefits, including residential treatment, crisis stabilization and withdrawal management within 24 months of demonstration approval;
- b. **Use of Evidence-based SUD-specific Patient Placement Criteria:** Establishment of a requirement that MCOs and providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the ASAM Criteria or other comparable assessment and placement tools that reflect evidence-based clinical treatment guidelines within 24 months of demonstration approval;
- c. **Patient Placement:** Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 24 months of demonstration approval;
- d. **Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities:** Currently, residential treatment service providers must be accredited by the Commission on the Accreditation of Rehabilitation Facilities and must be a licensed organization, pursuant to the residential service provider qualifications described in the Kentucky Medicaid state plan. The state will establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other comparable, nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of

- clinical care, and credentials of staff for residential treatment settings within 24 months of SUD program demonstration approval;
- e. **Standards of Care:** Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of SUD program demonstration approval;
 - f. **Standards of Care:** Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of SUD program demonstration approval;
 - g. **Sufficient Provider Capacity at Critical Levels of Care including Medication Assisted Treatment for OUD:** An assessment of the availability of providers in the key levels of care throughout the state, or in the regions of the state participating under the demonstration including those that offer MAT, within 12 months of SUD program demonstration approval over the course of the demonstration;
 - h. **Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD:** Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand access to naloxone;
 - i. **SUD Health IT Plan:** Implementation of the milestones and metrics as described in Attachment E; and
 - j. **Improved Care Coordination and Transitions between levels of care:** Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of SUD program demonstration approval.

94. SUD Monitoring Protocol. The state must submit an SUD Monitoring Protocol within 150 calendar days after approval of the demonstration. The SUD Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. Upon approval, the SUD Monitoring Plan Protocol will be incorporated into these STCs, as Attachment D. At a minimum, the SUD Monitoring Protocol will include reporting relevant to each of the program implementation areas listed in STC 93. In addition, the SUD Monitoring Protocol will include regular reporting by the state on access to medication assisted therapy (MAT) in each county of the state, availability of MAT providers in each county, the number of individuals accessing MAT including methadone in each county, as well as the estimated cost of providing NEMT for accessing methadone in each county. The protocol will also describe the data collection, reporting and analytic methodologies for performance measures identified by the state and CMS for inclusion in the protocol. The SUD Monitoring Protocol will specify the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in these STCs. In addition, for each performance measure, the SUD Monitoring Protocol will identify a baseline, a target to be achieved by the end of the demonstration and an annual goal for closing the gap

between baseline and target expressed as percentage points. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings. CMS will closely monitor demonstration spending on services in IMDs to ensure adherence to budget neutrality requirements.

- 95. Mid-Point Assessment.** The state must conduct an independent mid-point assessment within ninety (90) days after the third year after approval of this demonstration. The assessor must collaborate with key stakeholders, including representatives of MCOs, SUD treatment providers, beneficiaries, and other key partners in the design, planning and conducting of the mid-point assessment. The assessment will include an examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Protocol, and toward closing the gap between baseline and target each year in performance measures as approved in the SUD Monitoring Protocol. The assessment will also include a determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date, and a determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and the risk of possibly missing those milestones and performance targets. For each milestone and measure target at medium to high risk of not being achieved, the assessor will provide for consideration by the state, recommendations for adjustments in the state’s implementation plan or to pertinent factors that the state can influence that will support improvement. The assessor will provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. A copy of the report will be provided to CMS. CMS will be briefed on the report.

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

- 96. Deferral of Federal Financial Participation (FFP) from IMD Claiming for Insufficient Progress Towards Milestones.** Up to \$5M in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones and goals as evidenced by reporting on the milestones in Table 2 and the required performance measures in the Monitoring Protocol agreed upon by the state and CMS. Once CMS determines the state has not made adequate progress, up to \$5M will be deferred in the next calendar quarter and each calendar quarter thereafter until the CMS has determined sufficient progress has been made.
- 97. SUD Evaluation.** The SUD Evaluation will be subject to the same terms as the overall demonstration evaluation, as listed in Section XIII of these STCs.
- 98. SUD Evaluation Design.** The state must submit, for CMS comment and approval, a draft SUD Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after approval of the demonstration. Failure to submit an acceptable and timely evaluation design along with any required monitoring, expenditure, or other

evaluation reporting will subject the state to a \$5 million deferral. The state must use an independent evaluator to design the evaluation.

- a. **Evaluation Design Approval and Updates.** The state must submit a revised draft SUD Evaluation Design within sixty (60) days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved SUD Evaluation Design within thirty (30) days of CMS approval. The state must implement the SUD Evaluation Design and submit a description of its evaluation implementation progress in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in these STCs.
- b. **Evaluation Questions and Hypotheses Specific to the SUD Program.** The state must follow the general evaluation questions and hypotheses requirements as specified in STC 82. In addition, hypotheses for the SUD program should include an assessment of the objectives of the SUD component of this demonstration, to include (but is not limited to) initiative and compliance with treatment, utilization of health services (emergency department and inpatient hospital settings), and a reduction in key outcomes such as deaths due to overdose. The SUD Evaluation Design must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. The hypotheses should include an assessment of the objectives of SUD section 1115 demonstrations, to include (but is not limited to): initiation and compliance with treatment; utilization of health services including emergency department and inpatient hospital settings; effectiveness of MAT; interaction of MAT impact and access to NEMT; impact of the demonstration on key outcomes including deaths due to overdose; and cost effectiveness of the demonstration, particularly services provided in IMDs and the waiver of NEMT.

Proposed measures should be selected from nationally-recognized sources and national measure sets, where possible. Measures set could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF). Data to evaluate the NEMT waiver impact on MAT shall include a beneficiary survey to be approved by CMS.

99. **SUD Interim Evaluation Report.** The state must submit a SUD Interim Evaluation Report for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the SUD Interim Evaluation Report should be posted to the state's website with the application for public comment.
 - a. The SUD Interim Evaluation Report will discuss evaluation progress and present findings to date as per the approved evaluation design.

- b. For demonstration authority that expires prior to the overall demonstration's expiration date, the SUD Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
- c. If the state is seeking to renew or extend the demonstration, the draft SUD Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses, and how the design will be adapted, should be included. If the state is not requesting a renewal for a demonstration, a SUD Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft SUD Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
- d. The state must submit the final Interim Evaluation Report 60 days after receiving CMS comments on the draft SUD Interim Evaluation Report and post the document to the state's website.
- e. The SUD Interim Evaluation Report must comply with Attachment B of these STCs.

- 100. SUD Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with Attachment B of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.
- a. Unless otherwise agreed upon in writing by CMS, the state shall submit the final Summative Evaluation Report within 60 days of receiving comments from CMS on the draft.
 - b. The final Summative Evaluation Report must be posted to the state's Medicaid website within 30 days of approval by CMS.

Attachment A: Developing the Evaluation Design

Introduction

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

Expectations for Evaluation Designs

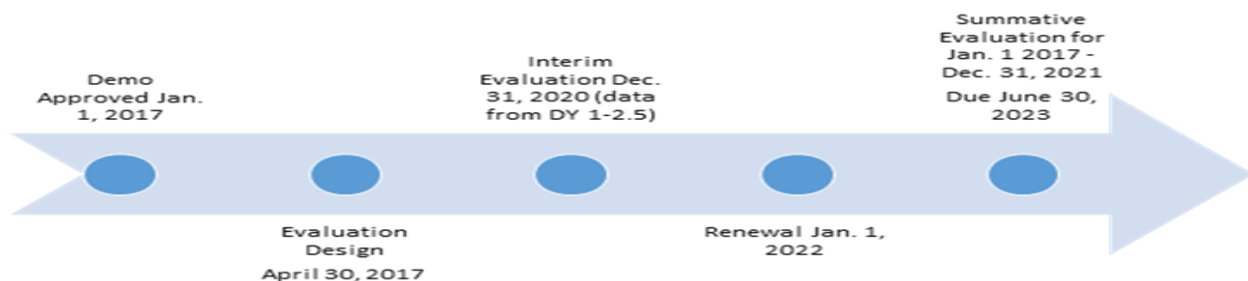
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, the state must 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 thirty (30) days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of All Evaluation Designs

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

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

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

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

- 1) Describe how the state’s demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.

- 2) Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: <https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf>
- 3) Identify the state’s hypotheses about the outcomes of the demonstration:
 - a. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
 - b. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

C. Methodology – In this section, the state is to describe in detail the proposed research methodology. The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

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

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

- a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
 - b. Qualitative analysis methods may be used, and must be described in detail.
 - c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
 - d. Proposed health measures could include CMS’s Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
 - e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
 - f. Among considerations in selecting the metrics must 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. For example:

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

- 2) When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
 - a. Operating smoothly without administrative changes; and
 - b. No or minimal appeals and grievances; and
 - c. No state issues with CMS 64 reporting or budget neutrality; and
 - d. No Corrective Action Plans (CAP) for the demonstration.

E. Attachments

A. 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. This includes “No Conflict of Interest” signed conformation statements.

B. Evaluation Budget. A budget for implementing 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. 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.

D. 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 must incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

Attachment B: Preparing the Interim and Summative Evaluation Reports

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration 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. As these valid analyses multiply (by a single state or by multiple states with similar demonstrations) and the data sources improve, the reliability of evaluation findings will be able to shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

Intent of this Guidance

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 Guidance is intended to assist states with organizing the required information in a standardized format and understanding the criteria that CMS will use in reviewing the submitted Interim and Summative Evaluation Reports.

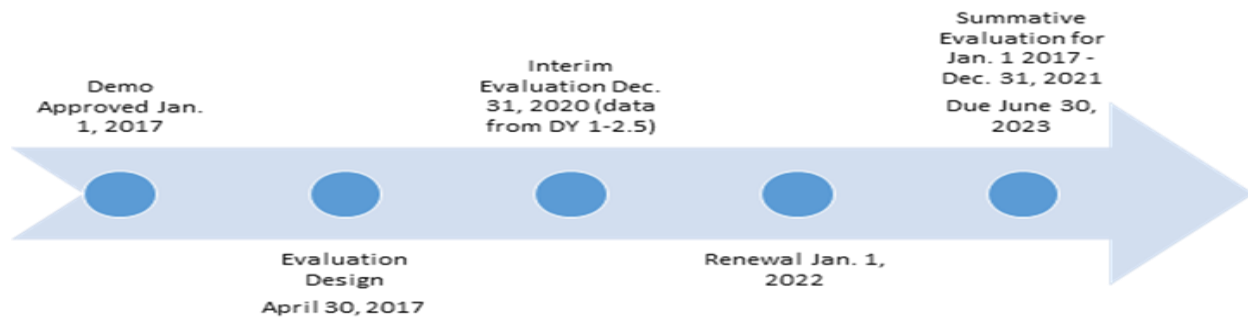
The format for the Interim and Summative Evaluation reports is as follows:

- A. Executive Summary;
- B. General Background Information;
- C. Evaluation Questions and Hypotheses;
- D. Methodology;
- E. Methodological Limitations;
- F. Results;

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

Submission Timelines

There is a specified timeline for the state’s submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish the evaluation design and reports to the state’s website within thirty (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 guidance) must be included with an explanation of the depicted information. The Evaluation Report should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. Therefore, the state’s submission must include:

- A. Executive Summary** – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.
- B. General Background Information about the Demonstration** – In this section, the state should include basic information about the demonstration, such as:
 - 1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential

- magnitude of the issue, and why the state selected this course of action to address the issues.
- 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
 - 3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
 - 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
 - 5) Describe the population groups impacted by the demonstration.

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

- 1) Describe how the state’s demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
- 2) Identify the state’s hypotheses about the outcomes of the demonstration;
 - a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
 - b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
 - c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

D. Methodology – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design. The evaluation Design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An interim report should provide any available data to date, including both quantitative and qualitative assessments. The Evaluation Design should assure there is appropriate data development and collection in a timely manner to support developing an interim evaluation.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how.

Specifically, this section establishes that the approved Evaluation Design was followed by describing:

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

E. Methodological Limitations

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

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

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

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

H. Interpretations, Policy Implications and Interactions with Other State Initiatives –

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

- I. Lessons Learned and Recommendations** – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the “opportunities” for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:
1. What lessons were learned as a result of the demonstration?
 2. What would you recommend to other states which may be interested in implementing a similar approach?

J. Attachment

Evaluation Design: Provide the CMS-approved Evaluation Design

Attachment C: SUD Implementation Protocol
[To be incorporated after CMS approval.]

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

ATTACHMENT E: SUD Health Information Technology (Health IT)

Health Information Technology (“Health IT”). The state will provide CMS with an assurance that it has a sufficient health IT infrastructure/“ecosystem” at every appropriate level (i.e. state, delivery system, health plan/MCO and individual provider) to achieve the goals of the demonstration—or it will submit to CMS a plan to develop the infrastructure/capabilities. This “SUD Health IT Plan,” or assurance, will be included as a section of the state’s “Implementation Plan” (see STC 93) to be approved by CMS. The SUD Health IT Plan will detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The plan will also be used to identify areas of SUD health IT ecosystem improvement.

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

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

³ *Ibid.*

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

- g. In developing the Health IT Plan, states shall use the following resources.
 - 1. States may use resources at Health IT.Gov (<https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/>) in “Section 4: Opioid Epidemic and Health IT.”
 - 2. States may also use the CMS 1115 Health IT resources available on “Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability” at <https://www.medicare.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 94) 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 an addendum to its Annual Reports (see STC 58).
- j. As applicable, the state should advance the standards identified in the ‘Interoperability Standards Advisory—Best Available Standards and Implementation Specifications’ (ISA) in developing and implementing the state’s SUD Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.
 - 1. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state should use the federally-recognized standards, barring no other compelling state interest.
 - 2. Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally-recognized ISA standards, barring no other compelling State interest.

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