DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Administrator
Washington, DC 20201

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Carol H. Steckel
Commissioner, Department for Medicaid Services
Commonwealth of Kentucky
Cabinet for Health and Family Services
275 East Main Street, 6 West A
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Dear Ms. Steckel:

Under Section 1115 of the Social Security Act (the Act), the Secretary of Health and Human Services may approve any experimental, pilot, or demonstration project that, in the judgment of the Secretary, is likely to assist in promoting the objectives of certain Act programs including Medicaid. Congress enacted section 1115 of the Act to ensure that federal requirements did not "stand in the way of experimental projects designed to test out new ideas and ways of dealing with the problems of public welfare recipients." S. Rep. No. 87-1589, at 19 (1962), *as reprinted in* 1962 U.S.C.C.A.N. 1943, 1961. As relevant here, section 1115(a)(1) of the Act allows the Secretary to waive compliance with the Medicaid program requirements of section 1902 of the Act, to the extent and for the period he finds necessary to carry out the demonstration project. In addition, section 1115(a)(2) of the Act allows the Secretary to provide federal financial participation for demonstration costs that would not otherwise be considered as federally matchable expenditures under section 1903 of the Act, to the extent and for the period prescribed by the Secretary.

On January 12, 2018, the Centers for Medicare & Medicaid Services (CMS) approved 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). A district court subsequently vacated the approval of the demonstration project component known as Kentucky HEALTH, on the ground that CMS "never adequately considered whether Kentucky HEALTH would in fact help the state furnish medical assistance to its citizens, a central objective of Medicaid." *Stewart v. Azar*, 313 F. Supp. 3d 237, 243 (D.D.C. 2018). The district court remanded the matter to CMS for further review. On July 19, 2018, CMS opened a new 30-day comment period to give interested stakeholders an opportunity to comment on the issues raised in the litigation and in the court's decision.

For the reasons discussed below, CMS is approving Kentucky HEALTH as a component of the KY HEALTH demonstration, in accordance with section 1115(a) of the Act. Consistent with the Secretary's authority, the demonstration is being approved for a 5-year period, subject to the limitations specified in the attached expenditure authorities, waivers, and special terms and conditions (STCs). The state may deviate from Medicaid state plan requirements only to the

extent those requirements have been listed as waived, to the extent the state has been granted expenditure authority, or to the extent requirements are identified as not applicable to the expenditure authorities. This statewide demonstration component, Kentucky HEALTH, is approved effective April 1, 2019, through September 30, 2023.

Objectives of the Medicaid Program

As noted above, the Secretary may approve a demonstration project under section 1115 of the Act if, in his judgment, the project is likely to assist in promoting the objectives of title XIX. The purposes of Medicaid include an authorization of appropriation of funds to "enabl[e] each State, as far as practicable under the conditions in such State, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care." Act § 1901. This provision makes clear that an important objective of the Medicaid program is to furnish medical assistance and other services to vulnerable populations. But there is little intrinsic value in paying for services if those services are not advancing the health and wellness of the individual receiving them, or otherwise helping the individual attain independence. Therefore, we believe an objective of the Medicaid program, in addition to furnishing services, is to advance the health and wellness needs of its beneficiaries, and that it is appropriate for the state to structure its demonstration project in a manner that prioritizes meeting those needs.

Section 1115 demonstration projects present an opportunity for states to experiment with reforms that go beyond just routine medical care and focus on evidence-based interventions that drive better health outcomes and quality of life improvements, and that may increase beneficiaries' financial independence. Such policies may include those designed to address certain health determinants and those that encourage beneficiaries to engage in health-promoting behaviors and to strengthen engagement by beneficiaries in their personal health care plans. These tests will necessarily mean a change to the status quo. They may have associated administrative costs, particularly at the initial stage, and section 1115 acknowledges that demonstrations may "result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing." Act § 1115(d)(1). But in the long term they may create incentives and opportunities that help enable many beneficiaries to enjoy the numerous personal benefits that come with improved health and financial independence.

Section 1115 demonstration projects also provide an opportunity for states to test policies that ensure the fiscal sustainability of the Medicaid program, better "enabling each [s]tate, as far as practicable under the conditions in such [s]tate" to furnish medical assistance, Act § 1901, while making it more practicable for states to furnish medical assistance to a broader range of persons in need. For instance, measures designed to improve health and wellness may reduce the volume of services consumed, as healthier, more engaged beneficiaries tend to consume fewer medical services and are generally less costly to cover. Further, measures that have the effect of helping individuals secure employer-sponsored or other commercial coverage or otherwise transition from Medicaid eligibility may decrease the number of individuals who need financial assistance from the state. Such measures may enable states to stretch their resources further and enhance

their ability to provide medical assistance to a broader range of persons in need, including by expanding the services and populations they cover.[1] By the same token, such measures may also preserve states' ability to continue to provide the optional services and coverage they already have in place.

Our demonstration authority under section 1115 of the Act allows us to offer states more flexibility to experiment with different ways of improving health outcomes and strengthening the financial independence of beneficiaries. Demonstration projects that seek to improve beneficiary health and financial independence improve the well-being of Medicaid beneficiaries and, at the same time, allow states to maintain the long-term fiscal sustainability of their Medicaid programs and to provide more medical services to more Medicaid beneficiaries. Accordingly, such demonstration projects advance the objectives of the Medicaid program.

Background on Medicaid Coverage in Kentucky

Effective January 1, 2014, Kentucky amended its state plan to include coverage of the ACA expansion population. As of September 2018, more than 454,000 individuals received medical assistance under the Kentucky state plan as a result of Kentucky's decision to participate in that expansion. Kentucky's ACA expansion population includes not only childless adults but also many parents of dependent children, who otherwise were not eligible for coverage under the Kentucky state plan unless their household income was equal to or less than 24 percent of the federal poverty level.

In addition to providing non-mandatory coverage for the adult expansion population, Kentucky's state plan provides coverage for other non-mandatory populations, such as the medically needy and lawfully residing immigrant children under age 19. In addition, the Kentucky plan currently covers an array of non-mandatory benefits, including over-the-counter drugs, vision benefits, and dental benefits.

Extent and Scope of Demonstration

The KY HEALTH demonstration encompasses several initiatives, including the program called Kentucky HEALTH, into which Kentucky will enroll certain non-elderly adult beneficiaries who

[1] States have considerable flexibility in the design of their Medicaid programs, within federal guidelines. Certain benefits are mandatory under federal law, but many benefits may be provided at state option, such as prescription drug benefits, vision benefits, and dental benefits. Similarly, states have considerable latitude to determine whom their Medicaid programs will cover. Certain eligibility groups must be covered under a state's program, but many states opt to cover additional eligibility groups that are optional under the Medicaid statute. The optional groups include a new, non-elderly adult population (ACA expansion population) that was added to the Act at section 1902(a)(10)(A)(i)(VIII) by the Patient Protection and Affordable Care Act (ACA). Coverage of the ACA expansion population became optional as a result of the Supreme Court's decision in *NFIB v. Sebelius*, 567 U.S. 519 (2012). Accordingly, several months after the *NFIB* decision was issued, CMS informed the states that they "have flexibility to start or stop the expansion." CMS, *Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid* at 11 (Dec. 10, 2012). In addition to expanding Medicaid coverage by covering optional eligibility groups and benefits beyond what the Medicaid statute requires, many states also choose to cover benefits beyond what is authorized by statute by using expenditure authority under section 1115(a)(2) of the Act. For example, recently, many states have been relying on this authority to expand the scope of services they offer to address substance use disorders beyond what the statute explicitly authorizes.

do not qualify for Medicaid on the basis of a disability. Groups in the Kentucky HEALTH program primarily include the ACA expansion population and two groups of low-income parents and caretaker relatives: those described in section 1931(b) and (d) of the Act, and those described in sections 1925 and 1931(c)(2) of the Act who are transitioning off of Medicaid due to increases in their income.[2] Central elements of the demonstration are described below.

Kentucky will implement a community engagement requirement (described in STCs 42-47) 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, survivors of domestic violence, 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 and report 80 hours per month of community engagement activities, such as employment, education, job skills training, job search activities, and community service. Beneficiaries will have their eligibility suspended for failure to report 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. The option to take a course to re-enter from suspension is available one time per 12-month benefit period. 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 procedural protections for affected beneficiaries, and will also provide opportunities for beneficiaries to demonstrate good cause in certain circumstances for failing to meet the requirement. Additionally, beneficiaries can re-activate Medicaid coverage if, during a suspension, they become eligible for an exemption from the community engagement requirement, or become eligible under a Medicaid eligibility category not subject to the requirement.

Kentucky HEALTH also includes two consumer-driven tools, the *My Rewards Account* (described in STC 29) and the *Deductible Account* (described in STC 28). Beneficiaries will receive incentives that have a dollar value equivalent (but have no actual monetary value) for healthy behavior and community engagement in their *My Rewards Account* that can be used to obtain additional benefits: vision benefits, dental benefits, over-the-counter medications, and limited fitness-related services such as a gym membership. Pregnant women, former foster care youth, beneficiaries who are medically frail, survivors of domestic violence, and adults in Kentucky HEALTH who are not in the ACA expansion population (i.e., the groups described in sections 1925 and 1931(b), (c)(2), and (d)) will continue to receive vision, dental, and over-the-counter medications pursuant to the state plan, but will have the choice to opt-in to the *My Rewards Account* to access the limited fitness-related services.

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[2] In addition to these groups, pregnant women and former foster care youth are included in Kentucky HEALTH, but they are generally exempt from many of the Kentucky HEALTH program's requirements, as described below and in the STCs. They are included in the demonstration in part because Kentucky needs section 1115(a)(1) waiver authority to limit coverage of former foster care youth to persons who were the responsibility of another state or a tribe on the date they turned 18. Their inclusion also, in part, is anticipated to smooth transition into all features of the Kentucky HEALTH program for a pregnant woman after the 60-day postpartum period, or when a former foster care youth reaches age 26. Additionally, including pregnant women and former foster care youth in the Kentucky HEALTH program gives them the option of accessing limited fitness services through the *My Rewards Account*.

The *Deductible Account* is an educational tool to inform beneficiaries about the cost of healthcare and encourage appropriate healthcare utilization. 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. If funds in the deductible account are exhausted before the end of a beneficiary's 12-month benefit period, the beneficiary still will be able to receive covered services just as services would be covered after satisfaction of a deductible under commercial coverage. Beneficiaries with funds remaining in their deductible account after the end of the 12-month benefit period may transfer up to 50 percent of the prorated balance to their *My Rewards Account*.

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

- Premiums (described in STCs 30-41), in lieu of the copayments required under the state plan, of not less than one dollar per month and not to exceed 4 percent of household income, for Kentucky HEALTH beneficiaries in the ACA expansion and low-income parent and caretaker groups (with exceptions for pregnant women, survivors of domestic violence, former foster care youth, beneficiaries who are eligible for transitional medical assistance as described in sections 1925 and 1931(c)(2) of the Act, and those determined medically frail), with specified consequences for beneficiaries who do not pay premiums after a 60-day payment period (including a six-month non-eligibility period for beneficiaries with household income over 100 percent of the federal poverty level) and procedural protections for affected beneficiaries, as well as opportunities to demonstrate good cause for failure to meet the requirements;

- A six month non-eligibility period (described in STCs 21-22) for beneficiaries who fail to provide the necessary information or documentation to complete the annual redetermination process, with exceptions for pregnant women, survivors of domestic violence, former foster care youth, and individuals determined to be medically frail, and procedural protections for affected beneficiaries, as well as opportunities to demonstrate good cause for failure to meet the requirements;

- Disenrollment and a six-month non-eligibility period (described in STCs 23-24) for beneficiaries who fail to report a change in circumstance that resulted in Medicaid ineligibility, with exceptions from the six-month non-eligibility period for pregnant women, survivors of domestic violence, former foster care youth, and beneficiaries who are medically frail, and with procedural protections for affected beneficiaries, as well as opportunities to demonstrate good cause for failure to meet the requirements;

- A waiver of retroactive eligibility (described in STC 19) for beneficiaries enrolled in Kentucky HEALTH, with exceptions for pregnant women and former foster care youth (the eligibility effective date for beneficiaries who become eligible for transitional

medical assistance as described in sections 1925 and 1931(c)(2) of the Act will be governed through the state plan); and

- A waiver of the requirement to provide non-emergency medical transportation (NEMT) (described in STC 26) for beneficiaries enrolled in the new adult group, with exceptions for beneficiaries who are medically frail, 19- or 20-year-old beneficiaries entitled to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services, former foster care youth, survivors of domestic violence, and pregnant women.

The broader KY HEALTH demonstration also includes other provisions, including a substance use disorder (SUD) program (described in STCs 92-100) available to all Kentucky Medicaid beneficiaries to ensure that a broad continuum of care is available to Kentuckians with a substance use disorder, including an opioid use disorder. CMS approved this program on January 12, 2018, and that approval remains in effect.

As noted above, the STCs for this approval are similar to those approved on January 12, 2018. However, CMS and Kentucky have made some changes, which include:

- The January 12, 2018, approval authorized a waiver of retroactive eligibility that would otherwise be required under section 1902(a)(34) of the Act, and CMS and the Commonwealth are now, in an abundance of caution, also adding a waiver of section 1902(a)(10) of the Act to the extent that it imposes an analogous requirement of retroactive eligibility;

- Revision of the premium requirement for beneficiaries who are eligible for transitional medical assistance;

- Updated monitoring and evaluation STCs; and

- A requirement for Kentucky to submit a demonstration implementation plan and a demonstration monitoring protocol, both of which must address community engagement and other key demonstration policies, consistent with CMS requirements in other community engagement demonstrations.

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

For reasons discussed below, the Secretary has determined that Kentucky HEALTH, working within the larger KY HEALTH demonstration program, is likely to assist in promoting the objectives of the Medicaid program.

The demonstration promotes beneficiary health and financial independence.

With approval of the demonstration, Kentucky and CMS will be able to evaluate the effectiveness of various policies that are designed to improve the health of Medicaid beneficiaries, encourage them to make responsible decisions about their health and accessing

health care, and promote beneficiary financial independence. Promoting beneficiary health and independence advances the objectives of the Medicaid program. Indeed, in 2012, HHS specifically encouraged states to develop demonstration projects "aimed at promoting healthy behaviors" and "individual ownership in health care decisions" as well as "accountability tied to improvement in health outcomes."[3]

Kentucky HEALTH's community engagement requirement is designed to encourage beneficiaries to obtain employment and/or undertake other community engagement activities that may lead to improved health and wellness.

Kentucky HEALTH is also designed to encourage more individuals to seek preventive care, which can help improve beneficiary health. During the first year of Kentucky's Medicaid expansion, fewer than 10 percent of beneficiaries in the ACA expansion population received an annual wellness or physical exam. The *My Rewards Account* incentives for healthy behaviors are intended to increase uptake of preventive services. The waiver of retroactive eligibility for the populations included in Kentucky HEALTH (with exceptions for pregnant women and former foster care youth) is also designed to encourage preventive care. It is designed to test whether these beneficiaries will be encouraged to obtain and maintain health coverage, even when healthy, and whether there will be a reduction in gaps in coverage when beneficiaries churn on and off Medicaid or sign up for Medicaid only when sick. Eligible individuals in these populations who wait until they are sick to enroll in Medicaid may be less likely to obtain preventive health services during periods when they are not enrolled due to out-of-pocket costs.

Kentucky will also evaluate whether the *My Rewards* and *Deductible* accounts, as well as redetermination and reporting requirements, will strengthen beneficiary engagement in their personal health and provide an incentive structure to support responsible consumer decision-making about maintaining health and accessing care and services. A prior evaluation of one demonstration project with beneficiary engagement components has shown some promise that these strategies can have a positive impact on beneficiary behavior.[4] Overall, the research findings on the effects of healthy behavior incentives in Medicaid have shown some promising results but require further study. 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 HEALTH, working in coordination with KY HEALTH, is also likely to promote the objective of helping beneficiaries attain or retain financial independence. The community engagement provisions generally require Kentucky HEALTH beneficiaries to work, look for work, or engage in activities that enhance their employability, such as job-skills training, education, and community service. Substance-use disorder treatment also qualifies as a community engagement activity, which not only supports beneficiaries' health needs, but may also lead to healthier beneficiaries who therefore may better be able to attain and sustain employment, which is incentivized through this demonstration. The demonstration will help the

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[3] CMS, *Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid* at 15 (Dec. 10, 2012) (noting also that "states have considerable flexibility under … [existing] law to design benefits for the new adult group and to impose cost-sharing, particularly for those individuals above 100 percent of the federal poverty level").

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

Commonwealth and CMS evaluate whether the community engagement requirement helps adults in Kentucky HEALTH transition from Medicaid to financial independence, thus reducing dependency on public assistance.

Because the demonstration is intended to encourage beneficiaries to attain greater levels of financial independence, it contains policies designed to prepare people for the commercial health insurance market, including to prepare them for the federally subsidized insurance that is available through the Exchanges. Kentucky's application noted the significant number of individuals in the Kentucky HEALTH program who are estimated to move between Medicaid eligibility and Exchange coverage. Kentucky HEALTH seeks to provide beneficiaries the tools to utilize commercial market health insurance successfully, thereby removing potential obstacles to a successful transition from Medicaid to commercial coverage.

Coverage for most individuals enrolled in Kentucky HEALTH is designed to work more like insurance products sold on the commercial market. Kentucky HEALTH includes premium payment requirements (with a non-eligibility period for certain beneficiaries for non-payment), deductibles, and limited enrollment windows, all of which beneficiaries are likely to encounter should they transition from Medicaid to 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. And, the waiver of NEMT is also aligned with the commercial insurance market, where this benefit is not typically available.

Kentucky HEALTH will also 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 has, in the past, rejected another state's request for a similar non-eligibility period for failure to complete redetermination, CMS now believes that this policy should be evaluated, because it is likely to support the objectives of Medicaid to the extent that it prepares individuals for a smooth transition to commercial health insurance coverage.

Similar to how commercial coverage operates, coverage eligibility under Kentucky HEALTH will be affected for certain individuals by nonpayment of premiums, failure to report changes in circumstances that affect eligibility, or failure to complete redetermination. However, Kentucky has provided for "on-ramps" that enable 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. One opportunity for early reactivation of coverage will be available per each 12-month benefit period, under each of these policies. That is, someone who loses coverage due to nonpayment of premiums can regain coverage early only once per 12-month benefit period, and if that person fails to pay premiums and loses coverage again during the 12-month benefit period, he or she will not be able to use the on-ramp again to regain coverage early. However, if that person uses an on-ramp to regain coverage early after nonpayment of premiums, and then loses coverage due to failure to report changes in

circumstances or failure to complete redetermination, he or she will have another opportunity within the same 12-month benefit period to use an on-ramp to regain coverage early. Kentucky has also taken steps to protect beneficiaries by exempting certain vulnerable populations, such as pregnant women, former foster care youth, survivors of domestic violence, and individuals who are medically frail, from these policies, as well as by allowing beneficiaries who cannot meet the applicable requirement to demonstrate good cause for failure to meet it.

The demonstration will furnish medical assistance in a manner that improves the sustainability of the safety net.

CMS has determined that KY HEALTH, including its component program, Kentucky HEALTH, is likely to promote the objective of furnishing medical assistance because it provides coverage beyond what Kentucky is required to provide. Kentucky expects that the reforms included in the demonstration will enable the Commonwealth to continue to offer Medicaid to the ACA expansion population. Kentucky has repeatedly stated that if it is unable to move forward with its Kentucky HEALTH demonstration project, it will discontinue coverage for the ACA expansion population, a choice it is entitled to make. Additionally, the over-the-counter medications, vision services, and dental services that can be accessed through the *My Rewards Account* are benefits that the Medicaid statute does not require states to cover. The limited fitness-related services accessible through the *My Rewards Account* would not ordinarily be covered under Medicaid at all, and are being covered by Kentucky only under section 1115(a)(2) of the Act expenditure authority, through the demonstration. The demonstration's SUD program also covers high-quality addiction services through expenditure authority under section 1115(a)(2) of the Act. This new, non-mandatory coverage for treatment of substance-use disorders is a matter of particular importance to Kentucky in light of the opioid crisis.

The demonstration includes policies, like the community engagement requirement and non-eligibility periods for certain beneficiaries for failure to comply with the requirements dealing with premiums, redetermination, or reporting a change in circumstances, that may impact overall coverage levels if the individuals subject to these demonstration provisions choose not to comply with them. However, the demonstration as a whole is expected to provide greater access to coverage for low-income individuals than would be available absent the demonstration. It furthers the Medicaid program's objectives to allow states to experiment with innovative means of deploying their limited state resources in ways that may allow them to provide services beyond the statutory minimum. Enhancing fiscal sustainability allows the state to provide services to Medicaid beneficiaries that it could not otherwise provide.

By incentivizing healthy behaviors and preventive care, as described above, KY HEALTH, including the Kentucky HEALTH program, is also designed to lead to higher quality care at a sustainable cost. Promoting improved health and wellness ultimately helps to keep health care costs at sustainable levels. To the extent that the policies discussed above, including the community engagement requirement, help individuals achieve improved health and financial independence, the demonstration may make these individuals less costly for Kentucky to care for, thus further advancing the objectives of the Medicaid program by helping Kentucky stretch its limited Medicaid resources, ensure the long-term fiscal sustainability of the program, and ensure that the health care safety net is available to those Kentucky residents who need it most.

And, to the extent the community engagement requirement helps individuals achieve financial independence and transition to commercial coverage, the demonstration may reduce dependency on public assistance, while still promoting Medicaid's purpose of helping states to furnish medical assistance.

The waivers of retroactive eligibility and NEMT for certain populations in Kentucky HEALTH are also expected to enable the Commonwealth to better contain Medicaid costs and more efficiently focus resources on providing accessible and high-quality health care, thereby promoting the sustainability of its Medicaid program.

Finally, the policies included in the demonstration are likely to improve the fiscal sustainability of Kentucky's Medicaid program because they are designed to improve program integrity while reasonably minimizing the impact of its negative effects on Kentucky's most vulnerable populations. For example, it is a longstanding requirement of the Medicaid program that a beneficiary report a change in circumstance that could affect eligibility. 42 CFR § 435.916. Under the demonstration, beneficiaries who fail to report a change that resulted in their ineligibility for Medicaid might, as a consequence, be subject to a six-month non-eligibility period. The ineligibility period creates an incentive for compliance. To mitigate the potential adverse impact of this incentive, the ineligibility period applies only when the change that the beneficiary failed to report was one that would affect his or her Medicaid eligibility under any group covered by Kentucky. Additionally, the ineligibility period does not apply to pregnant women, former foster care youth, survivors of domestic violence, and beneficiaries who are medically frail. The demonstration also includes procedural protections for beneficiaries who are not exempt, as well as opportunities to demonstrate good cause for failure to report as required.

Similarly, it is a longstanding requirement of the Medicaid program that beneficiaries undergo an annual process to redetermine their Medicaid eligibility. 42 CFR § 435.916. Beneficiaries who fail to submit required information during the redetermination process lose coverage. Kentucky has determined that the existing incentives do not go far enough to ensure compliance with the program's requirements. State data from 2017 indicated that, of those Medicaid beneficiaries from whom additional information was needed in order for the state to redetermine eligibility, only 37 percent submitted the necessary information. CMS is giving states flexibility to experiment with additional incentives to ensure compliance with the redetermination process. In this demonstration, Kentucky is testing a six month non-eligibility period for beneficiaries who fail to provide the necessary information or documentation to complete the annual redetermination process. However, there are exceptions for pregnant women, former foster care youth, survivors of domestic violence, and individuals determined to be medically frail, and procedural protections for affected beneficiaries, as well as opportunities to demonstrate good cause for failure to provide the required information or documentation.

While CMS and the Commonwealth are testing the effectiveness of incentive structures that attach penalties to failure to take certain measures, the program is designed to make compliance with its requirements achievable. Kentucky has taken steps to include adequate beneficiary protections to ensure that the demonstration's requirements apply only to those beneficiaries who can reasonably be expected to meet them, to notify beneficiaries of their responsibilities under

the demonstration, and to provide an opportunity to regain Medicaid coverage by coming back into compliance with the program. Any individual whose coverage is terminated for failure to meet the requirements, or who experiences any other adverse action, will have the right to appeal the state's decision as with other types of coverage terminations, consistent with all existing appeal and fair hearing protections. Furthermore, the incentives to meet the requirements, if effective, may result in individuals becoming ineligible because they have attained financial independence – a positive result for the individual.

As described in the STCs, if monitoring or evaluation data indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. Further, CMS reserves the right to withdraw waivers or expenditure authorities at any time it determines that continuing the waivers or expenditure authorities would no longer be in the beneficiaries' interest or promote the objectives of Medicaid.

Consideration of public comments

To increase the transparency of demonstration projects, section 1115(d)(1) and (2) of the Act direct the Secretary to issue regulations providing for two periods of public comment on a state's application for a section 1115 project that would result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing. The first comment period occurs at the state level before submission of the section 1115 application and the second occurs at the federal level after the application is received by the Secretary.

Section 1115(d)(2)(A) and (C) of the Act further specify that comment periods should be "sufficient to ensure a meaningful level of public input," but the statute imposes no additional requirement on the states or the Secretary to address those comments, as might otherwise be required under a general rulemaking. Accordingly, the implementing regulations issued in 2012 provide that CMS will review and consider all comments received by the deadline, but will not provide written responses to public comments.[5]

CMS received approximately 3,149 comments during the two initial federal comment periods[6] on KY HEALTH, and approximately 8,583 unique, substantive comments during the comment period that CMS provided after the district court's decision in *Stewart*.[7] Although CMS is not legally required to provide written responses to comments, CMS is addressing some of the central issues raised by the comments and summarizing CMS's analysis of those issues for the benefit of stakeholders. After carefully reviewing the public comments submitted during the

[5] 42 CFR § 431.416(d)(2); see also Medicaid Program; Review and Approval Process for Section 1115 Demonstrations; Application, Review, and Reporting Process for Waivers for State Innovation; Final Rules, 77 Fed. Reg. 11678, 11685 (Feb. 27, 2012) (final rule).

[6] CMS conducted a federal public-comment period on Kentucky's original application on September 8, 2016, and a combined state-federal public-comment period when Kentucky submitted its modified application on July 3, 2017. *See* https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/?entry=39258.

[7] There were 11,750 comments submitted during this public-comment period. Of those, 3167 comments were either duplicates, blank, non-responsive or unclear, or general testimonials about Medicaid that did not state a position on the demonstration.

most recent public comment period, CMS has concluded that KY HEALTH, including Kentucky HEALTH, advances the objectives of Medicaid.

General comments

The vast majority of the comments CMS received were from self-identified Kentucky citizens who opposed either the demonstration as a whole or certain features of it. Many of those comments expressed general concerns that the demonstration will result in many poor citizens losing Medicaid. CMS shares the commenters' concern that everyone who needs Medicaid and is eligible for it should have access to it. As previously stated, however, CMS believes the features of this demonstration are worth testing to determine whether there is a more effective way to furnish medical assistance to the extent practicable under the conditions in Kentucky. That is why CMS has carefully reviewed the demonstration as a whole to ensure it is likely to promote sometimes competing Medicaid objectives.

Specifically, this demonstration is designed to extend coverage. Kentucky has repeatedly made clear that its continued expansion of coverage to the ACA expansion population is conditioned on implementation of this demonstration. The demonstration is also designed to improve health outcomes and reduce dependency on public assistance by incentivizing healthy behaviors and giving beneficiaries the choice either to engage in those behaviors or to stop participating in Medicaid. CMS has worked together with Kentucky to include guardrails that will protect beneficiaries. These guardrails, which are contained in a series of assurances in the STCs (described in STC 22, 24, 32, and 47), include requirements that the state: provide opportunities for re-enrollment before the end of the six month non-eligibility period for beneficiaries who meet certain requirements, screen beneficiaries and determine eligibility for other categories of Medicaid eligibility prior to a non-eligibility period, review for eligibility for insurance affordability programs prior to a non-eligibility period, provide full appeal rights prior to disenrollment, and maintain a system that provides reasonable modifications related to meeting the community engagement requirements to beneficiaries with disabilities, among other assurances. The STCs include a provision granting CMS the authority to discontinue the demonstration if the agency determines that it is not promoting Medicaid's objectives. Moreover, CMS will regularly monitor Kentucky HEALTH and will work with the Commonwealth to resolve any issues that arise as Kentucky works to implement the demonstration.

Some comments argued that a demonstration cannot advance the Medicaid program's objectives if the project is expected to reduce Medicaid enrollment or Medicaid spending. We recognize that some individuals may choose not to comply with the conditions of eligibility imposed by the demonstration, and therefore may lose coverage, as may occur when individuals fail to comply with other requirements like participating in the redetermination process. But the goal of these policies is to incentivize compliance, not reduce coverage. Indeed, CMS has incorporated safeguards into the STCs intended to minimize coverage loss due to noncompliance, and CMS is committed to partnering with Kentucky to ensure that the demonstration advances the objectives of Medicaid. Furthermore, we anticipate that some beneficiaries may dis-enroll from Medicaid if they obtain employer-sponsored or other commercial coverage and no longer qualify for the program. Finally, we note that in some cases, reductions in Medicaid costs can further the

Medicaid program's objectives, such as when the reductions stem from reduced need for the safety net or reduced costs associated with healthier, more independent beneficiaries. These outcomes promote the best interests of the beneficiaries whose health and independence are improved, while also helping states stretch limited Medicaid resources and ensure the long-term fiscal sustainability of the states' Medicaid programs.

In a similar vein, some comments suggested that it is impermissible for a demonstration to rely on disenrollment and a non-eligibility period as incentives for compliance with the project's requirements. As noted above, section 1115 of the Act explicitly contemplates that demonstrations may "result in an impact on eligibility"; furthermore, the amended demonstration as a whole is expected to provide greater access to coverage for low-income individuals than would be available absent the demonstration. Other comments predicted that Kentucky HEALTH will fail to achieve its intended effects. For instance, some comments argued that beneficiaries subject to the community engagement requirement will be unable to comply. To some extent, these comments reflect a misunderstanding of the nature of the community engagement requirement, which the comments described as a work requirement. In fact, the community engagement requirement is designed to help beneficiaries achieve success, and CMS and Kentucky have made every effort to devise a requirement that beneficiaries should be able to meet. For example, the community engagement requirement may be satisfied through an array of activities, including education, job skills training, job search activities, and community service.

More generally, these comments reflect a misunderstanding of the nature of a demonstration project. It is not necessary for a state to show in advance that a proposed demonstration will in fact achieve particular outcomes; the purpose of a demonstration is to test hypotheses and develop data that may inform future decision-making. As HHS previously explained, demonstrations can "influence policy making at the [s]tate and Federal level, by testing new approaches that can be models for programmatic changes nationwide or in other [s]tates." 77 Fed. Reg. at 11680. For example, the Temporary Assistance for Needy Families (TANF) work requirements that Congress enacted in 1996 were informed by prior demonstration projects. *See, e.g.*, *Aguayo v. Richardson*, 473 F.2d 1090 (2d Cir. 1973) (upholding a section 1115 demonstration project that imposed employment requirements as conditions of AFDC eligibility). Regardless of the degree to which Kentucky's demonstration project succeeds in achieving the desired results, the information it yields will provide policymakers real-world data on the efficacy of such policies. That in itself promotes the objectives of the Medicaid statute.

Comments addressing coverage losses

Some comments argued that the demonstration will cause approximately 95,000 individuals to lose Medicaid coverage and, for that reason, the project cannot be consistent with the objectives of the Medicaid program. As an initial matter, these commenters appear to misunderstand the budget neutrality study and other materials from which they appear to have derived the 95,000 figure.[8] The cited projections are based on Kentucky's 2017 estimate of the change in "total

[8] Kentucky HEALTH § 1115 Demonstration Modification Request, Attachments A and B (July 3, 2017), *available at* https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ky/ky-health-pa2.pdf.

member months" covered by Medicaid during the demonstration. One member month is equal to one member enrolled for one month. Kentucky's projections show that, over its five-year life, the demonstration project was expected to cover slightly less than 5 percent fewer total member months than would have been covered without the demonstration project. The cited enrollment projections do not, however, predict how many recipients will become uninsured under the demonstration project. Thus, it is not accurate to assume, as some commenters did, that this study reflects that 95,000 individuals will completely lose coverage and not regain it. The projected decrease in total member months is likely attributable to a number of factors, including beneficiaries transitioning to commercial coverage, as well as the elimination of retroactive eligibility and beneficiaries who are temporarily suspended or otherwise lose eligibility for part of the year due to their noncompliance with program requirements. In addition, the projections were made prior to the inclusion of changes made to the demonstration at approval, including additional beneficiary guardrails expected to help beneficiaries maintain enrollment. Additionally, it is important to acknowledge that otherwise potentially eligible Medicaid beneficiaries lose coverage today for many reasons where they have failed to comply with program requirements.

We also note that the demonstration provides coverage to individuals that the state is not required to cover. Any potential loss of coverage that may result from a demonstration is properly considered in the context of a state's substantial discretion to eliminate non-mandatory benefits or to eliminate coverage for existing (but non-mandatory) populations, such as (in light of the Supreme Court's ruling in *NFIB v. Sebelius*) the ACA adult expansion population. As of September 2018, more than 454,000 individuals received medical assistance under the Kentucky state plan as a result of Kentucky's decision to participate in the ACA adult eligibility expansion. Kentucky's ACA expansion population includes not only childless adults but also many parents of dependent children, who are not eligible for coverage under the Kentucky state plan unless their household income is equal to or less than 24 percent of the federal poverty level. The Governor has indicated, however, that Kentucky will reconsider the ACA adult eligibility expansion if the Commonwealth is unable to implement the demonstration project. As noted in our letter of January 12, 2018, "Kentucky leaders have expressed the importance of this demonstration as a means of preserving coverage for individuals." Moreover, conditioning eligibility for Medicaid coverage on compliance with certain measures is an important element of the state's efforts, through experimentation, to improve beneficiaries' health and independence and enhance programmatic sustainability. To create an effective incentive for beneficiaries to take measures that promote health and independence, it may be necessary for states to attach penalties to failure to take those measures, including with conditions designed to promote health and financial independence. This may mean that beneficiaries who fail to comply will lose Medicaid coverage, at least temporarily. However, the incentives included in this demonstration are not designed to encourage this result; rather, they are intended to incorporate achievable conditions of continued coverage. And any loss of coverage as the result of noncompliance must be weighed against the benefits Kentucky hopes to achieve through the demonstration project, including both the improved health and independence of the beneficiaries who comply and the Commonwealth's enhanced ability to stretch its Medicaid resources and maintain the fiscal sustainability of the program.

It would be counterproductive to deny states the flexibility they need to implement demonstration projects designed to examine innovative ways to incentivize beneficiaries to engage in desired behaviors that improve outcomes and lower healthcare costs, as well as innovative ways to stretch limited state resources, given that states have the prerogative to terminate coverage for non-mandatory services and populations. Because a demonstration project, by its nature, is designed to test innovations, it is not possible to know in advance the actual impact that its policies will have on enrollment. That is one of the metrics to be measured. But even assuming that Kentucky HEALTH would result in a 5 percent decrease in covered member months as compared to the number of member months covered without the demonstration, and even assuming that most of these individuals would not transition to commercial coverage, that figure is likely dwarfed by the 454,000 newly eligible adults who stand to lose coverage if Kentucky elects to terminate the non-mandatory ACA expansion.

Furthermore, the Kentucky state plan covers other non-mandatory populations such as the medically needy and lawfully residing immigrant children under age 19, as well as non-mandatory services such as prescription drug, dental, and vision benefits. As a matter of federal law, it is a state's prerogative to reduce or eliminate non-mandatory coverage. Such judgments are left to the policy preferences of the state government and its electorate, and states are to be given great latitude in making tradeoffs in how the state furnishes medical assistance "as far as practicable under the conditions" in the state. Act § 1901. In evaluating Kentucky's demonstration project, it is appropriate to consider the possibility of coverage loss against the benefits that may accrue to the populations included in Kentucky HEALTH, as well as benefits that may accrue to the Commonwealth's other Medicaid eligibility groups as a result of the populations in Kentucky HEALTH growing more independent, healthier, and less expensive to cover. Moreover, as noted above, the projected decrease in enrollment that some commenters attributed to this demonstration is simply a projection. Kentucky will measure actual effects on enrollment as part of the demonstration, and that information should be useful in informing future Medicaid policy.

Commenters also expressed concerns that the demonstration's reporting requirements will cause beneficiaries to lose Medicaid coverage because of failure to report their community engagement hours, failure to report changes in circumstances, failure to provide information necessary to complete the annual redetermination process, or because of clerical errors by Kentucky's Medicaid agency. In general, these concerns reflect coverage loss that would occur only if the individual chooses not to comply with these requirements. In those cases, we note that individuals always are able to re-apply for Medicaid and have eligibility determined for other Medicaid groups for which they can be immediately enrolled. CMS has worked closely with Kentucky to ensure there are substantial beneficiary protections in place. The STCs provide for Kentucky to educate and reach out to beneficiaries and contain assurances that Kentucky will seek data from other sources, including SNAP, TANF, and other existing systems to permit beneficiaries to efficiently report community engagement hours and process beneficiary redeterminations. Clerical errors can occur in any program and are not reason to deny approval at the outset. Moreover, CMS will monitor the demonstration, and the STCs provided that CMS can amend or withdraw waivers or expenditure authority if it determines that continuing the demonstration would no longer be in the public interest or promote Medicaid's objectives.

Comments addressing individual demonstration features

The community engagement requirement

Some comments suggest that a community engagement requirement that many people will fulfill by working one or multiple part-time, minimum-wage jobs or through unpaid means (volunteering), will not directly lead to financial independence. CMS disagrees with that conclusion. While some of the activities that meet the community engagement requirement may not immediately cause all beneficiaries to be financially independent, those activities are nonetheless positive steps for beneficiaries to take on their path to financial independence. In addition, participation in these activities may reduce social isolation, which multiple studies have linked to higher rates of mortality.[9] At the very least, whether Kentucky HEALTH's community-engagement requirement will lead to beneficiaries' financial independence is an open question, which is why this demonstration project is necessary to test whether the incentive structure will have the desired effect. That is also why CMS will regularly evaluate the effects of Kentucky HEALTH on affected beneficiaries and reserves the right to discontinue specific waiver and expenditure authorities if CMS determines that it would no longer be in the public interest or promote Medicaid's objectives to continue them. Moreover, even if those activities do not cause beneficiaries to become financially independent, they are nevertheless linked to improved health outcomes, which itself furthers Medicaid's objectives.

Some commenters also suggest that suspending eligibility for beneficiaries who fail to comply with the community engagement requirement will make it harder for beneficiaries to find employment, and some cited research that shows a correlation between individuals' access to health coverage and their ability to find employment. CMS has reviewed and considered the research cited to by commenters and notes that other research also shows a positive link between community engagement and improved health outcomes.[10] None of the existing research, however, definitively shows whether a community-engagement requirement as a condition for continued Medicaid coverage will help beneficiaries attain financial independence and improve health outcomes. Thus, CMS has determined that it is appropriate to permit states to use section 1115 demonstration projects to determine whether they can achieve such an outcome using community engagement requirements.

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[9] Julianne Holt-Lunstad, et al., *Loneliness and Social Isolation as Risk Factors for Mortality: A Meta-Analytic Review*, 10 Persp. on Psychol. Sci. 227 (2015).

[10] Waddell, G. and Burton, AK. Is Work Good For Your Health And Well-Being? (2006) EurErg Centre for Health and Social Care Research, University of Huddersfield, UK;
Van der Noordt, M, Jzelenberg, H, Droomers, M, and Proper,K. Health effects of employment: a systemic review of prospective studies. BMJournals. Occupational and Environmental Medicine. 2014: 71 (10).
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Commenters also expressed concern regarding beneficiaries they believed to be subject to the community engagement requirement. Commenters opposed the requirement because they believed that it would negatively impact pregnant women, the elderly, caregivers to minor dependent children, beneficiaries who are medically frail, and beneficiaries with disabilities. CMS and Kentucky provide several protections for vulnerable beneficiaries who cannot meet the requirement or who may need assistance to meet the requirements. The Kentucky HEALTH program provides exemptions from the community engagement requirement for several populations including pregnant women, beneficiaries who are medically frail, primary caregivers of a dependent minor child, and beneficiaries over the age of 64. Kentucky also provides beneficiaries with the opportunity to avoid the consequences for failure to comply with the requirement by demonstrating that they had a good cause not to meet it, and provides reasonable modifications 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. Therefore, CMS believes that the demonstration adequately protects beneficiaries with circumstances which could prevent them from meeting the community engagement requirement, as well as other Kentucky HEALTH program requirements. Where individuals among the Kentucky HEALTH groups are capable of satisfying the community engagement requirement, CMS believes that including these individuals advances the purposes of Medicaid by improving beneficiary health and financial independence and enhancing the program's fiscal sustainability.

Premiums

Of the comments received on premiums, the majority of commenters were opposed to this requirement. Commenters were concerned that a monthly premium obligation creates a financial burden on beneficiaries, and creates a potential negative impact on health coverage and health outcomes. Kentucky designed the premium requirement in a way that minimizes potential impacts on beneficiaries. The premiums requirement is designed to align with requirements in the commercial insurance market, but also provides opportunities for beneficiaries to avoid the consequences of nonpayment if they can demonstrate they had a good cause for not meeting their premium obligation. Also, premiums are optional for several populations as an opportunity to access additional services not offered through the standard benefit package. For beneficiaries with a mandatory premium obligation, only beneficiaries with income above 100 percent of the federal poverty level are subject to a non-eligibility period for failure to meet the requirement. However, these beneficiaries will have a one-time opportunity, per year, to re-enter the program before the end of the non-eligibility period if they attend an early re-enrollment course and pay the premium required for the first month of re-entry.

Commenters also argued that premiums are inconsistent with the objectives of the Medicaid program, and do not have research value. CMS disagrees with this assertion. CMS has implemented premium obligations in several states and is currently evaluating the requirement; there is not sufficient evidence to assert that premium requirements do not advance the objectives of Medicaid. On the contrary, interim evaluation findings regarding premiums in one state found that beneficiaries who paid premiums are more likely to obtain primary care and preventive care, have better drug adherence, and rely less on the emergency room for treatment compared to

those who do not.[11] Additionally, premiums, when viewed as a component of the broader Kentucky HEALTH program, merit additional research and evaluation when viewed in conjunction with other demonstration features which together, seek to encourage beneficiaries to engage in health-promoting behaviors and to strengthen engagement by beneficiaries in their personal health care plans. Kentucky will evaluate the premium requirement, and CMS reserves the right to withdraw its authority if it is determined that premiums negatively impact health coverage or health outcomes.

The My Rewards Account; vision and dental benefits

Some comments expressed concern that under the demonstration, certain beneficiaries will not receive prescription drug, vision, and dental benefits under the state plan, and instead will be given the opportunity to obtain these benefits through the *My Rewards Account*. As an initial matter, Kentucky never proposed to stop offering prescription drugs under the state plan. Over-the-counter medications will be accessible for certain adults through the *My Rewards Account*. Moreover, Kentucky is not required to offer these medications or any of the other benefits available through the *My Rewards Account*; in fact, the fitness services available through the account are covered only *because* of CMS approval of the demonstration.

It furthers Medicaid's objectives to permit Kentucky to test incentives designed to promote healthy activities such as the *My Rewards Account*, which enables Kentucky to offer, or to continue to offer, the vision, dental, and over-the-counter medications available through the *My Rewards Account*, even if some beneficiaries may not earn them. As discussed above, it furthers the Medicaid program's objectives to allow states to experiment with innovative means of deploying their limited state resources in ways that may allow them to provide non-mandatory services. Providing non-mandatory services unquestionably advances the purposes of the Medicaid program.

Waiver of NEMT

Some commenters expressed concerns that the NEMT waiver for the new adult group will negatively impact Medicaid recipients in rural areas who lack consistent transportation options. Other commenters suggested that this waiver of NEMT will harm vulnerable beneficiaries, will undermine Kentucky's goal of improving beneficiaries' health, and is an impermissible benefits cut. To limit the impact on vulnerable beneficiaries, Kentucky chose to apply this waiver of NEMT to only the new adult group, and exempt pregnant women, survivors of domestic violence, beneficiaries who are medically frail, former foster care youth, and 19 and 20 year old beneficiaries entitled to early and periodic screening, diagnostic and treatment (EPSDT) services. CMS believes this approach adequately addresses commenters' concern, as it minimizes the impact on vulnerable beneficiaries while also achieving the state's goal of recreating the experience of the commercial insurance market, which does not offer the NEMT benefit. This component of Kentucky HEALTH is expected to improve the fiscal sustainability of the state's safety net and contribute to the provision of additional services offered through Kentucky HEALTH and KY HEALTH. Therefore, CMS believes that the benefit of offering NEMT to the

[11] The Lewin Group, Indiana Healthy Indiana Plan 2.0 Interim Evaluation Report (2016), available at: https://www.in.gov/fssa/files/Lewin_IN%20HIP%202%200%20Interim%20Evaluation%20Report_FINAL.pdf.

new adult group is outweighed by enhancements to programmatic sustainability and the value of the optional services that Kentucky will offer.

Waiver of Retroactive Eligibility

Some commenters expressed concerns that the waiver of retroactive eligibility will reduce coverage and therefore cannot promote Medicaid's objectives. The waiver of retroactive eligibility is likely to help promote Medicaid's objectives in at least two ways: (1) it may improve uptake of preventive services and thus improve beneficiary health; (2) it improves the fiscal sustainability of the Medicaid program, which helps to permit Kentucky to continue to provide Medicaid to the ACA expansion population, and to continue to cover non-mandatory benefits and eligibility groups.

Non-eligibility periods for failure to report a change in circumstances, failure to pay premiums, or failure to complete redetermination requirements

Some comments suggested that non-eligibility periods do not further Medicaid's objectives because they will cause beneficiaries to lose Medicaid coverage. These features of the demonstration are designed to incentivize program compliance and familiarize beneficiaries with the functioning of commercial insurance. These goals also further Medicaid's objectives by improving the financial sustainability of Kentucky's Medicaid program. CMS considered these provisions in the context of the whole demonstration and determined that the demonstration appropriately balances the Medicaid objectives of ensuring coverage and permitting states to furnish Medicaid "to the extent practicable under the conditions of each state."

Non-emergency use of the emergency room

A few commenters opposed Kentucky's *My Rewards Account* penalty for non-emergent use of the emergency room, citing concern that this penalty constitutes cost sharing that requires additional waiver authority. CMS seeks to clarify that the *My Rewards Account* penalty is not cost sharing because the *My Rewards Account* is an incentive tool that does not require monetary contributions from beneficiaries. The funds in the *My Rewards Account* are non-monetary credits. Beneficiaries are *never* required to pay out of pocket for *My Rewards Account* penalties or services, and to the extent a deduction is imposed in this context as a result of non-emergent use of the emergency room, a beneficiary would have only virtual credits reduced from his or her account. There would be no actual charges to the beneficiary. This penalty will not be imposed on beneficiaries who visit the emergency department for an emergency.

Other Information

CMS's 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. Valisha Andrus. She is available to answer any questions concerning your section 1115 demonstration. Ms. Andrus's contact information is as follows:

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

Official communications regarding program matters should be sent simultaneously to your project officer and Ms. Davida Kimble, Associate Regional Administrator in our Atlanta Regional Office. Ms. Kimble's contact information is as follows:

Ms. Davida Kimble
Associate Regional Administrator
Centers for Medicare & Medicaid Services
Division of Medicaid and Children Health Operations
61 Forsyth Street, South West, Suite 4T20
Atlanta, GA 30303-8909
Email: Davida.Kimble@cms.hhs.gov

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

Sincerely,

[redacted]

Paul Mango
Chief Principal Deputy Administrator
and Chief of Staff

Enclosures

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

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

TITLE: **KY HEALTH Section 1115 Demonstration**

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

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by the Commonwealth of Kentucky for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act, must, unless otherwise specified, be regarded as matchable expenditures under the state's Title XIX plan but are further limited by the special terms and conditions (STCs) for the KY HEALTH section 1115 demonstration. Expenditures associated with KY HEALTH are approved from January 12, 2018 through September 30, 2023. Expenditures associated with the Kentucky HEALTH program are effective April 1, 2019, and implementation of the Kentucky HEALTH program will begin no sooner than April 1, 2019.

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 through September 30, 2023. In addition, these waivers may only be implemented consistent with the approved STCs. Waivers associated with KY HEALTH are approved from January 12, 2018 through September 30, 2023. Waivers associated with the Kentucky HEALTH program are approved effective April 1, 2019 and implementation of the Kentucky HEALTH program will begin no sooner than April 1, 2019.

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

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

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

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

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

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)(10) and (a)(34)**

To the extent necessary to enable the state not to provide medical coverage for any month prior to the month in which a beneficiary's Medicaid application is filed, except for applicants who would have been eligible in or after the third month before the month in which an application was made, as either pregnant women or former foster care youth. The eligibility effective date for beneficiaries who become eligible for transitional medical assistance as described in sections 1925 and 1931(c)(2) of the Act will be governed through the state plan.

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 at or below 100 percent of the federal poverty level (FPL) and all beneficiaries who are eligible for transitional medical assistance as described in sections 1925 and 1931(c)(2) of the Act 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, survivors of domestic violence, 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, survivors of domestic violence, and beneficiaries found eligible through presumptive eligibility, as described in these STCs. The eligibility effective date for beneficiaries who become eligible for transitional medical assistance as described in sections 1925 and 1931(c)(2) of the Act will be governed through the state plan.

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 43 or 46(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 the following beneficiaries: those who are medically frail; those who are 19 or 20 years old and entitled to early and periodic screening, diagnostic, and treatment (EPSDT) services; former foster care youth; survivors of domestic violence; or 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) section 1115(a) Medicaid and CHIP demonstration (hereinafter "demonstration") to enable Kentucky (state) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted the state waivers of requirements under sections 1902(a) and section 2107 of the Social Security Act (the Act), and expenditure authorities authorizing federal matching of demonstration costs that are not otherwise matchable, and which are separately enumerated. These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration, and the state's obligations to CMS related to this demonstration. The KY HEALTH demonstration will be statewide and is approved from January 12, 2018 through September 30, 2023, with approval of the Kentucky HEALTH program effective April 1, 2019. Implementation of the Kentucky HEALTH program will begin no sooner than April 1, 2019.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Kentucky HEALTH Program 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 Evaluation Report
- Attachment C: Implementation Plan
- Attachment D: Monitoring Protocol
- Attachment E: SUD Implementation Protocol
- Attachment F: SUD Monitoring Protocol
- Attachment G: 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

On January 12, 2018, the Centers for Medicare & Medicaid Services (CMS) approved 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). This approval permitted Kentucky to continue to expand coverage to former foster care youth from another state effective January 12, 2018. The demonstration also included: expenditure authority to implement 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 a substance use disorder (including an opioid use disorder); a waiver of non-emergency medical transportation (NEMT) for methadone services; expenditure authority to enable the state to align a beneficiary's annual redetermination with their employer sponsored insurance open enrollment period; and the Kentucky HEALTH program.

On June 29 2018, a district court vacated the approval of the demonstration project component known as Kentucky HEALTH, on the ground that CMS "never adequately considered whether Kentucky HEALTH would in fact help the state furnish medical assistance to its citizens, a central objective of Medicaid." *Stewart v. Azar*, 313 F. Supp. 3d 237, 243 (D.D.C. 2018). The district court remanded the matter to CMS for further review. Approval of the broader KY HEALTH demonstration, including a SUD program available to all Kentucky Medicaid beneficiaries to ensure that a broad continuum of care is available to Kentuckians with a substance use disorder, including an opioid use disorder, remained in effect.
On July 19, 2018, CMS opened a new 30-day comment period to give interested stakeholders an opportunity to comment on the issues raised in the litigation and in the court's decision. On November 20, 2018, CMS approved the Kentucky HEALTH program portion of the KY HEALTH demonstration, which will be implemented no sooner than April 1, 2019. Kentucky will enroll certain non-elderly adult beneficiaries who do not qualify for Medicaid on the basis of a disability into Kentucky HEALTH. Groups in the Kentucky HEALTH program primarily include the ACA expansion population and two groups of low-income parents and caretaker relatives: those described in section 1931(b) and (d) of the Act, and those described in sections 1925 and 1931(c)(2) of the Act who are transitioning off of Medicaid due to increases in their income.

Kentucky will implement a community engagement requirement (described in STCs 42-47) 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, survivors of domestic violence, 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 and report 80 hours per month of community engagement activities, such as employment, education, job skills training, job search activities, and community service. Beneficiaries will have their eligibility suspended for failure to report 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. The option to take a course to re-enter from suspension is available one time per 12-month benefit period. 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 procedural protections for affected beneficiaries, and will also provide opportunities for beneficiaries to demonstrate good cause in certain circumstances for failing to meet the requirement. Additionally, beneficiaries can re-activate Medicaid coverage if, during a suspension, they become eligible for an exemption from the community engagement requirement, or become eligible under a Medicaid eligibility category not subject to the requirement.

Kentucky HEALTH also includes two consumer-driven tools, the *My Rewards Account* (described in STC 29) and the *Deductible Account* (described in STC 28). Beneficiaries will receive incentives that have a dollar value equivalent (but have no actual monetary value) for healthy behavior and community engagement in their *My Rewards Account* that can be used to obtain additional benefits: vision benefits, dental benefits, over-the-counter medications, and limited fitness-related services such as a gym membership. Pregnant women, former foster care youth, beneficiaries who are medically frail, survivors of domestic violence, and adults in Kentucky HEALTH who are not in the ACA expansion population (i.e., the groups described in sections 1925 and 1931(b), (c)(2), and (d)) will continue to receive vision, dental, and over-the-counter medications pursuant to the state plan, but will have the choice to opt-in to the *My Rewards Account* to access the limited fitness-related services.

The *Deductible Account* is an educational tool to inform beneficiaries about the cost of healthcare and encourage appropriate healthcare utilization. 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. If funds in the deductible account are exhausted before the end of a beneficiary's 12-month benefit period, the beneficiary still will be able to receive covered services just as services would be covered after satisfaction of a deductible under commercial coverage. Beneficiaries with funds remaining in their deductible account after the end of the 12-month benefit period may transfer up to 50 percent of the prorated balance to their *My Rewards Account.*

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

- Premiums (described in STCs 30-41), in lieu of the copayments required under the state plan, of not less than one dollar per month and not to exceed 4 percent of household income, for Kentucky HEALTH beneficiaries in the ACA expansion and low-income parent and caretaker groups (with exceptions for pregnant women, survivors of domestic violence, former foster care youth, beneficiaries who are eligible for transitional medical assistance as described in sections 1925 and 1931(c)(2) of the Act, and those determined medically frail), with specified consequences for beneficiaries who do not pay premiums after a 60-day payment period (including a six-month non-eligibility period for beneficiaries with household income over 100 percent of the federal poverty level) and procedural protections for affected beneficiaries, as well as opportunities to demonstrate good cause for failure to meet the requirements;
- A six month non-eligibility period (described in STCs 21-22 for beneficiaries who fail to provide the necessary information or documentation to complete the annual redetermination process, with exceptions for pregnant women, survivors of domestic violence, former foster care youth, and individuals determined to be medically frail, and procedural protections for affected beneficiaries, as well as opportunities to demonstrate good cause for failure to meet the requirements;
- Disenrollment and a six-month non-eligibility period (described in STCs 23-24) for beneficiaries who fail to report a change in circumstance that resulted in Medicaid ineligibility, with exceptions from the six-month non-eligibility period for pregnant women, survivors of domestic violence, former foster care youth, and beneficiaries who are medically frail, and with procedural protections for affected beneficiaries, as well as opportunities to demonstrate good cause for failure to meet the requirements;
- A waiver of retroactive eligibility (described in STC 19) for beneficiaries enrolled in Kentucky HEALTH, with exceptions for pregnant women and former foster care youth (the eligibility effective date for beneficiaries who become eligible for transitional medical assistance as described in sections 1925 and 1931(c)(2) of the Act will be governed through the state plan); and
- A waiver of the requirement to provide non-emergency medical transportation (NEMT) (described in STC 27) for beneficiaries enrolled in the new adult group, with exceptions for beneficiaries who are medically frail, 19- or 20-year-old beneficiaries entitled to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services, former foster care youth, survivors of domestic violence, and pregnant women.

III. GENERAL PROGRAM REQUIREMENTS

1. Compliance with Federal Non-Discrimination Laws. The state must comply with applicable federal civil rights laws relating to non-discrimination in services and benefits in its programs and activities. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and Section 1557 of the Affordable Care Act (Section 1557). Such compliance includes providing reasonable modifications to individuals with disabilities under the ADA, Section 504, and Section 1557 in eligibility and documentation requirements, to ensure

they understand program rules and notices, in establishing eligibility for an exemption from community engagement requirements on the basis of disability, and to enable them to meet and document community engagement requirements, as well as other program requirements necessary to obtain and maintain benefits.

2. Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy. All requirements of the Medicaid and CHIP programs, expressed in federal law, regulation, and written policy, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3. Changes in Medicaid and CHIP Law, Regulation, and Policy. The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid and/or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes of an operational nature without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 calendar days in advance of the expected approval date of the amended STCs to allow the state to provide comment.

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

a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration, as well as a modified allotment neutrality worksheet as necessary to comply with such change. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.

b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under federal law, whichever is sooner.

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

6. Changes Subject to the Amendment Process. If not otherwise specified in these STCs, changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other

comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7, except as provided in STC 3.

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

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

b. A data analysis worksheet which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detail projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;

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

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

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

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

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

a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 13, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its transition and phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.

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

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

state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

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

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

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

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

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

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

c. Federal Public Notice. CMS will conduct a 30-day federal public comment period consistent with the process outlined in 42 CFR 431.416 in order to solicit public input on the state's demonstration authority expiration plan. CMS will consider comments received during the 30-day period during its review of the state's demonstration authority expiration plan. The state must obtain CMS approval of the demonstration authority expiration plan prior to the implementation of the expiration activities. Implementation of expiration activities must be no sooner than fourteen (14) calendar days after CMS approval of the demonstration authority expiration plan.

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

11. Withdrawal of Waiver or Expenditure Authority. CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waivers or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX and title XXI. CMS must promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

12. Adequacy of Infrastructure. The state must ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.

13. Public Notice, Tribal Consultation, and Consultation with Interested Parties. The state must comply with the state notice procedures as required in 42 CFR 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request.

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

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

14. Federal Financial Participation (FFP). No federal matching for state expenditures under this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.

15. Common Rule Exemption. The state shall ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. The Secretary has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.101(b)(5).

IV. KENTUCKY HEALTH PROGRAM POPULATIONS AFFECTED

16. 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)

17. Effective Date of Coverage. All beneficiaries in the Kentucky HEALTH program, except 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, beneficiaries who are eligible for transitional medical assistance as described in sections 1925 and 1931(c)(2) of the Act, survivors of domestic violence, and pregnant women, are required

to make monthly premium payments as described in STC 33. Individuals determined eligible for Kentucky HEALTH who are not 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 20. Individuals required to pay premiums will have sixty (60) days from the date of their premium invoice to pay the premium payment. Once such 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 are required to pay premiums and 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 are required to pay premiums and 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 38(b).

As noted above, beneficiaries who are medically frail, former foster care youth, beneficiaries who are eligible for transitional medical assistance as described in sections 1925 and 1931(c)(2) of the Act, survivors of domestic violence, 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, or survivors of domestic violence 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. The eligibility effective date for beneficiaries who become eligible for transitional medical assistance as described in sections 1925 and 1931(c)(2) of the Act will be governed through the state plan.

18. 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 50(b). The pre-determined premium pre-payment amount shall be determined by the state, and may be modified in accordance with STC 33(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 33, 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.

19. 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 applicants who would have been eligible in or after the third month before the month in which an application was made, as either pregnant women or former foster care youth. The eligibility effective date for beneficiaries who become eligible for transitional medical assistance as described in sections 1925 and 1931(c)(2) of the Act will be governed through the state plan.

20. 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 38.

21. 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 21(d), will be prohibited from re-enrollment in the demonstration for up to six months, unless the individual demonstrates good cause as described in STC 22(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 40.

d. Pregnant women, former foster care youth, survivors of domestic violence, 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 demonstrate that they had good cause not to complete the annual redetermination requirements, as described in STC 22(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.

22. 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 opportunities for beneficiaries to demonstrate good cause for not completing annual redetermination requirements, which would allow beneficiaries to re-enroll under certain conditions without completion of early re-enrollment requirements as described in STC 40 or waiting six months. Good cause circumstances must include, 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; or

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.

e. Provide beneficiaries written notice of specific activities as described in STC 40 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.

f. Provide written notice to beneficiaries of any non-eligibility period exemptions and of the opportunity to demonstrate good cause, as described in STC 21(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 opportunities to demonstrate good cause, 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.

23. 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 coverage during which

the member was not 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, survivors of domestic violence, 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 24(b) and STC 40.

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.

24. 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 23 will have the opportunity to provide additional clarifying information indicating the beneficiary did report the change in circumstance or to demonstrate good cause for not reporting the change in circumstance, 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. Allow those beneficiaries who demonstrate good cause for not reporting a change in circumstance to re-enroll under certain conditions without completion of early re-enrollment requirements as described in STC 40 or waiting six months. Good cause circumstances must include, 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; or

v. The beneficiary was evicted from home or experienced homelessness 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 23.

d. Provide written notice to beneficiaries of specific activities as described in STC 40 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 of the opportunity to demonstrate good cause, as described in STC 23(a) and 24(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 opportunities to demonstrate good cause, 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

25. 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, survivors of domestic violence, beneficiaries who are eligible for transitional medical assistance as described in sections 1925 and 1931(c)(2) of the Act, 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.

26. 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, survivors of domestic violence, 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

27. 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.

28. 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 just as services would be covered after satisfaction of a deductible under commercial coverage.

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.

29. 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 25. 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 30 and 38, 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 a balance 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 survivors of domestic violence, 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 45.

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 a dollar-value equivalent for

negative $150 to reflect cumulative deductions. A beneficiary's My Rewards Account balance will be reduced for the following:

i. Non-payment of Premiums. A beneficiary's My Rewards Account balance will be reduced each time a beneficiary fails to meet their premium payment obligation outlined in STC 38.

ii. Non-emergent Use of the Emergency Department. A beneficiary's My Rewards Account balance 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. The My Rewards Account deduction is not cost-sharing within the meaning of 42 CFR 447.51 because the funds in the My Rewards Account are non-monetary credits and the deduction in question does not result in actual charges to the beneficiary. The credits charged against the My Rewards Account are therefore 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 balance can be reduced. Notwithstanding the fact that the My Rewards Account deduction is not cost sharing, the state must 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 balance 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 reduce the My Rewards Account balance 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 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 CONTRIBUTIONS

30. Premiums. All beneficiaries enrolled in the Kentucky HEALTH program, except pregnant women, former foster care youth, beneficiaries who are eligible for transitional medical assistance as described in sections 1925 and 1931(c)(2) of the Act, survivors of domestic violence, 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 33, 38, and 41.

31. 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.

32. 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 40.

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 38.

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 opportunities to demonstrate good cause for failure to pay premiums that would allow beneficiaries to avoid the consequences for non-payment described in STC 38, and (if applicable) to re-enroll under certain conditions without completion of early re-enrollment requirements or waiting the full six (6) months. Good cause circumstances must include, 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, or

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.

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 make program information available and accessible 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 reactivation of their My Rewards Account or early re-enrollment during a non-eligibility period, as described in STC 39 and 40, 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.

33. Premium Amounts. All Kentucky HEALTH beneficiaries, including beneficiaries receiving premium assistance, but not including beneficiaries who are medically frail, former foster care youth, beneficiaries who are eligible for transitional medical assistance as described in sections 1925 and 1931(c)(2) of the Act, survivors of domestic violence, and pregnant women, as described in STC 17 and 30, 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 30. 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 30.

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.

34. Household Limits. Premium payments apply towards all Kentucky HEALTH beneficiaries, as described in STC 30, 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.

35. 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).

36. 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.

37. 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 38.

38. 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 40. 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' My Rewards Account balance will be reduced pursuant to STC 29(g)(i).

iv. Beneficiaries who meet the requirements for demonstrating good cause as described as described in STC 32(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 40.

b. **Beneficiaries with Income At or Below 100 percent of FPL, and Beneficiaries Who Are Eligible for Transitional Medical Assistance as Described in Sections 1925 and 1931(c)(2) of the Act.**

i. Beneficiaries who are eligible for transitional medical assistance will have the option to pay a premium to access a My Rewards Account.

ii. Beneficiaries with income at or below 100 percent of the FPL and beneficiaries who are eligible for transitional medical assistance who fail to make premium payments will not be disenrolled.

iii. 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.

iv. Beneficiaries' My Rewards Account balance will be reduced pursuant to STC 29(g)(i).

v. Beneficiaries will have their My Rewards Account suspended (i.e., may not use or accrue incentive amounts) for up to six months.

vi. Beneficiaries may complete the requirements as described in STC 40 to end the copayment requirement and reactivate their My Rewards Account prior to the end of the six month period.

vii. 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.

viii. Beneficiaries who meet the requirements for demonstrating good cause as described in STC 32(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 40.

c. **Former Foster Care Youth, Survivors of Domestic Violence, and Beneficiaries Determined Medically Frail.**

i. Former foster care youth, survivors of domestic violence, and Kentucky HEALTH beneficiaries who have been identified as medically frail will have the option to pay premiums.

ii. Beneficiaries in these categories will not be subject to copayments for services, and will not be subject to disenrollment for nonpayment.

iii. Beneficiaries in these categories 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. Beneficiaries in these categories may reactivate their My Rewards Accounts by attending an early re-enrollment educational course as described in STC 40(a)(ii). They will not be required to pay past premiums owed to reactivate their My Rewards Account.

v. Beneficiaries in these categories who meet the requirements for demonstrating good cause as described in STC 32(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 40(a)(ii).

39. Eligibility Review. For each Kentucky HEALTH beneficiary subject to disenrollment for non-payment under STC 38, 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.

40. 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 38(a) or (b), for failure to complete a redetermination as described in STC 21, or for failure to report change in circumstance as described in STC 23, 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 38(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 38(a), early re-activation of their My Rewards Account as described in STC 38(b), early re-enrollment following failure to complete a redetermination as described in STC 21, or early re-enrollment following failure to report a change in circumstance as described in STC 23, 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 38(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.

41. Exemptions. Pregnant women will be exempt from all Kentucky HEALTH premiums. Kentucky HEALTH beneficiaries who are medically frail, beneficiaries who are eligible for transitional medical assistance as described in sections 1925 and 1931(c)(2) of the Act, survivors of domestic violence, and 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 38(b) and 38(c). Kentucky HEALTH beneficiaries with incomes at or below 100 percent FPL and beneficiaries who are eligible for transitional medical assistance as described in sections 1925 and 1931(c)(2) of the Act 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 38(b). Beneficiaries who are disenrolled and subject to a non-eligibility period as a result of non-payment of premiums but who 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 29.

VIII. COMMUNITY ENGAGEMENT INITIATIVE

42. 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 43 or 46(a). To maintain program eligibility, non-exempt beneficiaries will be required to participate in and report participation in specified activities that may include employment, education, or community service.

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

- Former Foster Care Youth;
- Pregnant women;
- Survivors of Domestic Violence
- 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 or report community engagement related activities to maintain eligibility.

44. **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.

45. Hour Requirements. The community engagement initiative will require beneficiaries to participate in and report 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. After the implementation date of the Kentucky HEALTH program, newly approved beneficiaries or Medicaid beneficiaries transitioning into the Kentucky HEALTH program will have an interim period of no fewer than 30 days from their date of eligibility or transition to Kentucky HEALTH before being required to meet the community engagement requirement. The community engagement requirement will begin on the first day of the second full month after the beneficiary's eligibility determination. After becoming subject to the requirement, all beneficiaries will be subject to the consequences described in STC 46. 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 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 provide reasonable modifications for program protections and procedures, including but not limited to assistance with demonstrating good cause; appealing suspension or disenrollment; documenting and reporting community engagement activities and other documentation requirements; understanding notices and program rules; 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.

46. Non-Compliance. Eligibility will be suspended, effective under the time frame described in this STC 46(d), for beneficiaries who fail to meet required community engagement hours for a month, unless the beneficiary successfully demonstrates a good cause for not meeting or reporting the requirement within the allotted time period, or unless the beneficiary appeals the suspension. Eligibility 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 43, or demonstrate good cause as described in STC 46(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**. The state will waive the suspension for beneficiaries who failed to meet the community engagement hours for a month, but who demonstrate good cause for failing to meet the requirement in that month. Beneficiaries may report a good cause for the state's approval up to 10 days prior to suspension. The recognized good cause circumstances 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).

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 survivor of domestic violence, 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.

47. 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 payments to a managed care organization when a beneficiary's eligibility is suspended for failure to comply with the community engagement requirement, 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 or obtain an exemption, in accordance with 42 CFR 435.907(a) and 435.945, 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 community engagement requirements 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 the community engagement requirements and a list of the specific activities that beneficiaries can engage in to cure an impending suspension, as described in STC 46(b);

iv. The specific number of community engagement hours per month that a beneficiary is required to complete to meet the requirement, and when and how the beneficiary must report participation or request an exemption or seeking to demonstrate good cause;

v. 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 the community engagement requirement;

vi. Information about how community engagement hours will be counted and documented;

vii. 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 demonstrate good cause for failure to meet the requirement, and what kinds of circumstances might give rise to good cause;

viii. 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;

ix. 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

x. If a beneficiary has sought to demonstrate good cause, whether good cause 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 46(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 suspension, 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 that lack public transportation to determine whether there should be further exemptions from the community engagement requirement and/or additional mitigation strategies, so that the community engagement requirement will not be unreasonably burdensome for beneficiaries to meet.

k. Provide each beneficiary whose eligibility has been suspended with information on how to access primary care and preventative care services at low or no cost to the individual. This material will include information about free health clinics and community health centers including clinics that provide behavioral health and substance use disorder services. Kentucky shall also maintain such information on its public-facing website and employ other broad outreach activities that are specifically targeted to beneficiaries whose eligibility has been have suspended.

l. 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.

m. Provide beneficiaries with written notice of the rights of people with disabilities to receive reasonable modifications related to meeting community engagement requirements.

n. 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

48. 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.

49. 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.

50. 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.

51. 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

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

provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

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

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

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

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

d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.

As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

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

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

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

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

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

55. Implementation Plan. The state must submit an Implementation Plan to CMS no later than 90 calendar days after approval of the demonstration. The Implementation Plan must cover at least the key policies being tested under this demonstration, including community engagement, premiums, incentives for healthy behaviors, consequences for failure to complete redetermination or report changes in circumstances, and the waivers of retroactive eligibility and NEMT. Once determined complete by CMS, the Implementation Plan will be incorporated into the STCs, as Attachment C. At a minimum, the Implementation Plan must include definitions and parameters of key policies, and describe the state's strategic approach to implementing the policies, including timelines for meeting milestones associated with these key policies. Other topics to be discussed in the Implementation Plan include application assistance, reporting, and processing; notices; coordinated agency responsibilities; coordination with other insurance affordability programs; appeals; renewals; coordination with other state agencies; beneficiary protections; and outreach.

56. Monitoring Protocol. The state must submit to CMS a Monitoring Protocol no later than 150 calendar days after approval of the demonstration. Once approved, the Monitoring Protocol will be incorporated into the STCs, as Attachment D.

At a minimum, the Monitoring Protocol will affirm the state's commitment to conduct quarterly and annual monitoring in accordance with CMS' template. Any proposed deviations from CMS' template should be documented in the Monitoring Protocol. The Monitoring Protocol will describe the quantitative and qualitative elements on which the state will report through quarterly and annual monitoring reports. For quantitative metrics (e.g., performance metrics as described in STC 57(b) below), CMS will provide the state with a set of required metrics, and technical specifications for data collection and analysis covering the key policies being tested under this demonstration, including but not limited to community engagement, premiums, incentives for healthy behaviors, consequences for failure to complete redetermination or report changes in circumstances, and waivers of retroactive eligibility and NEMT. The Monitoring Protocol will specify the methods of data collection and timeframes for reporting on the state's progress as part of the quarterly and annual monitoring reports. For the qualitative elements (e.g., operational updates as described in STC 57(a) below), CMS will provide the state with guidance on narrative and descriptive information which will supplement the quantitative metrics on key aspects of the demonstration policies. The quantitative and qualitative elements will comprise the state's quarterly and annual monitoring reports.

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

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

b. Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing towards meeting the milestones identified in CMS' framework which includes the following key policies under this demonstration -- community engagement, premiums, consequences for failure to complete redetermination or report changes in circumstances, incentives for health behaviors, and the waiver of retroactive eligibility. The performance metrics will also reflect all other components of the state's demonstration, including metrics associated with the waiver of NEMT. For example, these metrics will cover enrollment, disenrollment, or suspension by specific demographics and reason, participation in community engagement qualifying activities, access to care, and health outcomes.

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

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

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

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

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

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

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

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

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

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

e. A delay in submitting the draft or final version of the Close Out Report may subject the state to penalties described in STC 52.

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

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

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

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

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

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.

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

63. 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

64. 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").

65. 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.

66. 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 57, 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.

67. 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.

68. 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.

69. 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**.**

70. 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

71. 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 73. 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.

72. 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 73 and STC 74, 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.

73. 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 73(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 76. 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.

74. 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 76).

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%	N/A	$10.77	$11.31	$11.88	$12.47	$12.62

75. 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.

76. 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.

77. 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%**

78. 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.

79. 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

80. Cooperation with Federal Evaluators. As required under 42 CFR 431.420(f), the state shall cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to: commenting on design and other federal evaluation documents; providing data and analytic files to CMS; entering into a data use agreement that explains how the data and data files will be exchanged; and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state shall include in its contracts with entities that collect, produce or maintain data and files for the demonstration, a requirement that they make data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 52.

81. Independent Evaluator. Upon approval of the demonstration, the state must begin to arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party to sign an agreement that the independent party will conduct the demonstration evaluation in an independent manner in accord with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

82. Draft Evaluation Design. The state must submit, for CMS comment and approval, a draft Evaluation Design, no later than 180 calendar days after approval of the demonstration.

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

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

a. All applicable Evaluation Design guidance, including guidance about community engagement, premiums, incentives for healthy behaviors, consequences for failure to complete redetermination or report changes in circumstances, and the waivers of retroactive eligibility and NEMT. Community engagement hypotheses will include (but not be limited to): effects on enrollment and continuity of enrollment; and effects on employment levels, income, transition to commercial health insurance, health outcomes, and Medicaid program sustainability. Hypotheses for premiums and incentives for healthy behaviors will include (but not be limited to): effects on access to care; and health outcomes. Hypotheses for the waiver of retroactive enrollment will include (but not be limited to): the effects of the waiver on enrollment and eligibility continuity (including for different subgroups of individuals, such as individuals who are healthy, individuals with complex medical needs, prospective applicants, and existing beneficiaries in different care settings). Hypotheses applicable to the demonstration as a whole, and to all key policies referenced above, will include (but will not be limited to): the effects of the demonstration on health outcomes; the financial impact of the demonstration (for example, such as an assessment of medical debt and uncompensated care costs); and the effect of the demonstration on Medicaid program sustainability.

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

83. Evaluation Design Approval and Updates. The state must submit a revised draft Evaluation Design within sixty (60) calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the Monitoring Reports. Once CMS approves the Evaluation Design, if the state wishes to make changes, the state must submit a revised Evaluation Design to CMS for approval.

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

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 design or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.

86. Interim Evaluation Report. The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Report should be posted to the state's website with the application for public comment.

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

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

c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses, and how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.

d. The state must submit the final Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.

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

87. Summative Evaluation Report. The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Evaluation Report) of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 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 calendar days of receiving comments from CMS on the draft.

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

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

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

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

91. Additional Publications and Presentations. For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration over which the state has control. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does

not apply to the release or presentation of these materials to state or local government officials.

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, survivors of domestic violence, 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 E, 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 G; 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 F. 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.

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 84. 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

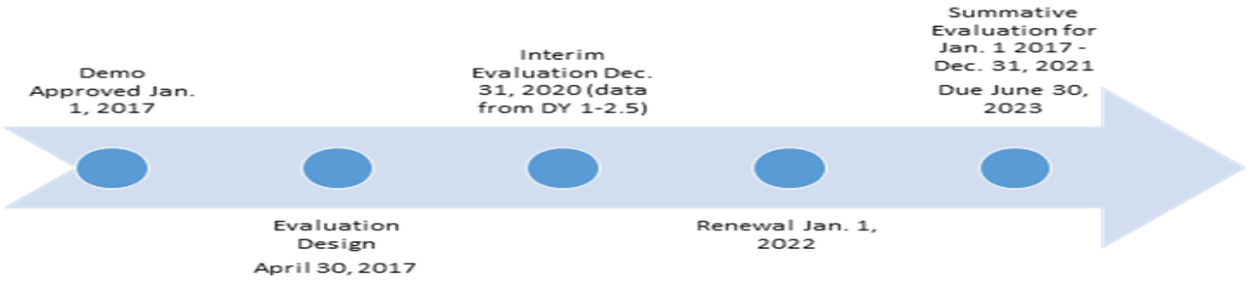
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

The format for the Evaluation Design is as follows:

A. General Background Information;
B. Evaluation Questions and Hypotheses;
C. Methodology;
D. Methodological Limitations;
E. Attachments.

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Design and Reports. (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within 30 days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



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

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

1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).

2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;

4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

5) Describe the population groups impacted by the demonstration.

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

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

2) Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf

3) Identify the state's hypotheses about the outcomes of the demonstration:
   a. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
   b. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

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

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

1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?

2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.

3) *Evaluation Period* – Describe the time periods for which data will be included.

4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:

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

5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

   If primary data (data collected specifically for the evaluation) – The methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection. (Copies of any proposed surveys must be reviewed with CMS for approval before implementation).

6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:
   a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.
   b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
   c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
   d. The application of sensitivity analyses, as appropriate, should be considered.

7) *Other Additions* – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

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

Research Question	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
Hypothesis 1				
Research question 1a	-Measure 1 -Measure 2 -Measure 3	-Sample e.g. All attributed Medicaid beneficiaries -Beneficiaries with diabetes diagnosis	-Medicaid fee-for-service and encounter claims records	-Interrupted time series
Research question 1b	-Measure 1 -Measure 2 -Measure 3 -Measure 4	-sample, e.g., PPS patients who meet survey selection requirements (used services within the last 6 months)	-Patient survey	Descriptive statistics
Hypothesis 2				
Research question 2a	-Measure 1 -Measure 2	-Sample, e.g., PPS administrators	-Key informants	Qualitative analysis of interview material

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

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

When the demonstration is considered successful without issues or concerns that would require more regular reporting, such as:

a. Operating smoothly without administrative changes; and
b. No or minimal appeals and grievances; and
c. No state issues with CMS 64 reporting or budget neutrality; and
d. No Corrective Action Plans (CAP) for the demonstration.

F. Attachments

1) **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include a "No Conflict of Interest" statement signed by the independent evaluator.

2) **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.

3) **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

Attachment B: Preparing the Evaluation Report

Introduction

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

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. With the following kind of information, states and CMS are best poised to inform and shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

Intent of this Attachment

Title XIX of the Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Attachment is intended to assist states with organizing the required information in a standardized format and understanding the criteria that CMS will use in reviewing the submitted Interim and Summative Evaluation Reports.

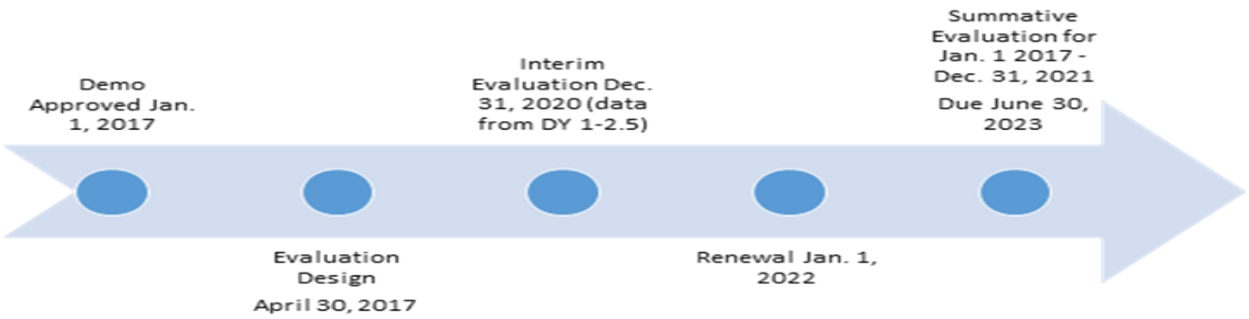
The format for the Interim and Summative Evaluation reports is as follows:

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

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

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish the evaluation design and reports to the state's website within 30 days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of Interim and Summative Evaluation Reports

The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. A copy of the state's Driver Diagram (described in the Evaluation Design Attachment) must be included with an explanation of the depicted information. The Evaluation Report should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. Therefore, the state's submission must include:

A. Executive Summary – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.

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

1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
5) Describe the population groups impacted by the demonstration.

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

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

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

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

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the

data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

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

E. Methodological Limitations

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

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

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

1) In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?

2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:
   a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

H. Interpretations, Policy Implications and Interactions with Other State Initiatives – In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long range planning. This should include interrelations of the demonstration with other aspects of the state's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretation of the data using evaluative reasoning to make

judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

I. Lessons Learned and Recommendations – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

1) What lessons were learned as a result of the demonstration?
2) What would you recommend to other states which may be interested in implementing a similar approach?

J. Attachment

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

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

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

Attachment E: SUD Implementation Protocol

Date: 10-05-18

Overview

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

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

- In 2012, Kentucky passed sweeping legislation that has become a national model. This statute required; the use of Prescription Drug Monitoring Program (PDMP) for all prescribers of controlled substances, regulated pain clinics by requiring them to be physician or hospital owned, and fostered increased cooperation among the PDMP, Kentucky licensure boards and law enforcement.
- In 2015, Kentucky passed several harm reduction measures including; Syringe Exchange, Naloxone Distribution and the Good Samaritan Law.
- In 2015, the Kentucky Board of Medical Licensure (KBML) promulgated a regulation containing buprenorphine prescribing guidelines to help improve the effectiveness of medication assisted treatment with buprenorphine.
- In 2017 House Bill 333 – Introduced as the professional standard of a 3-day prescribing limit on Schedule II controlled substances for acute pain.

[1] Slide 5 SUD DMS Provider Forums 2017 (using 2011-2016 data)

[2] Produced by the Kentucky Injury Prevention and Research Center, May 2016. Kentucky Inpatient Hospitalization Claims Files, Frankfort, KY, [2000-2015]; Cabinet for Health and Family Services, Office of Health Policy. Data for 2010-2015 are provisional; therefore these results are subject to change.

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

Section I – Milestone Completion

Milestones

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

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

- Outpatient Services;
- Intensive Outpatient Services;
- Medication assisted treatment (medications as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state);
- Intensive levels of care in residential and inpatient settings; and
- Medically supervised withdrawal management

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[3] Language from MCO SFY 18 Contracts

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

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

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

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

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

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

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

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

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

- Establish the presence or absence of a mental health disorder, substance use disorder, or co-occurring disorders;
- Determine the individual's readiness for change;
- Identify the individual's strengths or problem areas that may affect the treatment and recovery processes; and
- Engage the individual in developing an appropriate treatment relationship;

- Establish or rule out the existence of a clinical disorder or service need;
- Include working with the individual to develop a treatment and service plan; and
- Does not include psychological or psychiatric evaluations or assessments.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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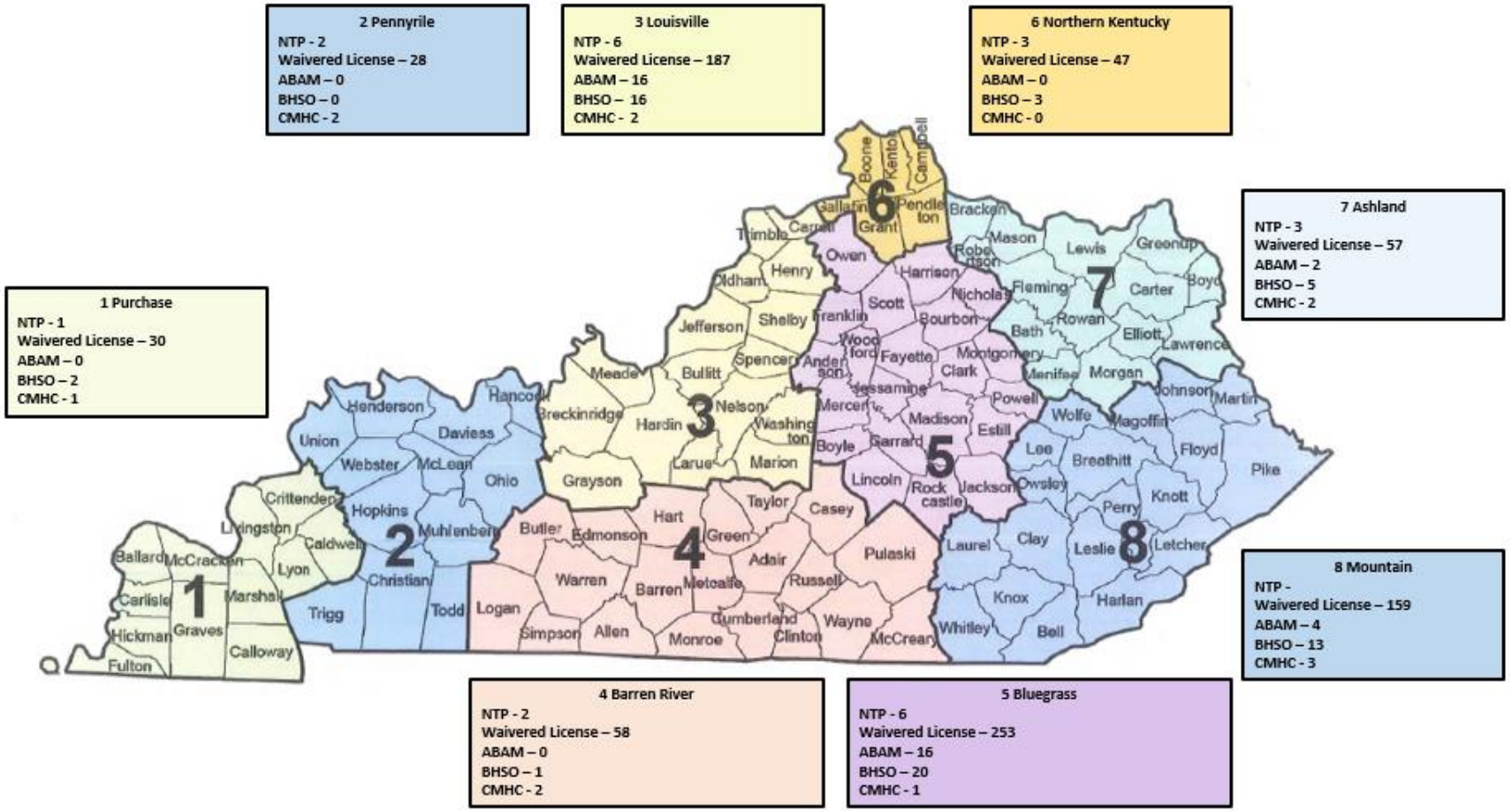

DMS to develop and conduct a survey for Medicaid and Non-Medicaid providers to determine what services they provide related to SUD levels of care and potential for Medicaid enrollment. As part of the survey, Kentucky will be looking at medication assisted treatment (MAT) service capability. Through onsite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

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

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

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

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

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

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

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

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

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

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

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

6. Improved Care Coordination and Transitions between Levels of Care

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

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

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

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

Section II – Implementation Administration

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

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

Section III – Relevant Documents

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

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

Attachment G –SUD Health Information Technology (IT) Plan

Section I.

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

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

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

a. Health IT.Gov in "Section 4: Opioid Epidemic and Health IT."[1]
b. CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" and, specifically, the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.[2]

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

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

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

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

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

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

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

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

Table 1. State Health IT / PDMP Assessment & Plan

Milestone Criteria	Current State	Future State	Summary of Actions Needed	Measurements
5. Implementation of comprehensive treatment and prevention strategies to address Opioid Abuse and OUD, that is: *--Enhance the state's health IT functionality to support its PDMP; and*	*Provide an overview of current PDMP capabilities, health IT functionalities to support the PDMP, and supports to enhance clinicians' use of the state's health IT functionality to achieve the goals of the PDMP.*	*Provide an overview of plans for enhancing the state's PDMP, related enhancements to its health IT functionalities, and related enhancements to support clinicians' use of the health IT functionality to*	*Specify a list of action items needed to be completed to meet the HIT/PDMP milestones identified in the first column. Include persons or entities responsible for completion of each action item. Include*	

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

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

	Card data, and the ability to review the prescriber controlled substance prescribing history to detect errors or fraud.	enhanced Prescriber Report Card that will include patient level data allowing prescribers easier identification of at-risk patients.	1.2 Implement phase 2 of the enhanced KASPER Prescriber Report Card. Responsibility: KASPER Project Manager. Target: completion date: 4/2020.	meetings between KASPER IT team and OIG.
Enhanced connectivity between the state's PDMP and any statewide, regional or local health information exchange	There is currently limited connectivity between KASPER and the statewide health information exchange, KHIE.	Planned projects to integrate KASPER with KHIE include the following: 1.1 Prescriber and pharmacist users can request medical information based on a suspected drug overdose in an Emergency Department (ED). 1.2 Integration with KHIE, so prescriber and pharmacist KHIE users will be able to access KASPER patient data	1.1 Drug toxicity screen results are being reported by the EDs to KHIE. The technical interface between KASPER and KHIE to obtain information regarding the presence of those results is under development. Responsibility: KASPER Project Manager. Target completion: 12/2018 1.2 Develop and implement technology	1.1 This interface is nearly complete. Will be ready by 12/2018. Weekly meetings are currently held. 1.2 This second phase of KASPER to KHIE integration will begin in 2019. Monthly meetings will be held. Should be completed by 12/2020.

		via KHIE without leaving the KHIE process workflow.	to allow integrated data requests and responses between KASPER and KHIE. Responsibility: KASPER Project Manager. Target completion: 12/2020.	
Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns[3] (see also "Use of PDMP" #2 below)	1. KASPER currently identifies and flags patients who are receiving a current daily morphine milligram equivalent dose level of 100 or more. This includes a warning that these patients may be at a higher risk of drug overdose, and that increased clinical vigilance may be appropriate.	1.1 KASPER reports are going to be updated to include warning flags for overlapping opioid prescriptions and overlapping opioid and benzodiazepine prescriptions. 1.2 OIG will utilize an epidemiologist to study the correlation between initial opioid use and ongoing use and abuse.	1.1 Modify KASPER reports to reflect overlapping controlled substance prescriptions. Responsibility: KASPER Project Manager. Target completion: 12/2019. 1.2 Study correlations between initial opioid use and patient misuse and abuse patterns, as well as potentially problematic controlled substance	1.1 This modification will take BA and Development work. Weekly meetings will be held. 12/2019. 1.2 This is an ongoing study that the Epidemiologist will lead.

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

			prescribing practices. Responsibility: OIG Epidemiologist. Target completion: ongoing.	
Current and Future PDMP Query Capabilities				
Facilitate the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP (i.e. the state's master patient index (MPI) strategy with regard to PDMP query)	1.1 KASPER currently utilizes advanced data analytics to match controlled substance prescription records to patients.	1.1 In March 2017 CHFS implemented a new KASPER Data Collection System. Via this system, CHFS is implementing new data reporting edits that are helping to improve the quality of data collected. The improved data quality results in increased probability of accurate patient data matching. 1.2 CHFS is planning to implement an Enterprise Data Warehouse (EDW)	1.1 Continue KASPER data quality improvement efforts. This is needed to ensure and improve data quality. Responsibility: KASPER Project Manager and Project Administrator. Target completion: ongoing. 1.2 Coordinate KASPER patient data matching processes and analytics to be consistent and support a Master Patient Indexing (MPI) within the	1.1 This includes Business Analysts and Resource Management Analysts. This is an ongoing, daily happening. 1.2 This will be done in conjunction with the Data Analytics group within the Commonwealth. Weekly meetings will be held. Target completion of 6/2020.

		that will house KASPER data.	EDW. Responsibility: KASPER Project Manager. Target completion: 6/2020.	
Use of PDMP – Supporting Clinicians with Changing Office Workflows / Business Processes				
Develop enhanced provider workflow / business processes to better support clinicians in accessing the PDMP prior to prescribing an opioid or other controlled substance to address the issues which follow	The KASPER system is currently fully integrated with a major pharmacy chain, and CHFS has received requests from additional health systems to integrate with their EHR systems. The existing pharmacy integration allows the pharmacists to access KASPER data in one simple step without leaving their pharmacy management system workflow.	Integrate with additional EHR and pharmacy systems using solutions that present KASPER data directly in the physician workflow. Capitalize on the integration work done by EHR/Pharmacy system vendors in other states.	1.1 To support additional KASPER/EHR integration and KASPER/KHIE integration, OATS is conducting capacity planning reviews to ensure sufficient resources to support new integration projects. CHFS is supporting federal efforts to develop an API/Web service for PDMP/EHR integration and may also develop an in-house API/Web service to support integration projects.	1.1 This process may be included in the KASPER Modernization project. Weekly meetings will be held during this process.

			Responsibility: KASPER Project Manager. Target completion: 9/2020.	
Develop enhanced supports for clinician review of the patients' history of controlled substance prescriptions provided through the PDMP—prior to the issuance of an opioid prescription	KASPER currently provides detailed prescription history and opioid MME data to health care provider users. Additional functionality is needed to improve the level of care.	1.1 Implement the ability for all KASPER users to obtain class A misdemeanor and felony drug conviction data for the patient. 1.2 Implement a patient dashboard capability to make it easier for healthcare provider KASPER users to identify overlapping prescriptions, early refills, multiple provider episodes, potential drug interactions and other indicators that may indicate overdose risk, or controlled substance abuse or diversion.	1.1 Implement a link to the Administrative Office of the Courts (AOC) CourtNet system to allow KASPER users to see drug conviction data for the previous five years. Responsibility: KASPER and AOC Project Managers. Target completion: 07/2018. 1.2 Evaluate existing patient dashboard tools and capabilities, and determine whether they can be implemented into the current KASPER system or as part of	1.1 This link is currently in the testing phase and will be completed by 7/2018. Weekly meetings are currently being held. 1.2 This evaluation will need to done prior to the modernization project.

			the KASPER modernization project. Responsibility: OIG and OATS. Target completion: 12/2019	
Master Patient Index / Identity Management				
Enhance the master patient index (or master data management service, etc.) in support of SUD care delivery.	While KASPER and KHIE are not currently integrated, KHIE has a defined algorithm MPI that provides match, merge and search capability.	1.1 As noted above, a KASPER/KHIE integration project is in the planning stage. As part of this project KHIE will utilize the enterprise MPI solution for querying KASPER.	1.1 Procurement of a new KHIE vendor solution was just completed. The KASPER/KHIE integration project will be undertaken after implementation of the new KHIE system. Responsibility: KASPER and KHIE Project Managers. Target completion: 11/2019.	1.1 This MPI will be part of the KHIE system. This will require weekly meetings to properly identify the appropriate matching parameters.
Overall Objective for Enhancing PDMP Functionality & Interoperability				
Leverage the above functionalities / capabilities / supports (in concert with any other state health IT, TA or workflow effort) to	1.1 KASPER currently includes a Prescriber Report Card that provides aggregated controlled substance prescribing data and allows prescribers to	1.1 Phase 2 of the Prescriber Report Card will include patient level data allowing prescribers easier identification of at-risk	1.1 Implement phase 2: the enhanced KASPER Prescriber Report Card. Responsibility:	1.1 This drill down option is expected by early 2020. This phase 2 option will have monthly meetings between

implement effective controls to minimize the risk of inappropriate opioid overprescribing—and to ensure that Medicaid does not inappropriately pay for opioids	compare their controlled substance prescribing with all Kentucky prescribers and with prescribers in their specialty area.	patients (drill down options) These Prescriber Report Cards are available to the Kentucky prescriber licensure boards to assist with reviewing for inappropriate or illegal controlled substance prescribing.	KASPER Project Manager. Target: completion date: 4/2020.	KASPER IT team and OIG.

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

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

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

Attachment A, Section II – Implementation Administration

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

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

Attachment A, Section III – Relevant Documents

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