

November 1, 2022

Dawn Stehle
Deputy Director for Health & Medicaid
Arkansas Department of Human Services
P.O. Box 1437
Slot S201
Little Rock, AR 72203-1437

Dear Dr. Stehle:

The Centers for Medicare & Medicaid Services (CMS) is approving Arkansas's request to amend the section 1115(a) demonstration titled, "Arkansas Health and Opportunity for Me" (ARHOME, or the "demonstration") (Project Number 11-W-00365/4), which was originally approved on December 21, 2021, in accordance with section 1115(a) of the Social Security Act ("Act"). Approval of this request will enable Arkansas ("the state"), through various expenditure authorities, to test the efficacy of innovative practices aimed at promoting consistently high-quality, evidence-based, coordinated, and integrated care with the combined goals of providing medical assistance and improving the health of the communities and populations served through the demonstration. The amendment will lead to additional services being furnished to Medicaid beneficiaries.

With this amendment, the state will address health-related social needs (HRSN) among targeted populations through coverage of intensive care coordination and other supports identified in a person-centered action plan provided by Life360 HOMEs. In addition, this amendment will align cost-sharing for the demonstration population with state plan requirements.

As reflected in the statute, the primary objective of the Medicaid program is to furnish medical assistance. This demonstration is expected to promote the objective of furnishing medical assistance by strengthening access to high quality care for all those covered under the demonstration. This amendment will address many of the complex challenges facing many of Arkansas's most vulnerable residents, including individuals with high-risk pregnancies, individuals in rural areas with serious mental illness (SMI) and substance use disorder (SUD) diagnoses, and young adults identified as most at risk for long-term poverty and poor health outcomes. The Life360 HOMEs aim to reduce maternal and infant mortality rates around the state, fill gaps in the continuum of care for individuals with SMI and SUD diagnoses, especially in rural areas, and increase active participation among beneficiaries in improving their health and addressing HRSN.

This approval is effective as of the date of the approval letter through December 31, 2026, upon which date, unless extended or otherwise amended, all authorities granted to operate this demonstration will expire. CMS's approval of this section 1115(a) demonstration amendment is subject to the limitations specified in the attached waiver and expenditure authorities, special terms and conditions (STC), and any supplemental attachments defining the nature, character, and extent of federal involvement in this project. The state may deviate from the Medicaid state plan requirements only to the extent those requirements have been specifically listed as waived or not applicable to expenditures or individuals covered by expenditure authority under the demonstration.

Extent and Scope of the Demonstration Amendment

This amendment provides Arkansas with expenditure authority to establish "Life360 HOMEs" to offer intensive care coordination and connection to services, pursuant to a person-centered support plan, to address various HRSN for the populations listed below. Through approving the Life360 HOMEs, CMS is permitting access to services that address an array of HRSN. Services to address HRSN also aim to help reduce health disparities that are often rooted in social and economic disadvantages. The state will work with local hospitals to implement LIFE360 HOMEs. The focus populations identified below will be served by three types of Life360 HOMEs:

- 1) Rural Life360 HOMEs will support individuals with SMI or SUD diagnosis who live in rural areas of the state;
- 2) Maternal Life 360 HOMEs will support individuals with high-risk pregnancies, as identified by their physician; and
- 3) Success Life360 HOMEs will support young adults (ages 19-27) at high-risk for long-term poverty due to prior incarceration, involvement with the foster care system, or young adults (ages 19-24) with involvement with the juvenile justice system and veterans ages 19-30 who are at high risk of homelessness.

Life360 HOMEs are designed to provide beneficiaries with intensive care coordination and connect them to necessary health services and community supports, address HRSNs, and actively engage beneficiaries in promoting their own health care.

CMS is also authorizing Arkansas to provide or increase coverage of certain services that address HRSN for Life360 HOME beneficiaries, as evidence indicates that HRSNs are a critical driver an individual's access to health services that help to keep them well.^{1,2} These services include

¹ As discussed in a letter to State Health Officials issued on January 7, 2021, <https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf>, addressing Social Determinants of Health can more effectively improve population health, reduce disability, and lower overall health care costs in the Medicaid program. While "social determinants of health" is a broad term that relates to the health of all people, HRSN relates more specifically to an individual's adverse conditions reflecting needs that are unmet and contribute to poor health. See also <https://www.healthaffairs.org/doi/10.1377/forefront.20191025.776011/full/>.

² Bachrach, D., Pfister, H., Wallis, K., Lipson, M. *Addressing Patients' Social Needs: An Emerging Business Case for Provider Investment*. The Commonwealth Fund; 2014; https://www.commonwealthfund.org/sites/default/files/documents/media_files_publications_fund_report_2014_may_1749_bachrach_addressing_patients_social_needs_v2.pdf.

critical housing and nutritional services as well as case management, outreach, and education, and infrastructure investments.

Services authorized in this demonstration to address HRSN must be medically appropriate for the eligible beneficiary. In Arkansas, Life360 HOME HRSN services will be provided for individuals enrolled in a Life360 HOME, as described above. Coverage of targeted Life360 HOME HRSN services and supports is likely to assist in promoting the objectives of Medicaid because it is expected to help individuals stay connected to coverage and is also expected to provide a regular source of needed care to meet individuals' comprehensive health needs, expanding the degree to which eligible individuals receive the medical assistance to which they are entitled. A central objective of Medicaid is to furnish medical assistance. The targeted Life360 HOME HRSN services can be expected to promote that key objective in a number of ways. For example, lack of stable housing or inadequate nutrition may impede an individual's ability to enroll in coverage and access needed health care. Such circumstances may create physical, social or emotional conditions that are counterproductive to the otherwise positive effects of the health care services an individual does receive, including through Medicaid.³ The housing and nutritional support services covered under the demonstration can be expected to stabilize the housing and nutritional situations of eligible Medicaid recipients and thus increase the likelihood that they will keep receiving and benefiting from the Medicaid-covered services to which they are entitled.

Moreover, the Medicaid statute, including both sections 1905 and 1915 of the Act, reflects the critical role of upstream services (i.e., those that help avert more intensive medical interventions) in meeting the medical assistance needs of certain Medicaid-eligible populations (e.g., individuals with disabilities). For example, medical assistance made available under a waiver authorized under section 1915(c) of the Act is provided as a home and community-based alternative to avoid the need for more intensive institutional-based care. Medical assistance made available under a state plan option authorized under section 1915(i) of the Act provides that same package of home and community-based services to individuals meeting needs-based criteria that are less stringent than criteria required for institutional placement. These services are also intended to avert a need for nursing facility care. Both provisions authorize services, including habilitation services such as pre-tenancy and tenancy support services, with a goal of preventing decline in beneficiary health that would require more intensive services. Similarly, medical assistance covering interventions aimed at improving asthma management and mitigating asthma triggers is another example of how the Medicaid statute gives states authority to help reduce beneficiary need for acute care services (e.g., emergency department visits).

Available evidence⁴ suggests that there may be populations in addition to those eligible under 1915(c) or 1915(i) criteria that would benefit clinically from the section 1915(c) or 1915(i) services described above, as well as additional upstream HRSN services that would benefit targeted populations, and that additional research is needed on the effects of providing those

³ Schilbach, F., Schofield, H., Mullainathan, S. The Psychological Lives of the Poor. American Economic Review: Papers & Proceedings; 2016; <http://dx.doi.org/10.1257/aer.p20161101>.

⁴ September 23, 2021. ASPE Contractor Project Report: Building the Evidence Base for Social Determinants of Health Interventions. <https://aspe.hhs.gov/reports/building-evidence-base-social-determinants-health-interventions>.

types of services to a broader group of people. Expanding who can receive these services is expected to help a broader range of Medicaid beneficiaries receive the medical assistance, to which they are entitled, and benefit from it, and this demonstration will test this hypothesis. This demonstration will test whether expanding eligibility for these services to additional populations or providing additional services will improve the health outcomes of certain Medicaid beneficiaries. Covering these services for a broader range of beneficiaries, which may improve their ability to access care, is also expected to enable the state's Medicaid program to reach more eligible individuals by promoting recipients' health, reducing the future and downstream cost of medical interventions, and thus allowing the program's resources to go farther. These services are also expected to further help to reduce health disparities that are often rooted in social and economic disadvantages.⁵ Thus, broadening the availability of certain HRSN services is expected to promote coverage, improve access to and quality of care, improve health outcomes, reduce health disparities, and create long-term, more cost-effective alternatives or supplements to traditional medical services.

CMS's authorization of limited infrastructure spending as part of this HRSN framework, such as paying for health information technology system investments and provider workforce investments, is expected to help providers that furnish covered services to beneficiaries improve the availability and quality of their services, thereby improving health outcomes for beneficiaries. CMS also expects the state to maintain existing state-level funding and efforts for HRSN services, without this demonstration authority supplanting existing efforts, and to have in place partnerships with other state and local entities to coordinate possible pathways to permanency for services to be provided without demonstration authorities.

To promote administrative simplicity for the state, this amendment will also align cost-sharing obligations for most members in the Qualified Health Plans (QHPs) with the Medicaid state plan and reflect nominal amounts allowed by statute and regulation. Cost-sharing will be subject to an aggregate cap of no more than 5 percent of family monthly or quarterly income. Cost-sharing limitations described in 42 CFR 447.56(a) will be applied to all program beneficiaries.

Budget Neutrality

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

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

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

called the budget neutrality expenditure limit and is based on a projection of the Medicaid expenditures that could have occurred absent the demonstration (the “without waiver” (WOW) costs). Historically, if a state’s “with waiver” (WW) costs for a demonstration approval period were less than the expenditure limit for that period, the unspent funds or “savings” rolled over into the next approval period, which meant that the state could incur higher WW costs during the new approval period.

CMS and states have generally been applying an approach to calculating budget neutrality that CMS described in a 2018 State Medicaid Director (SMD) Letter.⁶ In this approval, CMS has reevaluated and is modifying certain aspects of the budget neutrality approach described in the 2018 SMD Letter, in an attempt to better support state innovation, in line with Section 1115 of the Act, while maintaining its commitment to fiscal integrity. While CMS evaluates each demonstration proposal on a case-by-case basis, CMS anticipates that it will apply these or similar updates in its approach to budget neutrality consistently to all similarly situated states, going forward.

Specifically, CMS is treating certain HRSN expenditures as “hypothetical” for purposes of Arkansas’s budget neutrality calculation. As described in the 2018 SMD Letter, CMS effectively treats a hypothetical expenditure like an expenditure that the state could have made absent the demonstration, when calculating budget neutrality. As a result, hypothetical expenditures are included in both the WOW baseline and the estimate of the WW expenditures under the demonstration. States do not have to find demonstration “savings” to offset hypothetical expenditures. However, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued “savings” from hypothetical expenditures. That is, “savings” are not generated from a hypothetical population or service if the state does not spend up to the hypothetical expenditure limit. To allow for hypothetical expenditures, while preventing them from resulting in “savings,” CMS applies a separate, independent budget neutrality “supplemental test” for hypothetical expenditures. These supplemental budget neutrality tests subject the hypothetical expenditures to predetermined limits to which the state and CMS agree, and that CMS approves, during negotiations. If the state’s WW hypothetical spending exceeds the supplemental test’s expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending by finding “savings” elsewhere in the demonstration or to refund the federal matching funds to CMS. In the 2018 SMD Letter, CMS explained that it has historically considered demonstration expenditures to be “hypothetical” in the following circumstances: (1) when they are for populations or services that the state could otherwise have covered under its Medicaid state plan or other title XIX authority, such as a waiver under section 1915 of the Act; or (2) when a WOW spending baseline is difficult to estimate due to variable and volatile cost data resulting in anomalous trend rates (e.g., CMS has treated demonstration expenditures on the “adult group” described in section 1902(a)(10)(A)(i)(VIII) of the Act as hypothetical for this reason).

Under this approval, approved HRSN expenditures are considered “hypothetical” expenditures and are included in the budget neutrality WOW baseline. Some of these expenditures, as discussed above, are expenditures for services that the state could otherwise cover under other

⁶ August 22, 2018. SMD#18-009 RE: Budget Neutrality Policies for Section 1115(a) Medicaid Demonstration Projects. <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18009.pdf>

title XIX authority, such as tenancy and nutrition supports for certain beneficiaries. Treating those expenditures as hypothetical is consistent with how CMS has historically treated similar expenditures. While other approved HRSN expenditures could not otherwise be covered under title XIX authority, such as expenditures on section 1915(c) and 1915(i) services for beneficiaries who would not otherwise be eligible for them under section 1915, there are insufficient or inconsistent data to calculate a WOW baseline for at least some of these expenditures. Treating those expenditures as hypothetical is also consistent with how CMS has historically treated similar expenditures. As discussed above, based on robust academic-level research, it appears likely that these state expenditures could improve the quality and effectiveness of downstream services that can be provided under state plan authority.⁷ And, as also discussed above, covering HRSN services might improve recipients' health, reducing the future downstream costs of medical care for these beneficiaries. At the same time, predicting the downstream effects on overall Medicaid program costs of covering certain evidence-based HRSN services is extremely difficult, making it hard for CMS to pinpoint the estimated fiscal impact of these expenditures on demonstration budget neutrality or on the state's overall Medicaid program. Treating demonstration HRSN expenditures as hypothetical will give the state the flexibility to test these worthy innovations, especially as CMS anticipates that they might result in overall reductions in future Medicaid program costs.

Historically, CMS has often authorized expenditures through Section 1115 demonstrations subject to expenditure limits. In this case, to ensure that treating these HRSN expenditures as hypothetical will not have a significant negative impact on Medicaid fiscal program integrity, CMS is applying a budget neutrality spending cap to HRSN services expenditures and an additional sub-cap to HRSN infrastructure expenditures, and is referring to these expenditures as “capped hypothetical expenditures” in the STCs. The caps on expenditures for these HRSN services and related infrastructure activities differ from the usual limit CMS places on hypothetical expenditures under the “supplemental test” discussed above in several respects. Ordinarily, if a state exceeds the hypothetical expenditure limit it can offset the additional costs with savings from the rest of the demonstration. That will not be permitted with these HRSN expenditures. However, unspent expenditure authority allocated for HRSN infrastructure in a given demonstration year can be applied to HRSN services in the same demonstration year. Any unspent HRSN services expenditure authority may not be used to fund HRSN infrastructure. The expenditures subject to the cap are narrowly defined to reflect only expenditures associated with services that research indicates are likely to have certain positive downstream effects, as discussed above. Also, the upper limit on the cap is based on a range of estimates of the likely cost of these expenditures over the course of a five-year period, and set at a mid-point in that range. While this cap deviates from the traditional approach to hypothetical expenditures, it is consistent with CMS's historical approach to maintaining budget neutrality in Medicaid demonstrations and it does not alter the underlying financing structure of the Medicaid program. This cap will ensure that the state maintains its investment in the state plan benefits to which

⁷ Lipson, D. J. Medicaid's Role in Improving the Social Determinants of Health: Opportunities for States. National Academy of Social Insurance; 2017; https://www.nasi.org/wp-content/uploads/2017/06/Opportunities-forStates_web.pdf; Whitman, A., De Lew, N., Chappel, A., et al. Addressing Social Determinants of Health: Examples of Successful Evidence-Based Strategies and Current Federal Efforts. Assistant Secretary for Planning and Evaluation; 2022; <https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fac7474af82/SDOHEvidence-Review.pdf>.

enrollees are entitled while testing the benefit of the HRSN services described above. This cap will not apply to any other benefits or services.

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

Components of the Proposal Not Being Approved at This Time

Several components of the state’s request remain under review and are not being approved at this time. Arkansas proposes programmatic and eligibility changes that may impact ARHOME beneficiaries and QHP requirements. Details of these requests require additional development and discussion, and in some instances, the state has indicated it intends to further engage stakeholders in this development process. In addition, the state requested FFP for medical services for beneficiaries residing in institutions for mental diseases (IMD), but currently, Arkansas’s proposal does not fully align with the requirements outlined in the agency’s policy for the IMD authority stated in the State Medicaid Director Letters #17-003⁸ and #18-011,⁹ and therefore CMS is not approving this request at this time.

Monitoring and Evaluation

Consistent with CMS requirements for section 1115 demonstrations, and as outlined in the ARHOME demonstration STCs, the state is required to conduct systematic monitoring and robust evaluation of the demonstration, including the policies and initiatives approved through this amendment, per applicable CMS guidance and technical assistance. The demonstration’s monitoring activities must support tracking the state’s progress toward meeting the goals — including relative to their projected timelines—of the demonstration’s program and policy implementation and infrastructure investments. As was stated in the ARHOME demonstration approval in December 2021, the state must report on categories of metrics including, but not

⁸ <https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf>

⁹ <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18011.pdf>

limited to: enrollment and renewal, including enrollment duration, access to providers, utilization of services, enrollment by premium payment status, unpaid medical bills at application, quality of care, and health outcomes. The state is required to do robust reporting of quality of care and health outcomes aligned with the demonstration's policies and objectives, to be reported for all demonstration populations. Such reporting must also be stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, English language proficiency, primary language, disability status, and geography), and by demonstration components, to the extent feasible. Subpopulation reporting will support identifying any existing shortcomings or disparities in quality of care and health outcomes and help track whether the demonstration's initiatives help improve outcomes for the state's Medicaid population, including the narrowing of any identified disparities. To that end, CMS underscores the importance of the state's reporting of quality of care and health outcomes metrics known to be important for closing key equity gaps in Medicaid and CHIP (e.g. the National Quality Forum (NQF) "disparities-sensitive" measures) and prioritize key outcome measures and their clinical and non-clinical (i.e. social) drivers of health. In coordination with CMS, the state is expected to select such measures for reporting in alignment with a critical set of equity-focused measures CMS is finalizing as part of its upcoming guidance on the Health Equity Measure Slate.

For the Life360 HOMEs component of the demonstration, in addition to reporting on the metrics described above, the state must track beneficiary participation, screening, receipt of referrals and social services over time, as well as narratively report on the adoption of information technology infrastructure to support data sharing between the state or partner entities assisting in the administration of the demonstration and social service organizations. Furthermore, the state's enrollment and renewal metrics must also capture baseline data and track progress via Monitoring Reports for the percent of Medicaid renewals completed ex-parte (administratively), as well as the percentage of Medicaid beneficiaries enrolled in other public benefit programs (such as, Supplemental Nutrition Assistance Program (SNAP) and Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)) for which they are eligible. The Monitoring Reports must also provide status updates in accordance with the Monitoring Protocol on the implementation of infrastructure investments tied to HRSN initiatives. In addition, if the state, health plans, or health care providers will contract or partner with organizations to implement Life360 HOMEs, the state must use monitoring metrics that track the number and characteristics of contracted or participating organizations in specific demonstration programs and corresponding payment-related metrics. The state will continue reporting metrics data and pertinent information on the other demonstration components, as was established during the initial approval of the ARHOME demonstration. CMS and the state will work collaboratively to finalize the draft Monitoring Protocol the state prepared for the December 2021 ARHOME demonstration approval, and expand it—or develop a second Monitoring Protocol—to include the Life360 HOMEs programs. Once approved, this protocol will drive the demonstration's monitoring activities.

Furthermore, as was underscored with the ARHOME demonstration approval on December 21, 2021, and under the STCs and consistent with current CMS guidance, the state must develop a rigorous Evaluation Design that supports a comprehensive and meaningful evaluation of the demonstration to assess whether the demonstration components, including any components added to the demonstration through this amendment, are effective in producing the desired

outcomes for its beneficiaries and providers, and the state’s overall Medicaid program. In compliance with the STCs, Arkansas submitted to CMS a draft Evaluation Design for the policies approved in December 2021 (including premium requirements, premium assistance, and waiver of retroactive eligibility) using robust data sources and sound analytic approaches, which currently remains under CMS review. With this amendment approval, the state can choose either to amend its existing draft Evaluation Design or submit a separate Evaluation Design. The demonstration evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components—including those that were authorized in the initial approval of the ARHOME demonstration—that support understanding the demonstration’s impact on beneficiary coverage, access to and quality of care, and health outcomes, as well as its effectiveness in achieving the various policy goals and objectives.

In addition to the evaluation hypotheses for ARHOME policies that were previously approved in December 2021, hypotheses for the Life360 HOMEs component of the demonstration must focus on areas such as beneficiary utilization of HRSN services, severity of beneficiaries’ social needs, the effectiveness of services received in mitigation of identified needs, utilization of preventive and routine care, utilization of and costs associated with potentially avoidable, high-acuity health care, and beneficiary physical and mental health outcomes. More specifically, the evaluation must analyze—among other outcomes—maternal and infant health outcomes for participants in the Maternal Life360 HOMEs; utilization of behavioral health and substance use disorder treatments for individuals with relevant diagnoses in Rural Life360 HOMEs; and the impact of incentives and supports to assist individuals in Success Life360 HOMEs. Given the populations of focus and the program designs of the Life360 HOMEs, the state must also outline goals on how the demonstration may reduce inequities in health care access, quality of care, or health outcomes at the individual and/or community level and include corresponding research questions and hypotheses focused on understanding the impact of the Life360 HOMEs on health quality, including through the reduction of health disparities.

The evaluation must also assess the effectiveness of the infrastructure investments authorized through the demonstration to support the development and implementation of the HRSN initiatives. The state must also examine whether and how local investments in housing, nutrition, and any other type of allowable HRSN services change over time in concert with new Medicaid funding toward those services. In addition, in light of how demonstration HRSN expenditures are being treated for purposes of budget neutrality, the evaluation of the HRSN initiative must include a cost analysis to support developing comprehensive and accurate cost estimates of providing such services. The state is also required to include a robust assessment of potential improvements in the quality and effectiveness of downstream services that can be provided under the state plan authority, and associated cost implications. Additionally, as part of its evaluation efforts, the state must also conduct a demonstration cost assessment to include, but not be limited to, administrative costs of demonstration implementation and operation, Medicaid health services expenditures, and provider uncompensated care costs. In addition, the state must use findings from hypothesis tests aligned with other demonstration goals and cost analyses to assess the demonstration’s effects on the fiscal sustainability of the state’s Medicaid program.

The state is strongly encouraged to evaluate the implementation of the demonstration programs to better understand whether implementation of certain key demonstration policies happened as

envisioned during the demonstration design process and whether specific factors acted as facilitators of—or barriers to—successful implementation. The implementation evaluation can inform the state’s crafting and selection of testable hypotheses and research questions for the demonstration’s outcome and impact evaluations and provide context for interpreting the findings. In addition, CMS underscores the importance of the state undertaking a well-designed beneficiary survey and/or interviews to assess, for instance, beneficiary understanding of the various demonstration policy components, including the Life360 HOMEs, and beneficiary experiences with access to and quality of care.

Finally, to the extent feasible, evaluation activities must accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, English language proficiency, primary language, disability status, and geography). Such stratified data analyses will provide a fuller understanding of existing disparities in access to, and quality of, care and health outcomes, and help inform how the demonstration’s various policies might support reducing such disparities.

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 demonstration 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 comment period occurs at the federal level after the application is received by the Secretary. Section 1115(d)(2)(A) and (C) of the Act, further specifies 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 necessarily provide written responses to all public comments (42 CFR 431.416(d)(2)). Public comments on the demonstration features CMS is approving today were submitted during the public comment periods on the state’s initial ARHOME application. The state conducted a 30-day public notice and comment period on the draft proposal from June 13, 2021 through July 12, 2021. The state submitted the proposal to CMS on July 20, 2022, but the application package was found to be incomplete due to lack of posting the full public notice document. The state conducted an additional 30-day public notice and comment period on the proposal, including the full public notice document, from August 15, 2021 through September 13, 2021.

The federal comment period was open from September 24, 2021 through October 24, 2021. A total of 13 comments were submitted, which CMS analyzed. Eleven of the 13 comments expressed concerns about cost sharing and the barriers that premiums and copayments may present for certain populations. CMS took such public comments and the body of available evidence on premium policies in section 1115 demonstrations under consideration and stipulated a phase-out of the premiums authority in the ARHOME demonstration by the end of the first year of the demonstration approval period in the December 21, 2021 ARHOME demonstration approval. In regard to concerns about copayments, all changes included in this amendment are in

line with Medicaid cost-sharing regulations. While more people will be required to pay copayments, the amounts are at or below the required nominal amounts for beneficiaries with income less than 100 percent FPL.

These eleven comments also opposed the state's proposal to reduce the period of retroactive coverage from 90 to 30 days. As was mentioned in the initial ARHOME approval letter issued in 2021, CMS continues to collaborate with the state on its monitoring and evaluation efforts to rigorously assess the effects of this policy on beneficiaries and providers. For example, CMS is currently working with the state in designing a comprehensive evaluation of the policy using robust data, including a well-designed beneficiary survey.

Comments of support for the demonstration were generally related to the establishment of the Life360 HOMEs and the state's goal of addressing HRSN through intensive care management services, although commenters did have questions about implementation of the Life360 HOME program, such as how hospitals will create the infrastructure to support these programs. The infrastructural supports offered in the demonstration can be expected to serve an essential role in facilitating the Life360 HOMEs. CMS's authorization of limited infrastructure spending as part of this HRSN framework, such as paying for health information technology system investments and provider workforce investments is expected to help providers that furnish covered services to beneficiaries improve the availability and quality of their services, which CMS expects to also improve health outcomes for beneficiaries.

Other Information

CMS's approval of this amendment is conditioned upon compliance with the enclosed set of expenditure authorities and the STCs defining the nature, character, and extent of anticipated federal involvement in the demonstration.

The award is subject to CMS receiving written acceptance of this award within thirty (30) days of the date of this approval letter. Your project officer for this demonstration is Ms. April Wiley. She is available to answer any questions concerning the demonstration and these amendments. Ms. Wiley'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: April.Wiley@cms.hhs.gov

We appreciate your state's commitment to improving coverage and access to health care for people in Arkansas, and we look forward to partnering with you on the ARHOME section 1115(a) demonstration. 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,



Daniel Tsai
Deputy Administrator and Director

Enclosures

cc: Michala Walker, State Monitoring Lead, Medicaid and CHIP Operations Group

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

NUMBER: 11-W-00379/6

TITLE: Arkansas Health and Opportunity for Me Section 1115
Demonstration

AWARDEE: Arkansas Department of Human Services

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by the state for the items identified below, which are not otherwise included as expenditures under section 1903 shall, for the period of this demonstration from January 1, 2022 through December 31, 2026, unless otherwise stated, be regarded as expenditures under the state's Title XIX plan, but are further limited by the special terms and conditions (STCs) for the Arkansas Health and Opportunity for Me (ARHOME) section 1115 demonstration.

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

- 1. Premium Assistance and Cost Sharing Reduction Payments.** Expenditures for part or all of the cost of private insurance premiums in the individual market, and for payments to reduce cost sharing under such coverage for certain beneficiaries as described in these STCs.
- 2. Life360 HOMEs and Health-Related Social Needs (HRSN) Services.** Effective November 1, 2022, expenditures for approved evidence-based health-related social needs services not otherwise eligible for Medicaid payment furnished to individuals who meet the qualifying criteria as described in STC 44.
- 3. Expenditures for Life360 HOME Services Infrastructure.** Effective November 1, 2022, expenditures for allowable administrative costs and infrastructure not otherwise eligible for Medicaid payment, to the extent such activities are authorized as part of the approved Infrastructure activities in STC 42.
- 4. Maternal Life360 HOME Services.** Expenditures for Maternal Life360 HOME services for up to 2 years postpartum for individuals with high risk pregnancies, as defined by their physician, who become ineligible for Medicaid coverage during their enrollment in a Maternal Life360 HOME.

Requirements Not Applicable to Expenditure Authorities:

- 1. Cost Effectiveness** Section 1902(a)(4) and 42 CFR 435.2025(a)(4)

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To the extent necessary to permit the state to offer, with respect to beneficiaries through qualified health plans, premium assistance and cost sharing reduction payments that are determined to be cost effective using state developed tests of cost effectiveness that differ from otherwise permissible tests for cost effectiveness as described in these STCs.

2. Amount, Duration, and Scope of Services and Comparability **Section 1902(a)(10)(B) and 1902(a)(17)**

To the extent necessary to allow the state to offer Life360 HOME services as described in STC 40.

To the extent necessary to enable the state to provide Life360 HOME services based on systems of service that are not otherwise available to all beneficiaries in the same eligibility group.

3. Statewideness **Section 1902(a)(1)**

To the extent necessary to enable the State to provide Life360 HOME services on a less than statewide basis.

4. Freedom of Choice **Section 1902(a)(23)(A)**

To the extent necessary to enable Arkansas to limit beneficiaries' freedom of choice with respect to Life360 HOME Services to providers participating in a Life360 HOME.

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

NUMBER: 11-W-00379/6

TITLE: Arkansas Health and Opportunity for Me Section 1115
Demonstration

AWARDEE: Arkansas Department of Human Services

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, shall apply to the demonstration project effective January 1, 2022 through December 31, 2026. In addition, these waivers may only be implemented consistent with the approved Special Terms and Conditions (STCs).

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

1. Freedom of Choice **Section 1902(a)(23)(A)**

To the extent necessary to enable Arkansas to limit beneficiaries' freedom of choice among providers to the providers participating in the network of the beneficiary's Qualified Health Plan. No waiver of freedom of choice is authorized for family planning providers.

2. Payment to Providers **Section 1902(a)(13) and Section 1902(a)(30)**

To the extent necessary to permit Arkansas to provide for payment to providers equal to the market-based rates determined by the Qualified Health Plan.

3. Prior Authorization **Section 1902(a)(54) insofar as it incorporates Section 1927(d)(5)**

To permit Arkansas to require that requests for prior authorization for drugs be addressed within 72 hours, and for expedited review in exigent circumstances within 24 hours, rather than 24 hours for all circumstances as is currently required in their state policy. A 72- hour supply of the requested medication will be provided in the event of an emergency.

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

To the extent necessary to enable Arkansas to collect monthly premium payments, for

beneficiaries with incomes above 100 up to and including 133 percent of the federal poverty level (FPL) as described in these STCs. This waiver authority will sunset on December 31, 2022.

5. Comparability

Section 1902(a)(10)(B)

To the extent necessary to enable the state to impose targeted cost sharing on beneficiaries as described in these STCs.

6. Retroactive Eligibility

Section 1902(a)(34)

To enable the state to not provide beneficiaries in table 1 retroactive eligibility but for 30 days prior to the date of the application for coverage under the demonstration.

**CENTERS FOR MEDICARE AND MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS**

NUMBER: 11-W-00379/6

TITLE: Arkansas Health and Opportunity for Me

AWARDEE: Arkansas Department of Human Services

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the Arkansas Health and Opportunity for Me (ARHOME) section 1115(a) Medicaid demonstration (hereinafter demonstration) to enable the Arkansas Department of Human Services (state) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted waivers of requirements under section 1902(a) of the Social Security Act (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 during the life of the demonstration.

These STCs are effective January 1, 2022 through December 31, 2026, unless otherwise stated.

The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description and Objectives
- III. General Program Requirements
- IV. ARHOME Program Populations Affected
- V. ARHOME Premium Assistance Enrollment
- VI. Premium Assistance Delivery System
- VII. Benefits
- VIII. Improving Health Outcomes Through Intensive Care Coordination for Populations Most At Risk of Poor Health (Life360 HOMEs)
- IX. Premiums & Cost Sharing
- X. Fair Hearings
- XI. Monitoring and Reporting Requirements
- XII. General Financial Requirements
- XIII. Monitoring Budget Neutrality
- XIV. Evaluation of the Demonstration
- XV. Schedule of Deliverables

Attachment A: Copayment Amounts

Attachment B: Developing the Evaluation Design

Attachment C: Preparing the Interim and Summative Evaluation Reports

Attachment D: New Initiatives Implementation Plan (reserved)
Attachment E: Monitoring Protocol (reserved)
Attachment F: Evaluation Design (reserved)
Attachment G: Life360 HOME Definitions and Eligibility
Attachment H: Life360 HOME Services Details (reserved)
Attachment I: Protocol for Assessment of Beneficiary Eligibility and Needs, Infrastructure Planning, and Provider Qualifications (reserved)

II. PROGRAM DESCRIPTION AND OBJECTIVES

Under the prior section 1115 demonstration, Arkansas Works, the state provided premium assistance to support the purchase by beneficiaries eligible under the adult group under the state plan of coverage from qualified health plans (QHPs) offered in the individual market through the Marketplace. Enrollment activities for the adult population began on October 1, 2013, for QHPs with eligibility effective January 1, 2014. Beginning in 2014, individuals eligible for coverage under the adult group are described at Section 1902(a)(10)(A)(i)(VIII) of the Social Security Act and were further specified in the state plan. The Arkansas Works demonstration terminated on December 31, 2021.

Effective January 1, 2022, the ARHOME demonstration began providing the premium assistance for the adult group.

As of November 1, 2022, the ARHOME demonstration will also provide additional supportive services to targeted populations through Life360 HOMEs, as specified in these STCs. Life360 HOMEs will provide participants with intensive care coordination to connect them to needed health services and community supports, address health-related social needs (HRSN), and actively engage them in promoting their own health. Beneficiary participation in a Life360 HOME will be voluntary and services available under a Life360 HOME will be supplemental to any medical services already covered by the beneficiary's QHP or Medicaid fee for service (FFS). ARHOME will create three types of Life360 HOMEs:

1. Maternal Life360 HOMEs will support individuals with high-risk pregnancies, as identified by their physician, and up to two years post-partum, even if the individual is no longer eligible for Medicaid under any other category, either through Maternal Life360 HOME's provision of evidence-based home visitation or through contracts with evidence-based home visitation programs;¹
2. Rural Life360 HOMEs will support individuals with a serious mental illness (SMI) or substance use disorder (SUD) diagnosis who live in rural areas of the state through intensive care coordination provided directly or through contracts with organizations to provide care coordination; and

¹ The Maternal Life360 HOME will include leveraging the state home visiting program infrastructure that is being implemented in counties statewide and administered by the Arkansas Department of Health with Maternal, Infant and Early Childhood Home Visiting (MIECHV) program to expand current access and capacity for evidence-based home visiting for high-risk pregnant individuals. Funding authorized under this demonstration will expand access to this home visiting program and current funding levels for MIECHV will not be reduced.

3. Success Life360 HOMEs will support young adults (ages 19-27) at high-risk for long-term poverty due to prior incarceration, involvement with the foster care system, or young adults (ages 19-24) with involvement with the juvenile justice system and veterans ages 19-30 who are at high risk of homelessness. Success Life360s will provide intensive care coordination directly or contract with organizations to provide care coordination.

Throughout the demonstration period, the state will work towards achieving several demonstration goals. These goals will inform the state's Evaluation Design hypotheses, subject to CMS approval, as described in these STCs. The demonstration's goals include, and are not limited to, the following:

- Providing continuity of coverage for individuals,
- Improving access to providers,
- Improving continuity of care across the continuum of coverage, and
- Furthering quality improvement and delivery system reform initiatives that are successful across population groups.
- Improving the health outcomes among Arkansans especially in maternal and infant health, rural health, behavioral health, and those with chronic diseases
- Providing supports to assist individuals, especially young adults in target populations, to move out of poverty; and
- Slowing the rate of growth in federal and state spending on the program so the demonstration will be financially sustainable.

Arkansas proposes that the demonstration will provide integrated coverage for low-income Arkansans, leveraging the efficiencies and experience of the private market to improve continuity, access, and quality of care for ARHOME beneficiaries that should ultimately result in lowering the rate of growth in premiums across population groups. The state proposes that the demonstration will also drive structural health care system reform and more competitive premium pricing for all individuals purchasing coverage through the Marketplace by at least doubling the size of the population enrolling in QHPs offered through the Marketplace. The state proposes to demonstrate the following key features:

Continuity of coverage and care - The demonstration will allow qualifying households to stay enrolled in the same plan regardless of whether their coverage is subsidized through Medicaid, or Advanced Premium Tax Credits (APTC).

Support equalization of provider reimbursement and improve provider access - The demonstration will support equalization of provider reimbursement across payers, toward the end of expanding provider access and eliminating the need for providers to cross-subsidize. Arkansas Medicaid provides rates of reimbursement lower than Medicare or commercial payers, causing some providers to forego participation in the program and others to "cross subsidize" their Medicaid patients by charging more to private insurers.

Integration, efficiency, quality improvement and delivery system reform - Arkansas is proposing taking an integrated and market-based approach to covering uninsured Arkansans. It

is anticipated that QHPs will bring the experience of successful private sector models that can improve access to high quality services and lead delivery system reform.

III. GENERAL PROGRAM REQUIREMENTS

- 1. Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and Section 1557 of the Affordable Care Act (Section 1557).
- 2. Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid program and CHIP programs, expressed in federal law, regulation, and policy statement, that are 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 policy statement, come into compliance with changes in law, regulation, or written policy affecting the Medicaid 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 as needed 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. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.
- 4. Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
 - a. To the extent that a change in federal law, regulation, or written 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 and/or a modified allotment neutrality worksheet for the demonstration as necessary to comply with such change. The modified budget neutrality and/or modified allotment neutrality agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. 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, regulation, or policy require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

5. **State Plan Amendments.** The state will not be required to submit title XIX or 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 is required, except as otherwise noted in these STCs. In all such instances the Medicaid and CHIP state plan governs.
6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, evaluation design, 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 or begin operational changes to these demonstration elements without prior approval. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available for amendments to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3 or as otherwise specified in the STCs.
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 required reports and other deliverables according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:
 - a. An explanation of the public notice process used by the state, consistent with the requirements of STC 13. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;
 - b. A detailed description of the amendment including impact on beneficiaries, with sufficient supporting documentation;
 - c. A data analysis worksheet which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable “with waiver” and “without waiver” status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the “with waiver” expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
 - d. An up-to-date CHIP allotment neutrality worksheet, if necessary; and
 - e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design

and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

8. **Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS from the Governor of the state in accordance with the requirements of 42 CFR § 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit a phase-out plan consistent with the requirements of STC 9.
9. **Demonstration Phase Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.
 - a. **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 draft transition and phase-out plan. The state must submit a notification letter and a draft plan to CMS no less than 6 months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft 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 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 redeterminations of Medicaid or CHIP eligibility prior to the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will take 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 begin 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 redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR 435.916(f)(1) or for children in CHIP consider eligibility for other insurance affordability programs under 42 CFR 457.350. For individuals determined ineligible for Medicaid and CHIP, the Commonwealth must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR

435.1200(e). The state must comply with all applicable notice requirements for Medicaid found in 42 CFR, part 431 subpart E, including sections 431.206 through 431.214 or for CHIP found at 42 CFR 457.340(e), including information about a right to a review consistent with 42 CFR 457.1180. In addition, the state must assure all applicable Medicaid appeal and hearing rights are afforded to Medicaid 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 Medicaid benefits as required in 42 CFR §431.230.

- 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).** If the project is terminated or any relevant waivers are suspended by the state, FFP must 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. **CMS Right to Terminate or Suspend.** CMS may suspend or terminate the demonstration, in whole or in part, at any time before the date of expiration, whenever it determines following a hearing that the state has materially failed to comply with the terms of the project. CMS must promptly notify the state in writing of the determination and the reasons for the suspension or termination, together with the effective date.
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 waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX or title XXI. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS's 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 the public notice procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

In states with federally recognized Indian tribes, consultation must be conducted in accordance with the consultation process outlined in the July 17, 2001, letter or the consultation process in the state's approved Medicaid state plan if that process is specifically applicable to consulting with tribal governments on waivers (42 CFR Section 431.408(b)(2)).

- 14. Federal Financial Participation (FFP).** No federal matching for 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. Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, managed care plans, and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.
- 16. Common Rule Exemption.** The state shall ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs; procedures for obtaining Medicaid or CHIP benefits or services; possible changes in or alternatives to Medicaid or CHIP programs and procedures; or possible changes in methods or levels of payment for Medicaid and CHIP benefits or services under those programs. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(b)(5).

IV. ARKANSAS HEALTH AND OPPORTUNITY FOR ME (ARHOME) PROGRAM POPULATIONS AFFECTED

The state will use this demonstration to ensure coverage for ARHOME eligible beneficiaries provided primarily through QHPs offered in the individual market instead of the FFS delivery system that serves the traditional Medicaid population. The state will

provide premium assistance to aid ARHOME beneficiaries in enrolling in coverage through QHPs in the Marketplace.

- 17. Populations Affected by the ARHOME Demonstration.** Except as described in STCs 18 and 19, the ARHOME demonstration affects adults aged 19 through 64 eligible under the state plan under section 1902(a)(10)(A)(i)(VIII) of the Act and 42 CFR Section 435.119 (the adult group). Eligibility and coverage for ARHOME beneficiaries are subject to all applicable Medicaid laws and regulations in accordance with the Medicaid state plan, except as expressly waived in this demonstration and as described in these STCs. Any Medicaid state plan amendments that apply to the adult group will apply to this demonstration.

Table 1. Eligibility Groups

Eligibility Group	Federal Poverty Level	Services	Funding Stream
Adult Group	Adults up to and including 133 percent of the FPL who meet the other criteria specified in Section 1902(a)(10)(A)(i)(VIII) of the Social Security Act	All services authorized through the demonstration	Title XIX
Maternal Life360 HOME non-Medicaid Eligible Individuals	Individuals enrolled in a Maternal Life360 HOME who become ineligible for Medicaid coverage for up to two years, consistent with expenditure authority 4.	Maternal Life360 Services only	1115 demonstration

- 18. Medically Frail Individuals.** Arkansas has instituted a process to determine whether a beneficiary is medically frail. The process is described in the Alternative Benefit state plan. Beneficiaries excluded from enrolling in QHPs through the ARHOME as a result of a determination of medical frailty as defined in the Alternative Benefit Plan (ABP) state plan amendment (SPA) will have the option of receiving direct coverage through the state of either the same ABP offered to the beneficiaries or an ABP that includes all benefits otherwise available under the approved Medicaid state plan (the standard Medicaid benefit package). Direct coverage will be provided through a FFS system or the PASSE program.
- 19. American Indian/Alaska Native Individuals.** Beneficiaries identified as American Indian or Alaskan Native (AI/AN) will not be required to enroll in QHPs in this demonstration, but can choose to opt into a QHP. New applicants will be subject to provisions of STC 17 and coverage will begin 30 days prior to the date an application is submitted for coverage. Beneficiaries who are AI/AN and who have not opted into a QHP will receive the ABP through a FFS system. An AI/AN beneficiary will be able to access covered benefits through Indian Health Service (IHS), Tribal or Urban Indian Organization (collectively, I/T/U) facilities funded through the IHS. Under the Indian Health Care Improvement Act (IHCIA), I/T/U facilities are entitled to payment notwithstanding network restrictions.

20. **Retroactive Eligibility.** The state will only provide coverage effective 30 days prior to the date a beneficiary submits an application. All other regulations governing retroactive eligibility are otherwise consistent with the requirements of 42 CFR 435.915, for coverage for beneficiaries in table 1.

V. ARKANSAS HEALTH AND OPPORTUNITY FOR ME (ARHOME) PREMIUM ASSISTANCE ENROLLMENT

21. **ARHOME.** For ARHOME beneficiaries, except as noted in STCs 18 and 19, enrollment in a QHP is a condition of receiving benefits.
22. **QHP Selection.** The QHPs in which ARHOME beneficiaries enroll are certified through the Arkansas Insurance Department's QHP certification process. The QHPs available for selection by the beneficiary are determined by the Medicaid agency.
23. **Auto-assignment.** In the event that a beneficiary is determined eligible for coverage through the ARHOME QHP premium assistance program, but does not select a plan, the state will auto-assign the beneficiary to one of the available QHPs in the beneficiary's rating area. Beneficiaries who are auto-assigned will be notified of their assignment, and the effective date of QHP enrollment, and will be given a thirty-day period from the date of enrollment to request enrollment in another plan.
24. **Distribution of Members Auto-assigned.** ARHOME QHP auto-assignments will be distributed among QHP issuers in good standing with the Arkansas Insurance Department offering certified silver-level QHPs certified by the Arkansas Insurance Department.
25. **Changes to Auto-assignment Methodology.** The state will advise CMS prior to implementing a change to the auto-assignment methodology.
26. **Disenrollment.** Beneficiaries may be disenrolled from the demonstration if they are determined to be medically frail after they were previously determined eligible.

VI. PREMIUM ASSISTANCE DELIVERY SYSTEM

27. **Memorandum of Understanding for QHP Premium Assistance.** The Arkansas Department of Human Services and the Arkansas Insurance Department have entered into a memorandum of understanding (MOU) with each QHP that enrolls beneficiaries. Areas to be addressed in the MOU include, but are not limited to:
- a. Enrollment of beneficiaries in populations covered by the demonstration;
 - b. Payment of premiums and cost sharing reductions, including the process for collecting and tracking beneficiary premiums and cost sharing, and ceasing premium collections;
 - c. Reporting and data requirements necessary to monitor and evaluate the ARHOME demonstration including those referenced in STCs 63 and 64, ensuring beneficiary

- access to Early and Periodic Screening, Treatment and Diagnosis (EPSDT) and other covered benefits through the QHP;
 - d. Requirement for QHPs to provide, consistent with federal and state laws, claims and other data as requested to support state and federal evaluations, including any corresponding state arrangements needed to disclose and share data, as required by 42 CFR 431.420(f)(2), to CMS or CMS's evaluation contractors.
 - e. Noticing requirements; and
 - f. Audit rights.
- 28. Qualified Health Plans.** The state will use premium assistance to support the purchase of coverage for ARHOME beneficiaries through Marketplace QHPs.
- 29. Choice of QHPs.** Each ARHOME beneficiary required to enroll in a QHP will have the option to choose between at least two silver plans covering only Essential Health Benefits (EHBs) that are offered in the individual market through the Marketplace. The state will pay the full cost of QHP premiums, less the cost of the premium paid by the beneficiary in accordance with these STCs.
- a. ARHOME beneficiaries will be able to choose from at least two silver plans covering only EHBs that are in each rating area of the State.
 - b. ARHOME beneficiaries will be permitted to choose among all silver plans covering only EHBs that are offered in their geographic area and that meet the purchasing guidelines established by the State in that year, and thus all ARHOME beneficiaries will have a choice of at least two QHPs.
 - c. The state will comply with Essential Community Provider network requirements, as part of the QHP certification process.
 - d. ARHOME beneficiaries will have access to the same networks as other beneficiaries enrolling in QHPs through the individual Marketplace.
- 30. Coverage Prior to Enrollment in a QHP.** The state will provide coverage through FFS Medicaid from the date a beneficiary is determined eligible until the beneficiary's enrollment in the QHP becomes effective.
- a. For beneficiaries who enroll in a QHP (whether by selecting the QHP or through auto-assignment) between the first and fifteenth day of a month, QHP coverage will become effective as of the first day of the month following QHP enrollment.
 - b. For beneficiaries who enroll in a QHP (whether by selecting the QHP or through auto-assignment) between the sixteenth and last day of a month, QHP coverage will become effective as of the first day of the second month following QHP selection (or auto-assignment).
- 31. Family Planning.** If family planning services are accessed at a facility that the QHP considers to be an out-of-network provider, the state's FFS Medicaid program will cover those services.

32. **Non-Emergency Medical Transportation (NEMT).** Non-emergency medical transport services will be provided through the state's FFS Medicaid program. See STC 39 for further discussion of non-emergency medical transport services.
33. **Access to Federally Qualified Health Centers (FQHC) and Rural Health Centers (RHC).** ARHOME beneficiaries will have access to at least one QHP in each service area that contracts with at least one FQHC and RHC.

VII. BENEFITS

34. **ARHOME Benefits.** Beneficiaries affected by this demonstration will receive benefits as set forth in section 1905(y)(2)(B) of the Act and codified at 42 CFR Section 433.204(a)(2). These benefits are described in the Medicaid state plan.
35. **Alternative Benefit Plan.** The benefits provided under an alternative benefit plan for the adult group are reflected in the State ABP state plan.
36. **Medicaid Wrap Benefits.** The state will provide through its FFS system wrap-around benefits that are required for the ABP but not covered by QHPs. These benefits include NEMT and EPSDT services for beneficiaries participating in the demonstration who are under age 21.
37. **Access to Wrap Around Benefits.** In addition to receiving an insurance card from the applicable QHP issuer, ARHOME beneficiaries will have a Medicaid Client Identification Number (CIN) through which providers may bill Medicaid for wrap-around benefits. The notice containing the CIN will include information about which services ARHOME beneficiaries may receive through FFS Medicaid and how to access those services. This information is also posted on Arkansas Department of Human Services' Medicaid website and will be provided through information at the Department of Human Service's call centers and through QHP issuers.
38. **Early and Periodic Screening, Diagnosis, and Treatment.** The State must fulfill its responsibilities for coverage, outreach, and assistance with respect to EPSDT services that are described in the requirements of sections 1905(a)(4)(b) (services), 1902(a)(43) (administrative requirements), and 1905(r) (definitions).
39. **Access to Non-Emergency Medical Transportation.** The state will establish prior authorization for NEMT in the ABP. Beneficiaries served by IHS or Tribal facilities and medically frail beneficiaries will be exempt from such requirements.

VIII. IMPROVING HEALTH OUTCOMES THROUGH INTENSIVE CARE COORDINATION FOR POPULATIONS MOST AT RISK OF POOR HEALTH (Life360 HOMEs)

- 40. Life360 HOME Services.** The state may claim FFP for the evidence-based Life360 HOME services identified in STC 41, subject to the restrictions described below and in STC 43. There are three types of Life360 HOMEs: Maternal, Success and Rural. Expenditures for some Life360 HOME services are limited to costs not otherwise covered under Title XIX, but consistent with Medicaid demonstration objectives that enable the state to continue to improve health outcomes and increase the efficiency and quality of care. To receive Life360 HOME services, individuals in the targeted populations must have a documented need for the services. Life360 HOME services must be medically appropriate for the beneficiary and based on medical appropriateness using clinical and other health-related social needs criteria. The state is required to align clinical and social risk criteria across services with other non-Medicaid support agencies, to the extent possible. The Life360 HOME services may not supplant any other available funding sources such as housing or nutrition supports available to beneficiaries through local, state or federal programs. The Life360 HOME services will be the choice of the beneficiary; beneficiaries can opt out of Life360 HOME services at any time; and Life360 HOME services do not absolve the state of their responsibility to provide required coverage for other medically necessary services. Under no circumstances will the state be permitted to condition Medicaid coverage, or coverage of any benefit or service, on receipt of Life360 HOME services. The state must submit additional details on covered Life360 HOME services to CMS as outlined in STC 41 and Attachment H.
- 41. Allowable HRSN Services.** The state may cover the following Life360 HOME services in all three Life360 HOME types:
- a. Housing Supports, including:
 - i. Pre-tenancy and tenancy sustaining services, including tenant rights education and eviction prevention
 - ii. Housing transition navigation services
 - iii. One-time transition and moving costs (e.g., security deposits, first-month's rent, utilities activation fees, movers, and pest eradication)
 - iv. Housing deposits to secure housing, including application and inspection fees and fees to secure needed identification
 - b. Nutrition Supports
 - i. Nutrition counseling and education, including healthy meal preparation
 - c. Case management, outreach, and education including linkages to other state and federal benefit program application assistance, and benefit program application fees, as described in attachment G.
- 42. Life360 HOME Infrastructure.**
- a. The state may claim FFP in infrastructure investments in order to support the development and implementation of Life360 HOME services, subject to STC 40. This FFP will be available for the following activities:
 - i. Technology- e.g., electronic referral systems, shared data platforms, EHR modifications or integrations, screening tool and/or case management systems, databases/data warehouses, data analytics and reporting, data protections and privacy, accounting and billing systems

- ii. Development of business or operational practices – e.g., procurement and planning, developing policies and workflows for referral management, privacy, quality improvement, trauma-informed practices, evaluation, member navigation
 - iii. Workforce development – e.g., cultural competency training, trauma-informed training, community health worker certification, training staff on new policies and procedures
 - iv. Outreach, education, and stakeholder convening – e.g., design and production of outreach and education materials, translation, obtaining community input, investments in stakeholder convening
 - v. Costs consistent with the above categories necessary for the development of crisis stabilization capacity in rural hospitals to support Rural Life360 HOMEs
- b. The state may claim FFP in Life360 HOME infrastructure expenditures for no more than the annual amounts outlined in Table 2. In the event that the state does not claim the full amount of FFP for a given demonstration year, the unspent amounts will roll over to one or more demonstration years not to exceed this demonstration period and the state may claim the remaining amount in a subsequent demonstration year.

Table 2. Annual Limits in Total Computable LIFE360 HOME Infrastructure

	DY 1 (2022)	DY 2 (2023)	DY 3 (2024)	DY 4 (2025)	DY 5 (2026)
Total Computable Expenditures	\$0	\$2.7M	\$1.97M	\$3.0M	\$2.8M

- c. HRSN infrastructure funding must be claimed at the applicable administrative match rate, and approved HRSN Infrastructure funding will be matched at the applicable administrative match for the expenditure.
- d. This HRSN infrastructure funding is separate and distinct from the payment for delivery of Life360 HOME services. The state must ensure that Life360 HOME infrastructure expenditures are not factored into qualified health plan capitation payments, and that there is no duplication of funds.
- e. The state may not claim any FFP in Life360 HOME infrastructure expenditures until the Protocol for Assessment of Beneficiary Eligibility and Needs, Infrastructure Planning, and Provider Qualifications for Life 360 HOME Services is approved, as described in STC 48. Once approved, the state can claim FFP in Life360 HOME infrastructure expenditures retrospectively to the beginning of the demonstration approval date.
- f. To the extent the state requests any additional infrastructure funding, or changes to its scope as described within this STC, it must submit an amendment to the demonstration for CMS’s consideration.

- 43. Excluded Life360 HOME Services.** Excluded items, services and activities that are not covered as Life360 HOME services include, but are not limited to:

- a. Construction costs (bricks and mortar);
- b. Capital investments other than those as allowable as HRSN infrastructure as described in STC 42;
- c. Room and board, except as described in STC 41;
- d. Research grants and expenditures not related to monitoring and evaluation;
- e. Costs for services in prisons, correctional facilities or services for people who are civilly committed and unable to leave an institutional setting;
- f. Services provided to individuals who are not lawfully present in the United States or are undocumented;
- g. Expenditures that supplant services and activities funded by other state and federal governmental entities;
- h. School-based programs for children that supplant Medicaid state plan programs, or that are funded under the Department of Education and/or state or the local education agency;
- i. General workforce activities, not specifically linked to Medicaid or Medicaid beneficiaries; and
- j. Any other projects or activities not specifically approved by CMS as qualifying for demonstration coverage as Life360 HOME services.

44. Life360 HOMEs Covered Populations. Expenditures for Life360 services may be made for the targeted populations specified below. To receive Life360 HOME services, individuals in the targeted populations must have a documented need for the services and the services must be determined medically appropriate consistent with STC 40. Medical appropriateness must be based on clinical and social risk factors. This determination must be documented in the beneficiary's care plan or medical record. A beneficiary may only participate in one Life360 HOME at a time but may participate in more than one Life360 HOME throughout the demonstration approval period, if eligible. The allowable targeted populations for each of the Life360 HOME types are:

- a. Maternal Life360 HOMEs will support individuals with high-risk pregnancies, as diagnosed by their physician, and up to two years post-partum, even if the individual is no longer eligible for Medicaid under any other category,² either through the Maternal Life360 HOME's provision of intensive care coordination and evidence-based home visitation or through contracts with evidence-based home visitation programs;³
- b. Rural Life360 HOMEs will support individuals with a serious mental illness (SMI) or substance use disorder (SUD) diagnosis who live in rural areas of the

² If the individual would become no longer eligible for Medicaid under any eligibility category, they would still be able to receive the benefits under the Maternal Life360 HOME, (e.g., intensive care coordination, visiting home nursing and health related social needs assessments) based on continued need. The match for services to people who are no longer eligible for the adult group would be at regular FMAP.

³ The Maternal Life360 HOME will include leveraging the state home visiting program infrastructure that is being implemented in counties statewide and administered by the Arkansas Department of Health with Maternal, Infant and Early Childhood Home Visiting (MIECHV) program to expand current access and capacity for evidence-based home visiting for high-risk pregnant individuals. Funding authorized under this demonstration will expand access to this home visiting program and current funding levels for MIECHV will not be reduced.

- state through provision of intensive care coordination provided directly or through contracts with organizations to provide care coordination; and,
- c. Success Life360 HOMEs will support young adults (ages 19-27) most at risk of long-term poverty due to prior incarceration, involvement with the foster care system, or young adults (ages 19-24) with involvement with the juvenile justice system and veterans ages 19-30 who are at high risk of homelessness. Success Life360 HOMEs will provide intensive care coordination directly or contract with organizations to provide care coordination.

- 45. Definition of Intensive Care Coordination for Life360 HOMEs.** The key function of each Life360 HOME is to provide intensive care coordination to identify HRSN and engage with the beneficiary to ensure successful connection to medical services and nonmedical supports in the community to meet the beneficiary's HRSN consistent with these STCs. Intensive Care Coordination means: a collaborative process in which a care coordinator meets regularly virtually or in person with the beneficiary and assesses, plans, implements, coordinates, monitors and evaluates the options, services and supports necessary to meet the beneficiary's health and health-related social needs. It includes advocacy on behalf of participants in health care settings, communication, and resource management and promotes quality interventions and outcomes. In addition to accessing medical services, it includes ensuring that beneficiaries attain and maintain their HRSN service goals identified in their Person-Centered Action Plan (PCAP). The Life360 will develop an individualized PCAP for each beneficiary to address their HRSN. Each beneficiary will have a care coordinator that will directly connect the beneficiary with services and supports needed to meet the goals identified in the PCAP, which should include activities beyond providing a referral. By interacting in person on a regular basis with their beneficiaries, the care coordinator will help beneficiaries develop and strengthen life skills. Maternal Life360 will provide the intensive care coordination within an evidence-based home visiting model during pregnancy and up to 2 years following childbirth.

The use of medical care typically depends on the individual's own initiative to seek care. Care coordinators will go out into the community to meet people where they live. Qualifications of care coordinators will vary depending upon the type of Life360.

- 46. Life360 HOMEs Applicant Selection Process.** The following hospitals enrolled as a provider with the Arkansas Medicaid program and as defined as eligible in Arkansas state statute,⁴ can apply to implement a Life360 HOME:
- a. Maternal Life360 HOME – the hospital must be a birthing facility
 - b. Rural Life360 HOME – the hospital must be a rural hospital with 50 or fewer beds
 - c. Success Life360 HOME – the hospital must be an acute care facility

⁴ A.C.A. § 23-61-1010 and A.C.A. § 23-61-1003

There is no limit to the number of HOME types a hospital may establish, consistent with these STCs and subject to state review and approval.

The state must require that Life360 HOME applicants identify the target population(s) to be served (Maternal, Rural, and/or Success), service area and partners as applicable, and complete an analysis of the service area population demographics and a community resource inventory to determine the referral network/gaps and to implement data collection and sharing processes. The state must also require applicants to demonstrate they can provide, or establish contracts to provide, the required supports or model for the target population and will also need to set an annual budget and specifications for IT systems as part of their application.

- 47. Life360 HOME Program Integrity.** The state will ensure that all Life360 payments are made consistent with these STCs. Program integrity activities for Life360 HOMEs will include at a minimum:
- a. **Completing progress reporting on Life360-funded activities.** All Selected Applicants will be expected to submit progress reports that document Life360 HOME-funded activities. The state will require hospitals that apply to operate a Life360 HOME and are selected by the state to do so (Selected Applicants) attest to non-duplication of funding with other federal, state, and local funds. The state must monitor for funding irregularities and potential duplication across all Life360 HOMEs.
 - b. **Participating in audit processes.** The state must conduct audits in accordance with all required policies for Medicaid funding to ensure that Life360 HOME funds are being spent on permissible uses and are being reported appropriately. The state must include results from these audits in its Annual Monitoring Reports, which are described in STC 64.
 - c. **Ensuring action is taken to address noncompliance.** The state will ensure that action is taken to address any identified non-compliance with Life360 HOME funding parameters. If the state determines that a Selected Applicant has failed to demonstrate appropriate performance, including enrolling an insufficient number of beneficiaries, the state may impose corrective actions that may include caps on funding, recoupment of funds, or discontinuation of Life360 HOME funding. The state may also impose corrective actions for a Selected Applicant if it determines the Life360 HOME is out of compliance with requirements set forth in the STCs and attachments, the agreement between the Selected Applicant and the state, and/or policy letters or guidance set forth by the state. Prior to initiating any corrective action on a Selected Applicant, the state shall provide the Selected Applicant notice and an opportunity to comment regarding the identified area of non-compliance. CMS reserves the right to require the state to return FFP associated with recoupment of funding for Selected Applicant due to noncompliance.
- 48. Protocol for Assessment of Beneficiary Eligibility and Needs, Infrastructure Planning, and Provider Qualifications for Life360 HOMEs.** Within 180 days of

approval the state must complete and submit to CMS for review and approval a Protocol for Assessment of Beneficiary Eligibility and Needs, Infrastructure Planning, and Provider Qualifications (Protocol) for conducting the assessment of beneficiary eligibility and needs, Life360 HOME infrastructure, and provider qualifications for Life360 HOME services. This Protocol must include a list of the Life360 HOME services and service descriptions, outlining the name and description of each proposed service, the criteria for defining when each service is medically appropriate, the process by which that criteria will be applied including care plan requirements or other documented processes, proposed uses of Life360 HOME infrastructure, and provider qualification criteria for each service. The state must resubmit an updated protocol if CMS provides feedback on the initial submission. The Protocol may be updated as details are changed or added. The state may not claim FFP for Life360 HOME service or Life360 HOME infrastructure expenditures until CMS approves the protocol. Once approved, the state can claim FFP for Life360 HOME services and Life360 HOME infrastructure expenditures retrospectively to the beginning of the amendment approval date. The approved protocol will be attached to the STCs as Attachment I.

Specifically, the Protocol must include the following information:

- a. Proposed uses of HRSN infrastructure expenditures, including the type of entities to receive funding, the intended purpose of the funding, the projected expenditure amounts, and an implementation timeline
- b. A list of the covered HRSN services (not to exceed those allowed under STC 41), with associated service descriptions and service-specific provider qualification requirements
- c. A description of the process for identifying beneficiaries with health-related social needs, including outlining beneficiary eligibility, implementation settings, screening tool selection, and rescreening approach and frequency, as applicable
- d. A description of the process by which clinical criteria will be applied, including a description of the documented process wherein a provider, using their professional judgment, may deem the service to be medically appropriate
 - i. Plan to identify medical appropriateness based on clinical and social risk factors
 - ii. Plan to publicly maintain these clinical/social risk criteria to ensure transparency for beneficiaries and stakeholders
- e. A description of the process for developing care plans based on assessment of need
 - i. Plan to initiate care plans and closed-loop referrals to social services and community providers based on the outcomes of screening
 - ii. Description of how the state will ensure that HRSN screening and service delivery are provided to beneficiaries in ways that are culturally responsive and/or trauma-informed

49. **Sources of Non-federal Share of Funding for Life360 Expenditures.** The state shall provide permissible sources for the non-federal share of all Life360 HOME expenditures

derived from state funds that do not utilize impermissible provider taxes or intergovernmental transfers (IGTs) as the source of revenue.

50. **Compliance with Federal Requirements.** The state shall ensure Life360 HOME services are delivered in accordance with all applicable federal statute, regulation or guidance.
51. **Rate Methodologies.** All rate and/or payment methodologies for authorized Life360 HOME services outlined in these STCs must be submitted to CMS for review and approval at least 60 days prior to implementation. These methodologies, including but not limited to fee-for-service payment as well as non-risk payments and capitation rates in managed care delivery systems, must be included in the New Initiatives Implementation Plan. States must submit all documentation requested by CMS, including but not limited to the payment rate methodology as well as other documentation and supporting information (e.g., state responses to Medicaid non-federal share financing questions). 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 fee-for-service payment rates.
52. **Maintenance of Effort (MOE).** The state must maintain the level of state funding for social service programs related to housing transitions supports and nutrition supports for the duration of the demonstration. Within 90 days of approval of the Life360 amendment, the state must submit a plan to CMS as part of the New Initiatives Implementation Plan (see STC 62) that outlines how it will assess the current availability of these services throughout the state. The annual MOE will be reported and monitored as part of the Annual Monitoring Reports described in STC 64, including any justifications necessary to describe the findings.
53. **Partnerships with State and Local Entities.** The state must have in place partnerships with other state and local entities (e.g., HUD Continuum of Care Program, local housing authority, SNAP state agency, etc.) to assist beneficiaries in obtaining non-Medicaid funded housing and nutrition supports, if available, upon the conclusion of temporary Medicaid payment for such supports, in alignment with beneficiary needs identified in the person-centered plans as appropriate. The state must submit a plan to CMS as part of the New Initiatives Implementation Plan (see STC 62) that outlines how it will put into place the necessary arrangements with other state and local entities and also work with those entities to beneficiaries in obtaining available non-Medicaid funded housing and nutrition supports upon conclusion of temporary Medicaid payment as stated above. The plan must provide a timeline for the activities outlined. As part of the Quarterly Monitoring Reports described in STC 64, the state will provide the status of the state's fulfillment of its plan and progress relative to timeline, and whether and to what extent the non-Medicaid funding supports are being accessed by beneficiaries as planned. Once the state's plan is fully implemented, the state may conclude its status updates in the Quarterly Monitoring Reports.

IX. PREMIUMS & COST SHARING

- 54. Premiums & Cost Sharing.** Cost sharing for ARHOME beneficiaries must be in compliance with federal requirements that are set forth in statute, regulation and policies, including requirements and limitations from cost sharing set forth in 42 CFR Section 447.50-57. Waiver authority for premiums will sunset on December 31, 2022.
- 55. Premiums & Cost Sharing Parameters for the ARHOME Program.** With the approval of this demonstration:
- a. Beneficiaries up to and including 20 percent of the FPL will have no cost sharing.
 - b. Beneficiaries above 20 percent of the FPL will have cost sharing consistent with Medicaid requirements beginning January 1, 2023.
 - c. Beneficiaries above 100 percent of the FPL will be required to pay monthly premiums of up to 2 percent of household income until the authority sunsets on December 31, 2022.
 - d. Premiums and cost sharing will be subject to an aggregate cap of no more than 5 percent of family quarterly income.
 - e. Cost sharing requirements and/or limitations described in 42 CFR 447.50-57 will be applied to all program beneficiaries.
 - f. Copayment and coinsurance amounts will be consistent with federal requirements regarding Medicaid cost sharing and with the state's approved state plan; copayment and coinsurance amounts are listed in Attachment A.
 - g. Medically frail individuals and American Indian/Alaska Native individuals, and individuals ages 19 and 20, will be exempt from cost sharing.
- 56. Payment Process for Payment of Cost Sharing Reduction to QHPs.** Agreements with QHP issuers may provide for advance monthly cost-sharing reduction (CSR) payments to cover the costs associated with the reduced cost sharing for ARHOME beneficiaries. Such payments will be subject to reconciliation at the conclusion of the benefit year based on actual expenditures by the QHP for cost sharing reduction. If a QHP issuer's actuary determines during the benefit year that the estimated advance CSR payments are significantly different than the CSR payments the QHP issuer will be entitled to during reconciliation, the QHP issuer may ask Arkansas' Department of Human Services to adjust the advance payments. Arkansas' reconciliation process will follow 45 CFR Section 156.430 to the extent applicable.
- 57. Grace Period/Debt Collection.** The grace period/debt collection process will be consistent with federal requirements regarding Medicaid cost sharing, including requirements at 42 CFR 447.55(b). ARHOME beneficiaries will have two months from the date of the payment invoice to make the required monthly premium contribution. Arkansas and/or its vendor may attempt to collect unpaid premiums and the related debt from beneficiaries, but may not report the debt to credit reporting agencies, place a lien on an individual's home, refer the case to debt collectors, file a lawsuit, or seek a court order to seize a portion of the individual's earnings for beneficiaries at any income level.

The state and/or its vendor may not “sell” the debt for collection by a third party. The waiver authorizing this policy will sunset on December 31, 2022.

X. FAIR HEARINGS

58. The state will afford beneficiaries in the demonstration fair hearing rights in accordance with 42 CFR part 431 subpart E. No waiver will be granted related to fair hearings. The state must ensure compliance with all federal and state requirements related to beneficiary fair hearing rights, including compliance with the approved state plan.

XI. MONITORING AND REPORTING REQUIREMENTS

59. **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 singly or collectively referred to as “deliverable(s)”) are not submitted timely to CMS or found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

The following process will be used: 1) 30 calendar days after the deliverable 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) 30 calendar days after CMS has notified the state in writing that the deliverable was not accepted due to 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 submissions of required deliverables.
- b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable. The extension request must explain the reason why the required deliverable was not submitted, the steps that the state has taken to address such issue, and state’s anticipated date of submission. Should CMS agree to the state’s request, a corresponding extension of the deferral process described below 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 plan or, despite the corrective action plan, 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.

60. **Submission of Post-Approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined in these STCs.
61. **Compliance with Federal Systems Innovation.** As federal systems continue to evolve and incorporate additional section 1115 demonstration reporting and analytics functions, the state will work with CMS to:
 - a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
 - b. Ensure all section 1115, 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.
62. **New Initiatives Implementation Plan.** The state is required to submit a New Initiatives Implementation Plan to cover certain key policies being tested under this demonstration, including those approved through any amendments. The Implementation Plan will contain applicable information for the following expenditure authorities: Life360 HOME HRSN Services, Life360 HOME HRSN Infrastructure. The New Initiatives Implementation Plan, at a minimum, must provide a description of the state's strategic approach to implementing the key demonstration policies, including timelines for meeting critical implementation stages or milestones, as applicable, to support successful implementation.

The state must submit the Maintenance of Effort information required by STC 52 for CMS approval no later than 90 calendar days after approval of the Life360 HOMEs amendment. All other Implementation Plan requirements outlined in this STC must be submitted for CMS approval no later than 9 months after the approval of the demonstration amendment. The state must submit any required clarifications or revisions to their Implementation Plan submission within 60 calendar days after receipt of CMS feedback. Once approved, the finalized Implementation Plan will be incorporated into the STCs as Attachment D and may be further altered only with CMS approval.

In the Implementation Plan, the state is expected only to provide additional details regarding the implementation of the demonstration policies that are not already captured

in the STCs or available elsewhere publicly. Furthermore, for the state's HRSN-related authorities, the Implementation Plan does not need to repeat any information submitted to CMS in the Protocol for Assessment of Beneficiary Eligibility and Needs, Infrastructure Planning, and Provider Qualifications for Life360 HOME Services (see STC 48); however, as applicable, the information provided in the two deliverables must be aligned and consistent with one another.

The Implementation Plan can be updated as necessary to align with state operations. CMS may provide the state with a template to support the state in developing and obtaining approval of the Implementation Plan.

The New Initiatives Implementation Plan must include information on, but not limited to, the following:

- a. A plan for establishing and/or improving data sharing and partnerships with an array of health system and social services stakeholders to the extent those entities are vital to provide needed administrative and HRSN-related data on screenings, referrals, and provision of services, which are critical for understanding program implementation and conducting demonstration monitoring and evaluation
- b. Information about key partnerships related to HRSN service delivery, including plans for capacity building for community partners and for soliciting and incorporating input from impacted groups (e.g., community partners, health care delivery system partners, and beneficiaries)
- c. Plans for changes to information technology (IT) infrastructure that will support HRSN-related data exchange, including development and implementation of data systems necessary to support program implementation, monitoring, and evaluation. These existing or new data systems should, at a minimum, collect data on beneficiary characteristics, eligibility and consent, screening, referrals, and service provision.
- d. A plan for tracking and improving the share of Medicaid beneficiaries who are eligible and enrolled in the Supplemental Nutrition Assistance Program (SNAP), the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), and federal and state housing assistance programs, relative to the number of total eligible beneficiaries, including establishing a timeline for reporting.
- e. An implementation timeline and evaluation considerations impacted by the timeline, such as staged rollout that can facilitate robust evaluation designs if these implementation strategies are culturally appropriate
- f. Information as required per STC 52 (MOE)
- g. Information as required per STC 53 (Partnerships with State and Local Entities)

Failure to submit a New Initiatives Implementation Plan 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 Life360 HOMEs programs under this demonstration.

- 63. Monitoring Protocol.** The state must submit to CMS a Monitoring Protocol no later than 150 calendar days after approval of the demonstration. The state must submit a revised

Monitoring Protocol within 60 days after receipt of CMS's comments. Once approved, the Monitoring Protocol will be incorporated into the STCs as Attachment E. In addition, the state must submit an updated or a separate Monitoring Protocol for any amendments to the demonstration, such as the Life 360 HOMEs, no later than 150 calendar days after the approval of the amendment. Such amendment Monitoring Protocols are subject to same requirement of revisions and CMS approval, as described above.

At a minimum, the Monitoring Protocol must affirm the state's commitment to conduct Quarterly and Annual Monitoring Reports in accordance with CMS's guidance and technical assistance and using CMS-provided reporting templates, if applicable. Any proposed deviations from CMS's guidance must be documented in the Monitoring Protocol. The Monitoring Protocol must describe the quantitative and qualitative elements on which the state will report through Quarterly and Annual Monitoring Reports. For the overall demonstration and specific policies where CMS provides states with a suite of quantitative monitoring metrics (e.g., performance metrics described in STC 66b below), the state is required to calculate and report such metrics leveraging the technical specifications provided by CMS. CMS will provide the state with a set of required metrics, and technical specifications for data collection and metrics calculations covering reporting topics, including but not limited to, enrollment, access to care, quality of care and health outcomes, enrollment by premium payment status, and unpaid medical bills at application. The Monitoring Protocol must specify the methods of data collection and timeframes for reporting on the demonstration's progress as part of the Quarterly and Annual Monitoring Reports. In alignment with CMS guidance, the Monitoring Protocol must additionally specify the state's plans and timeline on reporting metrics data stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, English language proficiency, primary language, disability status, and geography) and demonstration component.

For the Life360 HOMEs amendment, the state can update its existing Monitoring Protocol or submit a new Monitoring Protocol within 150 days of the amendment approval. Metrics related to the Life360 HOMEs must include a selection of quality of care and health outcomes metrics and population stratifications based on CMS's upcoming guidance on the Health Equity Measure Slate, and must outline the corresponding data sources and reporting timelines. This slate of measures represents a critical set of equity-focused metrics known to be important for closing key equity gaps in Medicaid/CHIP (e.g. the National Quality Forum (NQF) "disparities-sensitive" measures) and prioritizes key outcome measures and their clinical and non-clinical (i.e. social) drivers. The Monitoring Protocol must also outline the state's planned approaches and parameters to track performance relative to the goals and milestones, as provided in the implementation plan, for the HRSN infrastructure investments.

In addition, the state must describe in the Monitoring Protocol methods to collect and analyze non-Medicaid administrative data to help calculate applicable monitoring metrics. These sources may include, but are not limited to: (1) community resource referral platforms, (2) records of social services receipt from other agencies (such as SNAP or

TANF benefits, or housing assistance), (3) other data from social services organizations linked to beneficiaries (e.g., services rendered, resolution of identified need, as applicable), (4) social needs screening results from electronic health records, health plans, or other partner agencies. Across data sources, the state must make efforts and consult with relevant non-Medicaid social service agencies to collect data in ways that support analyses of data on beneficiary subgroups. The Monitoring Protocol must also outline the state's planned approaches and parameters to track performance relative to the goals and milestones, as provided in the implementation plan, for the HRSN infrastructure investments.

For the qualitative elements (e.g., operational updates as described in STC 64a 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.

- 64. Monitoring Reports.** The state must submit three Quarterly Monitoring Reports and one Annual Monitoring Report each DY. The fourth-quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual Monitoring Report. The Quarterly Monitoring Reports are due no later than 60 calendar days following the end of each demonstration quarter. The Annual Monitoring Report (including the fourth-quarter information) is due no later than 90 calendar days following the end of the DY. The state must submit a revised Monitoring Report within 60 calendar days after receipt of CMS's comments, if any. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Quarterly and Annual Monitoring Reports must follow the framework to be provided by CMS, which is subject to change as monitoring systems are developed/evolve, and will be provided in a structured manner that supports federal tracking and analysis.
- a. Operational Updates. Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports must provide sufficient information to document key operational and other challenges, underlying causes of challenges, and how challenges are being addressed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. In addition, Monitoring Reports should describe key achievements, as well as the conditions and efforts to which these successes can be attributed. Monitoring Reports should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
 - b. Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing toward meeting the demonstration's goals – including relative to their projected timelines – of the demonstration's program and policy implementation and infrastructure investments, and must cover all key policies

under this demonstration. Additionally, 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 or experience of care surveys, if conducted, as well as grievances and appeals.

The demonstration's metrics reporting must cover categories including, but not limited to: enrollment and renewal, including enrollment duration, access to providers, utilization of services, enrollment by premium payment status, unpaid medical bills at application and those who experienced a gap in coverage, and quality of care and health outcomes. The state must undertake robust reporting of quality of care and health outcomes metrics aligned with the demonstration's policies and objectives, to be reported for all demonstration populations. Such reporting must also be stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, English language proficiency, primary language, disability status, and geography) and by demonstration component, to the extent feasible. Subpopulation reporting will support identifying any existing shortcomings or disparities in quality of care and health outcomes, and help track whether the demonstration's initiatives help improve outcomes for the state's Medicaid population, including the narrowing of any identified disparities. To that end, CMS underscores the importance of the state's reporting of quality of care and health outcomes metrics known to be important for closing key equity gaps in Medicaid/CHIP (e.g. the National Quality Forum (NQF) "disparities-sensitive" measures) and prioritizing key outcome measures and their clinical and non-clinical (i.e. social) drivers of health. In coordination with CMS, the state is expected to select such measures for reporting in alignment with a critical set of equity-focused measures CMS is finalizing as part of its upcoming guidance on the Health Equity Measure Slate.

For the Life360 HOMEs amendment, in addition to reporting on the metrics described above, the state must track beneficiary participation, screening, receipt of referrals and social services over time, as well as narratively report on the adoption of information technology infrastructure to support data sharing between the state or partner entities assisting in the administration of the demonstration and social services organizations. Furthermore, the state's enrollment and renewal metrics must capture baseline data and track progress via Monitoring Reports for the percent of Medicaid renewals completed ex-party (administratively), as well as the percentage of Medicaid beneficiaries enrolled in other public benefit programs (such as, Supplemental Nutrition Assistance Program (SNAP) and Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)) for which they are eligible. The Monitoring Reports must also provide status updates in accordance with the Monitoring Protocol on the implementation of infrastructure investments tied to HRSN initiatives. In addition, if the state, health plans, or health care providers will contract or partner with organizations to implement Life360 HOMEs, the state must use monitoring metrics that track the number and characteristics of contracted or participating organizations in specific demonstration programs and corresponding payment-related metrics.

- c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state 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.

65. Corrective Action Plan Related to Monitoring. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 11. CMS will withdraw an authority, as described in STC 11, when metrics indicate substantial and sustained directional change inconsistent with the state's demonstration goals, and the state has not implemented corrective action. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

66. 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 Close-Out Report must comply with the most current guidance from CMS.
- b. In consultation with CMS, and per guidance from CMS, the state will include an evaluation of the demonstration (or demonstration components) that are to phase out or expire without extension along with the Close-Out Report. Depending on the timeline of the phase-out during the demonstration approval period, in agreement with CMS, the evaluation requirement may be satisfied through the Interim and/or Summative Evaluation Reports stipulated in STCs 102 and 103, respectively.
- c. The state will present to and participate in a discussion with CMS on the Close-Out report.
- d. The state must take into consideration CMS's comments for incorporation into the final Close-Out report.

- e. A revised Close-Out report is due to CMS no later than thirty (30) calendar days after receipt of CMS's comments.
 - f. A delay in submitting the draft or final version of the Close-Out report may subject the state to penalties described in STC 59.
- 67. 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, enrollment and access, 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.
- 68. Post Award Forum.** Pursuant to 42 CFR 431.420(c), within 6 months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least thirty (30) calendar days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state must also post the most recent Annual Monitoring Report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the public comments in the Annual Monitoring Report associated with the year in which the forum was held.

XII. GENERAL FINANCIAL REQUIREMENTS

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

quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

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

- c. The state may use intergovernmental transfers (IGT) to the extent that the transferred funds are public funds within the meaning of 42 CFR 433.51 and are transferred by units of government within the state. Any transfers from units of government to support the non-federal share of expenditures under the demonstration must be made in an amount not to exceed the non-federal share of the expenditures under the demonstration.
- d. Under all circumstances, health care providers must retain 100 percent of their payments for or in connection with furnishing covered services to beneficiaries. Moreover, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local governments, or third parties to return and/or redirect to the state any portion of the Medicaid payments in a manner inconsistent with the requirements in section 1903(w) of the Act and its implementing regulations. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.
- e. The State Medicaid Director or his/her designee certifies that all state and/or local funds used as the state's share of the allowable expenditures reported on the CMS-64 for this demonstration were in accordance with all applicable federal requirements and did not lead to the duplication of any other federal funds.

73. Financial Integrity for Managed Care Delivery Systems. As a condition of demonstration approval, the state attests to the following, as applicable:

- a. All risk-based managed care organization, prepaid inpatient health plan (PIHP), and prepaid ambulatory health plan (PAHP) payments, comply with the requirements on payments in 42 CFR 438.6(b)(2), 438.6(c), 438.6(d), 438.60, and 438.74.

74. Requirements for Health Care-Related Taxes and Provider Donations. As a condition of demonstration approval, the state attests to the following, as applicable:

- a. Except as provided in paragraph (c) of this STC, all health care-related taxes as defined by section 1903(w)(3)(A) of the Act and 42 CFR 433.55 are broad-based as defined by section 1903(w)(3)(B) of the Act and 42 CFR 433.68(c).
- b. Except as provided in paragraph (c) of this STC, all health care-related taxes are uniform as defined by section 1903(w)(3)(C) of the Act and 42 CFR 433.68(d).
- c. If the health care-related tax is either not broad-based or not uniform, the state has applied for and received a waiver of the broad-based and/or uniformity requirements as specified by 1903(w)(3)(E)(i) of the Act and 42 CFR 433.72.
- d. The tax does not contain a hold harmless arrangement as described by section 1903(w)(4) of the Act and 42 CFR 433.68(f).
- e. All provider-related donations as defined by 42 CFR 433.52 are bona fide as defined by section 1903(w)(2)(B) of the Act, 42 CFR 433.66, and 42 CFR 433.54.

- 75. State Monitoring of Non-Federal Share.** If any payments under the demonstration are funded in whole or in part by a locality tax, then the state must provide a report to CMS regarding payments under the demonstration no later than 60 days after demonstration approval. This deliverable is subject to the deferral as described in STC 59. This report must include:
- a. A detailed description of and a copy of (as applicable) any agreement, written or otherwise agreed upon, regarding any arrangement among the providers including those with counties, the state or other entities relating to each locality tax or payments received that are funded by the locality tax;
 - b. Number of providers in each locality of the taxing entities for each locality tax;
 - c. Whether or not all providers in the locality will be paying the assessment for each locality tax;
 - d. The assessment rate that the providers will be paying for each locality tax;
 - e. Whether any providers that pay the assessment will not be receiving payments funded by the assessment;
 - f. Number of providers that receive at least the total assessment back in the form of Medicaid payments for each locality tax;
 - g. The monitoring plan for the taxing arrangement to ensure that the tax complies with section 1903(w)(4) of the Act and 42 CFR 433.68(f); and
 - h. Information on whether the state will be reporting the assessment on the CMS form 64.11A as required under section 1903(w) of the Act.
- 76. Extent of Federal Financial Participation for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the following demonstration expenditures, subject to the budget neutrality expenditure limits described in STC 85:
- a. Administrative costs, including those associated with the administration of the demonstration;
 - b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
 - c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third-party liability.
- 77. Program Integrity.** The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.
- 78. Medicaid Expenditure Groups:** Medicaid Expenditure Groups (MEG) are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and

other purposes related to monitoring and tracking expenditures under the demonstration. The Master MEG Chart Table 3 provides a master list of MEGs defined for this demonstration

Table 3: Master MEG Chart					
MEG	Which BN Test Does Applies?	WOW Per Capita	WOW Aggregate	WW	Brief Description
Adult Group	Hypo 1	X		X	Adult Group
HRSN Services	Capped Hypo		X	X	All expenditures for Life360 HOME HRSN services
HRSN Infrastructure	Capped Hypo		X	X	All infrastructure expenditures related to the provision of Life360 HOME HRSN services
ADM	N/A				All additional administrative costs that are directly attributable to the demonstration and are not described elsewhere and are not subject to budget neutrality

BN – budget neutrality; MEG – Medicaid expenditure group; WOW – without waiver; WW – with waiver

79. Reporting Expenditures and Member Months. The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00365/4). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

- a. **Cost Settlements.** The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (forms CMS-64.9P Waiver) for the summary sheet line 10b (in lieu of lines 9 or 10c, or line 7. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost

settlements must be reported by DY consistent with how the original expenditures were reported.

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

Table 4. MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 or 64.10 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
Adult Group	Report all medical assistance expenditures for eligible adult group individuals enrolled in ARHOME		Follow standard CMS 64.9 Category of Service Definition	Date of service	MAP	Y	1/1/2022	12/31/2026
HRSN Services	Report all expenditures for approved HRSN initiatives, excluding infrastructure	See STC# 41	Follow standard CMS 64.9 or CMS 64.10 Category of Service Definitions	Date of service/Date of payment	MAP/ADM	N	11/1/22	12/31/26
HRSN Infrastructure	Report all infrastructure expenditures for approved HRSN initiatives	See STC# 42	Follow standard CMS 64.10 Category of Service Definitions	Date of payment	ADM	N	11/1/22	12/31/26
ADM	Report all additional administrative costs that are directly attributable to the demonstration and are not described elsewhere and are not subject to budget neutrality		Follow standard CMS 64.10 Category of Service Definitions	Date of Payment	ADM	N	1/1/22	12/31/26

ADM – administration; DY – demonstration year; MAP – medical assistance payments; MEG – Medicaid expenditure group;

- 80. Demonstration Years.** The Demonstration Years (DY) for this demonstration are defined in Table 5.

Table 5. Demonstration Populations

Demonstration Year 1 (DY1)	January 1, 2022	12 months
Demonstration Year 2 (DY2)	January 1, 2023	12 months
Demonstration Year 3 (DY3)	January 1, 2024	12 months
Demonstration Year 4 (DY4)	January 1, 2025	12 months
Demonstration Year 5 (DY5)	January 1, 2026	12 months

- 81. Budget Neutrality Monitoring Tool.** The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the performance metrics database and analytics (PMDA) system. The tool incorporates the “Schedule C Report” for comparing the demonstration’s actual expenditures to the budget neutrality expenditure limits described in section XII. CMS will provide technical assistance, upon request.⁵
- 82. Claiming Period.** The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.
- 83. Future Adjustments to Budget Neutrality.** CMS reserves the right to adjust the budget neutrality expenditure limit:

⁵ Per 42 CFR 431.420(a)(2), that states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and 431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS’s current approach is to include language in STCs requiring, as a condition of demonstration approval, that states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget neutrality limit. CMS has obtained Office of Management and Budget (OMB) approval of the monitoring tool under the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and states agree to use the tool as a condition of demonstration approval.

- a. To be consistent with enforcement of laws and policy statements, including regulations and guidance, regarding impermissible provider payments, health care related taxes, or other payments. CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.
- b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.

The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

84. **Budget Neutrality Mid-Course Correction Adjustment Request.** No more than once per demonstration year, the state may request that CMS make an adjustment to its budget neutrality agreement based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

- a. **Contents of Request and Process.** In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 87.c. If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. Within 120 days of acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 6. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration, are outside of the state's control, and/or that result from a new

expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

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

XIII. MONITORING BUDGET NEUTRALITY

85. **Limit on Title XIX Funding.** The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit consists of a Hypothetical Budget Neutrality Test and a Capped Hypothetical Budget Neutrality Test, as described below. CMS's assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which

summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.

- 86. Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 3. Master MEG Chart, and Table 4, MEG Detail for Expenditure and Member Month Reporting. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions, however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.
- 87. Calculation of the Budget Neutrality Limits and How They Are Applied.** To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.
- 88. Main Budget Neutrality Test.** This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical and Capped Hypothetical Budget Neutrality Tests. If the state exceeds the budget neutrality limits under the Hypothetical or Capped Hypothetical Budget Neutrality Tests it must return the excess FFP to CMS.
- 89. Hypothetical Budget Neutrality.** When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), or when a WOW spending baseline for certain WW expenditures is difficult to estimate due to variable and volatile cost data resulting in anomalous trend rates, CMS considers these expenditures to be “hypothetical,” such that the expenditures are treated as if the state could have received FFP for them absent the demonstration. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the expenditures on those services. When evaluating budget neutrality, CMS does not offset

non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures; that is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state's WW hypothetical spending exceeds the Hypothetical Budget Neutrality Test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending through savings elsewhere in the demonstration (if available) or to refund the FFP to CMS.

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

Table 6. Hypothetical Budget Neutrality Test 1									
MEG	PC or Agg	WOW Only, WW Only, or Both	Base Year	Trend Rate	DY 01	DY 02	DY 03	DY 04	DY 05
Adult Group	PC	Both	2019	5.8%	\$717.25	\$758.85	\$802.86	\$849.43	\$898.69

- 91. Capped Hypothetical Budget Neutrality for Evidence-Based HRSN Initiatives.** When expenditure authority is provided for specified HRSN initiatives in the demonstration (in this approval, as specified in STC 41), CMS considers these expenditures to be "capped hypothetical" expenditures; that is, the expenditures are eligible to receive FFP up to a specific aggregate spending cap per demonstration year, based on the state's expected expenditures. States can also receive FFP for capacity-building, infrastructure, and operational costs for the HRSN initiatives (per STC 42); this FFP is limited by a sub-cap of the aggregate spending cap and is determined by CMS based on the amount the state expects to spend. Like all hypothetical expenditures, capped hypothetical expenditures do not need to be offset by savings, and cannot produce savings; however, unspent expenditure authority allocated for HRSN infrastructure in a given demonstration year can be applied to HRSN services in the same demonstration year. Any unspent HRSN services expenditure authority may not be used to fund HRSN infrastructure. To allow for capped hypothetical expenditures and to prevent them from

resulting in savings that would apply to the rest of the demonstration, CMS currently applies a separate, independent Capped Hypothetical Budget Neutrality Test, which subjects capped hypothetical expenditures to pre-determined aggregate limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If actual HRSN initiative spending is less than the Capped Hypothetical Budget Neutrality Test's expenditure limit for a given demonstration year, the difference is not considered demonstration savings. Unspent HRSN expenditure authority under the cap for each demonstration year can be carried, shifted, or transferred across future demonstration years. However, unspent HRSN expenditure authority cannot roll over to the next demonstration approval period. If the state's capped hypothetical spending exceeds the Capped Hypothetical Budget Neutrality Test's expenditure limit, the state agrees (as a condition of CMS approval) to refund any FFP in excess of the cap to CMS.

92. **Capped Hypothetical Budget Neutrality Test: HRSN.** Table 7 identifies the MEGs that are used for the Capped Hypothetical Budget Neutrality Test. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Capped Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from the Capped Hypothetical Budget Neutrality Test cannot be offset by savings under the Hypothetical Budget Neutrality Test.

Table 7. Capped Hypothetical Budget Neutrality Test							
MEG	PC or Agg	WOW Only, WW Only, or Both	DY01	DY02	DY03	DY04	DY05
HRSN services	Agg	Both	\$0	\$8.4M	\$19.5M	\$25.8M	\$31.1M
HRSN Infrastructure	Agg	Both	\$0	\$2.7M	\$1.97M	\$3.0M	\$2.8M

93. **Composite Federal Share.** The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through the MBES/CBES

and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

- 94. Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the demonstration period, which extends from January 1, 2022 to December 31, 2026. If at the end of the demonstration approval period a Hypothetical or Capped Hypothetical Budget Neutrality Test has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the budget neutrality agreement, the budget neutrality test shall be based on the time elapsed through the termination date.
- 95. Corrective Action Plan.** If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

Table 8. Budget Neutrality Test Corrective Action Plan Calculation		
Demonstration Year	Cumulative Target Definition	Percentage
DY 1	Cumulative budget neutrality limit plus:	2.0 percent
DY 1 through DY 2	Cumulative budget neutrality limit plus:	1.5 percent
DY 1 through DY 3	Cumulative budget neutrality limit plus:	1.0 percent
DY 1 through DY 4	Cumulative budget neutrality limit plus:	0.5 percent
DY 1 through DY 5	Cumulative budget neutrality limit plus:	0.0 percent

XIV. EVALUATION OF THE DEMONSTRATION

- 96. Cooperation with Federal Evaluators and Learning Collaborative.** As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the

demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities that collect, produce or maintain data and files for the demonstration, that they make data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. This may also include the state's participation – including representation from the state's contractors, independent evaluators, and organizations associated with the demonstration operations, as applicable – in a federal learning collaborative aimed at cross-state technical assistance, and identification of lessons learned and best practices for demonstration measurement, data development, implementation, monitoring and evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 59.

97. **Independent Evaluator.** The state must use an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The independent party must sign an agreement to conduct the demonstration evaluation in an independent manner in accordance with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.
98. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design no later than 180 days after the approval of the demonstration. The Evaluation Design must be drafted in accordance with Attachment A (Developing the Evaluation Design) of these STCs, and any applicable CMS evaluation guidance and technical assistance for the demonstration's policy components. The Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, such as quasi-experimental methods like difference-in-differences and interrupted time series, as well as establishing valid comparison groups and assuring causal inferences in demonstration evaluations. In addition to these requirements, if determined culturally appropriate for the communities impacted by the demonstration, the state is encouraged to consider implementation approaches involving randomized control trials and staged rollout (for example, across geographic areas, by service setting, or by beneficiary characteristic)—as these implementation strategies help create strong comparison groups and facilitate robust evaluation.

The state is strongly encouraged to use the expertise of the independent party in the development of the draft Evaluation Design. The draft Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STCs 102 and 103.

For any amendment to the demonstration, the state will be required to update the approved Evaluation Design or submit a new Evaluation Design to accommodate the amendment component. The amended Evaluation Design must be submitted to CMS for review no later than 180 calendar days after CMS's approval of the demonstration amendment. Depending on the scope and timing of the amendment, in consultation with CMS, the state may provide the details on necessary modifications to the approved Evaluation Design via the monitoring reports. The amendment Evaluation Design must also be reflected in the state's Interim and Summative Evaluation Reports, described below.

- 99. Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within 60 calendar days after receipt of CMS's comments, if any. Upon CMS approval of the Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish to its website the approved Evaluation Design within 30 days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation progress in each of the Quarterly and Annual Monitoring Reports. Once CMS approves the Evaluation Design, if the state wishes to make changes, the state must submit a revised Evaluation Design to CMS for approval if the changes are substantial in scope; otherwise, in consultation with CMS, the state may include updates to the Evaluation Design in Monitoring Reports.
- 100. Evaluation Questions and Hypotheses.** Consistent with Attachments B and C (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Reports) of these STCs, the evaluation deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS evaluation guidance and technical assistance, the evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact and its effectiveness in achieving the goals.

The hypothesis testing should include, where possible, assessment of both process and outcome measures. The evaluation must study outcomes, such as likelihood of enrollment and enrollment continuity, and various measures of access, utilization, and health outcomes, as appropriate and in alignment with applicable CMS evaluation guidance and technical assistance, for the demonstration policy components. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Core Set of Health Care Quality Measures for Medicaid-Eligible Adults, the Behavioral Risk Factor Surveillance System (BRFSS) survey, and/or measures endorsed by National Quality Forum (NQF).

CMS underscores the importance of the state undertaking a well-designed beneficiary survey and/or interviews to assess, for instance, beneficiary understanding of and

experience with the various demonstration policy components, including the Life360 components, and waiver of retroactive eligibility, beneficiary experiences with access to and quality of care, as well as changes in incidence of beneficiary medical debt. In addition, the state is strongly encouraged to evaluate the implementation of the demonstration programs in order to better understand whether implementation of certain key demonstration policies happened as envisioned during the demonstration design process and whether specific factors acted as facilitators of—or barriers to—successful implementation. Implementation research questions can also focus on beneficiary and provider experience with the demonstration. The implementation evaluation can inform the state's crafting and selection of testable hypotheses and research questions for the demonstration's outcome and impact evaluations and provide context for interpreting the findings.

Specifically, hypotheses for the demonstration's program component authorizing premium assistance and cost-sharing reduction payments for beneficiaries in QHPs must focus on outcomes such as beneficiary enrollment, take-up rates, access and health outcomes, and unmet need for care. Hypotheses for the waiver of retroactive eligibility must relate to (but are not limited to) the following outcomes: likelihood of enrollment and enrollment continuity, enrollment when people are healthy, health status, and financial status. The state must also include descriptive research questions and hypotheses related to trends in enrollment, disenrollment, and reenrollment, beneficiary outreach, and challenges encountered during the premium policy phase out process.

With respect to the Life360 HOMEs amendment, evaluation hypotheses must focus on areas such as assessing the effectiveness of the HRSN services in mitigating identified needs of beneficiaries. Such assessment is expected to use applicable demonstration monitoring and other data on the prevalence and severity of beneficiaries' HRSNs and the provision of and beneficiary utilization of HRSN services. Furthermore, the HRSN evaluation must include an analysis of how the initiatives affect utilization of preventive and routine care, utilization of and costs associated with potentially avoidable, high-acuity health care, and beneficiary physical and mental health outcomes. More specifically, the evaluation must analyze—among other outcomes—maternal and infant health outcomes for participants in the Maternal Life360 HOMEs; utilization of behavioral health and substance use disorder treatments for individuals with relevant diagnoses in Rural Life360 HOMEs; and the impact of incentives and supports to assist individuals in Success Life360 HOMES. Given the populations of focus and the program designs of the Life360 HOMEs, the state must also outline goals on how the demonstration may reduce inequities in health care access, quality of care, or health outcomes at the individual and/or community level, and include corresponding research questions and hypotheses focused on understanding the impact of the demonstration on health quality, including through the reduction of health disparities. For example, by assessing the effects of the initiatives in reducing disparities in health care access, quality of care, or health outcomes at the individual, population, and/or community level.

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

Additionally, as part of its evaluation efforts, the state must also conduct a demonstration cost assessment to include, but not be limited to: administrative costs of demonstration implementation and operation, Medicaid health service expenditures, and provider uncompensated care costs. The state must analyze the budgetary effects of the HRSN services, and the overall Medicaid health medical assistance service expenditures. In addition, the state must use findings from hypothesis tests aligned with other demonstration goals and cost analyses together to assess the demonstration's effects on the fiscal sustainability of the state's Medicaid program.

The state must collect data to support analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, English language proficiency, primary language, disability status, and geography). Such stratified data analyses will provide a fuller understanding of existing disparities in access to and quality of care and health outcomes, and help inform how the demonstration's various policies might support reducing such disparities.

- 101. Evaluation Budget.** A budget for the evaluation must be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluation such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses, and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.
- 102. Interim Evaluation Report.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for extension, the Interim 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. In this report, the state

must also describe its findings related to unwinding the state's premium policies, and any potential lessons thereof.

- b. For demonstration authority or any components within the demonstration that expire prior to the overall demonstration's expiration date, and depending on the timeline of expiration/phase-out, the Interim Evaluation Report may include an evaluation of the authority, to be collaboratively determined by CMS and the state.
- c. If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted, or one year prior to the end of the demonstration, whichever is sooner. If the state is not requesting an extension for the demonstration, an Interim Evaluation Report is due one year prior to the end of the demonstration.
- d. The state must submit a revised Interim Evaluation Report 60 days after receiving CMS's comments on the draft Interim Evaluation Report, if any. Once approved by CMS, the state must post the final Interim Evaluation Report to the state's Medicaid website within 30 calendar days.
- e. The Interim Evaluation Report must comply with Attachment C (Preparing the Interim and Summative Evaluation Reports) of these STCs.

103. Summative Evaluation Report. 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 draft Summative Evaluation Report must be developed in accordance with Attachment C (Preparing the Interim and Summative Evaluation Reports) of these STCs, and in alignment with the approved Evaluation Design.

- a. The state must submit a revised Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.
- b. Once approved by CMS, the state must post the final Summative Evaluation Report to the state's Medicaid website within 30 calendar days.

104. 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 an extension process when associated with the state's Interim Evaluation Report, or as part of the review of the Summative Evaluation Report. A corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 11. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

- 105. 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.
- 106. Public Access.** The state shall post the final documents (e.g., Implementation Plans, Monitoring Protocol, 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.
- 107. Additional Publications and Presentations.** For a period of 12 months following CMS's approval of deliverables, CMS will be notified prior to presentation of these reports or their findings, including in related publications (e.g., 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 and other documents, CMS will be provided a copy including any associated press materials. CMS will be given 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.

XV. SCHEDULE OF DELIVERABLES

The state is held to all reporting requirements as outlined in the STCs; this schedule of deliverables should serve only as a tool for informational purposes only.

Date – Specific	Deliverable	Section Reference
Within 90 days of Life360 HOME amendment approval	New Initiatives Implementation Plan	STC 62
Within 60 days of receiving CMS comments	Revised New Initiatives Implementation Plan	STC 62
Within 150 days of approval date	Monitoring Protocol	STC 63
Within 60 days of receiving CMS comments	Revised Monitoring Protocol	STC 63
Within 180 calendar days from approval date	Draft Evaluation Design	STC 98
Within 60 days of receiving CMS comments	Revised Evaluation Design	STC 99
One year prior to demonstration expiration or with extension application	Draft Interim Evaluation Report	STC 102
Within 60 days of receiving CMS comments	Revised Interim Evaluation Report	STC 102
Within 18 months after the expiration of this demonstration period	Draft Summative Evaluation Report	STC 103

Date – Specific	Deliverable	Section Reference
Within 60 days of receiving CMS comments	Revised Summative Evaluation Report	STC 103
Within 120 days after the end of the demonstration	Draft Close-Out Report	STC 66
Within 30 days after receiving CMS comments	Revised Close-Out Report	STC 66
Within 180 days of Life360 HOME amendment approval	Protocol for Assessment of Beneficiary Eligibility and Needs, Infrastructure Planning, and Provider Qualifications for Life360 HOMEs	STC 48
<i>Annually</i>		
90 days after the end of each DY	Annual Monitoring Report (including Q4 monitoring information and budget neutrality)	STC 61
Within 30 days of receiving CMS comments	Revised Annual Monitoring Report	STC 61
<i>Quarterly</i>		
60 days following the end of the quarter	Quarterly Monitoring Reports	STC 61
30 days following the end of the quarter	Quarterly Expenditure Reports	STC 61
60 days following the end of the quarter, except for Q4 which is submitted with Annual Report	Quarterly Budget Neutrality Report	STC 61

Attachment A
Copayment Amounts

General Service Description	Cost Sharing for Beneficiaries with Incomes >20% FPL
Behavioral Health - Inpatient	\$0
Behavioral Health - Outpatient	\$4.70
Behavioral Health - Professional	\$4.70
Durable Medical Equipment	\$4.70
Emergency Room Services	\$0
FQHC	\$4.70
Inpatient	\$0
Lab and Radiology	\$4.70
Skilled Nursing Facility	\$20
Other	\$4.70
Other Medical Professionals	\$4.70
Outpatient Facility	\$4.70
Primary Care Physician	\$4.70
Specialty Physician	\$4.70
Pharmacy - Generics	\$4.70
Pharmacy - Preferred Brand Drugs	\$4.70
Pharmacy - Non-Preferred Brand Drugs, including specialty drugs	\$9.40

No copayments for individuals at or below 20% FPL.

Attachment B

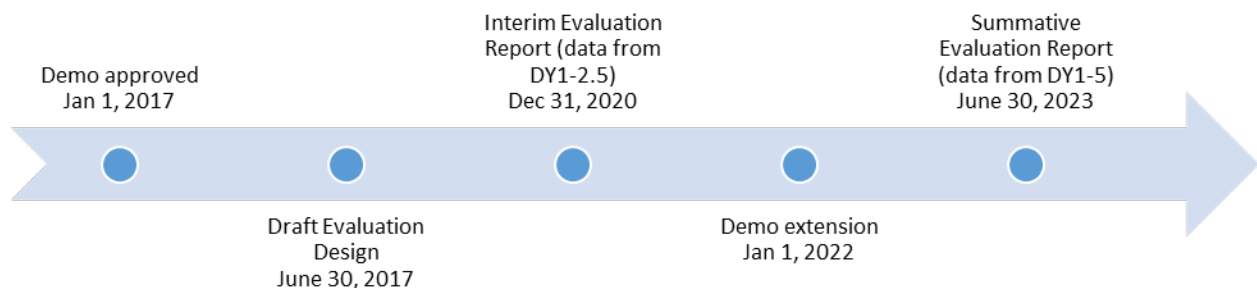
Developing the Evaluation Design

Introduction

Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. To that end, for states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. 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. Evaluations should include findings about 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 population of focus), and impacts of the demonstration (e.g., whether the outcomes observed in the population of focus differ from outcomes in similar populations not affected by the demonstration).

Submission Timelines

There is a specified timeline for the state's submission of its draft Evaluation Design and subsequent evaluation reports. The graphic below depicts an example of this timeline for a 5-year demonstration. 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 calendar days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Designs

CMS expects Evaluation Designs to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: <https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html>. If

the state needs technical assistance using this outline or developing the Evaluation Design, the state should contact its demonstration team.

All states with section 1115 demonstrations are required to conduct Interim and Summative Evaluation Reports, and the Evaluation Design is the roadmap for conducting these evaluations. 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.

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 description of the population groups impacted by the demonstration.
4. A brief description of the demonstration and history of its implementation, and whether the draft Evaluation Design applies to an amendment, extension, or expansion of, the demonstration.
5. For extensions, 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.

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

1. Identify the state’s hypotheses about the outcomes of the demonstration, and discuss how the evaluation questions align with the hypotheses and the goals of the demonstration.
2. Address how the hypotheses and research questions promote the objectives of Titles XIX and/or XXI.
3. 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 can be measured.
4. Include a Logic Model or 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, which includes information about the goals and features of the demonstration, is a particularly effective modeling tool when working to improve health and health care through specific interventions. A driver diagram depicts the relationship between the goal, the primary drivers that contribute directly to achieving the goal, 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>.
5. Include implementation evaluation questions to inform the state’s crafting and selection of testable hypotheses and research questions for the demonstration’s outcome and impact evaluations and provide context for interpreting the findings. Implementation evaluation research questions can focus on barriers, facilitators, beneficiary and provider experience with the demonstration, the extent to which demonstration components were implemented as planned, and the extent to which implementation of demonstration components varied by setting.

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, that the results are statistically valid and reliable, and that it builds upon other published research, using references where appropriate. The evaluation approach should also consider principles of equitable evaluation, and involve partners such as community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration who understand the cultural context in developing an evaluation approach. The state’s Request for Proposal for an independent evaluator, for example, could encourage research teams to partner with impacted groups.

This section also provides evidence that the demonstration evaluation will use the best available data. The state should report on, control for, and make appropriate adjustments for the limitations of the data and their effects on results, and discuss the generalizability of results. This section should provide enough transparency to explain what will be measured and how, in sufficient detail so that another party could replicate the results. Table A below

is an example of how the state might want to articulate the analytic methods for each research question and measure.

Specifically, this section establishes:

1. *Methodological Design* – Provide information on how the evaluation will be designed. For example, whether the evaluation will utilize pre/post data comparisons, pre-test or post-test only assessments. If qualitative analysis methods will be used, they must be described in detail.
2. *Focus and Comparison Populations* – Describe the characteristics of the focus and comparison populations, incorporating 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. The state also should include information about how it will define the numerators and denominators. Furthermore, the state should ensure the measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval. When selecting metrics, the state shall identify opportunities for improving quality of care and health outcomes, and controlling cost of care. The state also should incorporate benchmarking and comparisons to national and state standards, where appropriate.

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.) 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 Core Set of Health Care Quality Measures for Medicaid-Eligible Adults, metrics drawn from the Behavioral Risk Factor Surveillance System (BRFSS) survey, and/or measures endorsed by National Quality Forum. 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.

5. *Data Sources* – Explain from where the data will be obtained, describe any efforts to validate and clean the data, and discuss the quality and limitations of the data sources. If the state plans to collect primary data (i.e., data collected specifically for the evaluation), include the methods by which the data will be collected, the source of the proposed questions and responses, and the frequency and timing of data collection. Additionally,

copies of any proposed surveys must be provided to CMS for approval before implementation.

6. *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative analysis measures that will 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).
 - b. Explain how the state will isolate the effects of the demonstration from other initiatives occurring in the state at the same time (e.g., through the use of comparison groups).
 - c. Include a discussion of how propensity score matching and difference-in-differences designs may be used to adjust for differences in comparison populations over time, if applicable.
 - d. Consider the application of sensitivity analyses, as appropriate.
7. *Other Additions* – The state may provide any other information pertinent to the Evaluation Design for 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 more detailed information about the limitations of the evaluation. This could include limitations about the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize these 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.

CMS also 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. For example, if a demonstration is long-standing, it may be difficult for the state to include baseline data because any pre-test data points may not be relevant or comparable. Other examples of considerations include:

1. When the demonstration is:
 - a. Non-complex, unchanged, or has previously been rigorously evaluated and found to be successful; or
 - b. Could now be considered standard Medicaid policy (CMS published regulations or guidance).

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

E. 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 and prepare objective Evaluation Reports. 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 costs, 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, if CMS finds that the draft Evaluation Design is not sufficiently developed, or if the estimates appear to be excessive.
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 milestones for the development and submission of the Interim and Summative Evaluation Reports. 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 C

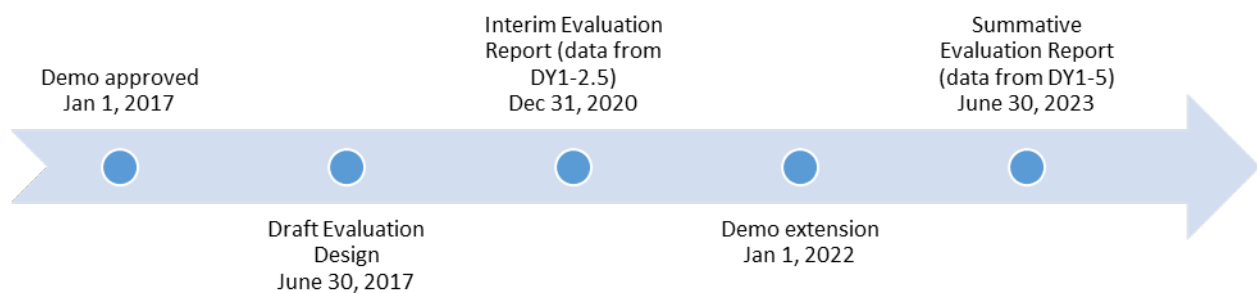
Preparing the Interim and Summative Evaluation Reports

Introduction

Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. To that end, for states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. 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. Evaluations should include findings about 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 population of focus), and impacts of the demonstration (e.g., whether the outcomes observed in the population of focus differ from outcomes in similar populations not affected by the demonstration).

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 a deliverables timeline for a 5-year demonstration. 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 Interim and Summative Evaluation Reports to the state's website within 30 calendar days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Reports

All states with Medicaid section 1115 demonstrations are required to conduct evaluations that are 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). 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. When

conducting analyses and developing the evaluation reports, every effort should be made to follow the methodology outlined in the approved Evaluation Design. 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.

CMS expects Interim and Summative Evaluation Reports to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: <https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html>. If the state needs technical assistance using this outline or developing the evaluation reports, the state should contact its demonstration team.

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 evaluation report submissions must provide comprehensive written presentations 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.

Required Core Components of Interim and Summative Evaluation Reports

The Interim and Summative Evaluation Reports present research and findings about the section 1115 demonstration. It is important that the reports 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. The evaluation reports 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.

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).

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 issue/s 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 description of the population groups impacted by the demonstration.
4. A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, or expansion of, the demonstration.
5. For extensions, 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. Additionally, the state should explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable).

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

1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the goals of the demonstration align with the evaluation questions and hypotheses.
2. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.
3. 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.
4. The inclusion of a Logic Model or 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.

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, (using references), meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An Interim Evaluation 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 Report.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used. The state also should report on, control for, and make 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, in sufficient detail so that another party could replicate the results. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1. *Methodological Design* – Whether the evaluation included an assessment of pre/post or post-only data, with or without comparison groups, etc.
2. *Focus and Comparison Populations* – Describe the focus and comparison populations, describing inclusion and exclusion criteria.
3. *Evaluation Period* – Describe the time periods for which data will be collected.
4. *Evaluation Measures* – List the measures used to evaluate the demonstration and their respective measure stewards.
5. *Data Sources* – Explain from where the data were obtained, and efforts to validate and clean the data.
6. *Analytic Methods* – Identify specific statistical testing which was 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 demonstrate whether and to what degree the evaluation questions and hypotheses of the demonstration were addressed. The findings should visually depict the demonstration results, using tables, charts, and graphs, where appropriate. This section should include findings from the statistical tests conducted.

G. Conclusions – In this section, the state will present the conclusions about the evaluation results. Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically, the state should answer the following questions:

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?
 - a. If the state did not fully achieve its intended goals, why not?
 - b. 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 interpretations 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. Interpreting the implications of evaluation findings should include involving partners, such as community groups, beneficiaries, health plans, health care providers, social service agencies and providers, and others impacted by the demonstration who understand the cultural context in which the demonstration was implemented.

I. Lessons Learned and Recommendations – This section of the evaluation report involves the transfer of knowledge. Specifically, it should include potential “opportunities” for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders. Recommendations for improvement can be just as significant as identifying current successful strategies. Based on the evaluation results, the state should address the following questions:

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?

Attachment D
New Initiatives Implementation Plan (RESERVED)

Attachment E
Monitoring Protocol (RESERVED)

Attachment F
Evaluation Design (RESERVED)

Attachment G
Life360 HOME Definitions & Eligibility

Life360 HOME	Services Definition	Eligibility	Duration	Settings and Referrals
Maternal Life360 HOME	<p>Beneficiaries will receive intensive care coordination through home visitation services based on one of the models that has demonstrated effectiveness as assessed by the U.S. Department of Health and Human Services and linkages to community resources and supports. The Life360 HOME hospital will incorporate screening that includes health and social-related needs (HSRN) as well as any other required health screenings, which will help inform the supports to be delivered to improve outcomes in each of the following domains:</p> <ul style="list-style-type: none"> • Maternal Health • Child Health • Family Economic Self-Sufficiency • Positive Parenting Practices <p>Referral to community supports to address identified HRSN as</p>	<p>An individual is eligible for the Maternal Life360 HOME if :</p> <ul style="list-style-type: none"> • Lives in the Maternal Life360 identified service area; and Is pregnant with a high-risk pregnancy diagnosis <p>High-risk pregnancy may be determined by the Maternal Life360 HOME if not already documented through a medical provider.</p>	<p>Services begin during pregnancy and continue up to two years after birth of the baby even if the individual is no longer eligible for Medicaid under any eligibility category⁶ based upon continued need of home visiting support.</p>	<p>Intensive Care Coordination will be delivered primarily in the home setting but could also be delivered in community or clinic settings.</p> <p>Maternal Life360 HOMEs will accept referrals for Maternal Life360 HOME Services from a diverse array of health and social service organizations, medical providers, and non-medical supports in the community through formal and informal agreements.</p>

⁶ If the individual would become no longer eligible for Medicaid under any eligibility category, they would still be able to receive the benefits under the Maternal Life360, based upon continued need, e.g., intensive care coordination, visiting home nursing and health related social needs assessments. The match for services to people who are no longer eligible for the adult group would be at regular FMAP.

Life360 HOME	Services Definition	Eligibility	Duration	Settings and Referrals
	permitted under these STCs			
Rural Life360 HOME	<ul style="list-style-type: none"> • Screening for HRSN using a standardized tool • Referral to community supports to address identified HRSN as permitted under these STCs <p>In addition to the services above, individuals with a mental health or substance use disorder and identified HRSN needs will receive Intensive Care Coordination services which will include:</p> <ul style="list-style-type: none"> • Conducting an in-depth 1:1 interview to determine the HRSN, any unmet needs related to medical services and nonmedical supports, and system involvement such as criminal justice if applicable. • Developing an individualized Person-Centered Action Plan (PCAP) reflecting the beneficiary's preferences for addressing the needs identified. Goals may include but are not limited to establishing and maintaining regular care for behavioral 	<p>All individuals living in the Rural Life360 HOME identified service area are eligible to receive a HRSN Screening and referrals to needed community supports regardless of Medicaid eligibility.</p> <p>An individual is eligible for Rural Life360 HOME intensive care coordination if the individual:</p> <ul style="list-style-type: none"> • Is eligible for the ARHOME program; • Lives in the Rural Life360 identified service area; • Has a mental health or substance use disorder diagnosis; and • Has at least one HRSN need identified through a HRSN screen. 	<p>Intensive Care Coordination can be received as long as the individual is eligible for the ARHOME demonstration and resides in the service area.</p>	<p>Intensive Care Coordination will be delivered primarily in the home setting but could also be delivered in community, medical clinic, behavioral health clinic, or hospital settings.</p> <p>Hospitals will accept referrals for Rural Life360 services from a diverse array of health and social service organizations, medical providers and non-medical supports in the community through formal and informal agreements. It is expected that most referrals will come from mental health or substance used disorder treatment providers.</p>

Life360 HOME	Services Definition	Eligibility	Duration	Settings and Referrals
	<p>health and medical needs; strengthening life and family skills; emotional and mental wellness; and obtaining or sustaining safe housing.</p> <ul style="list-style-type: none"> • Working directly with the beneficiary to improve their skills to be healthy and thrive in their community and connecting them to identified medical services and nonmedical supports. • Documenting care coordination activities including new goals and barriers/successes experienced by beneficiary 			
Success Life360 HOME	<p>Beneficiaries will receive Intensive Care Coordination services, which will include:</p> <ul style="list-style-type: none"> • Screening for HRSN using a standardized tool as prescribed by the program model • Conducting in-depth 1:1 interview to determine the HRSN, any unmet needs related to medical services and nonmedical supports, and system involvement such as criminal justice if applicable. 	<p>An individual is eligible for Success Life360 intensive care coordination if the individual:</p> <ul style="list-style-type: none"> • Lives in the Success Life360 identified service area; • Has a chronic health condition; and • Meets the criteria for at least one of the following categories: <ul style="list-style-type: none"> ○ Between nineteen (19) and twenty-four (24) years of age and has been previously placed under the 	<p>Length of time to receive intensive care coordination based upon obtainment of PCAP goals and is expected to be completed in 24 months or less. Services may remain in place at lesser intensity for longer than 24 months if PCAP goals have not been completed and</p>	<p>Intensive Care Coordination will be delivered primarily in the home or shelter setting but could also be delivered in community, educational or job training settings.</p> <p>Hospitals will accept referrals for Success Life360 services from a diverse array of health and social service organizations, medical providers and non-medical supports in the community through formal and informal agreements. A large</p>

Life360 HOME	Services Definition	Eligibility	Duration	Settings and Referrals
	<ul style="list-style-type: none"> Developing an individualized PCAP reflecting the beneficiary's preferences for addressing the needs identified. Goals may include but are not limited to establishing and maintaining regular care for behavioral health and/or medical needs; strengthening life skills; emotional and mental wellness; support applying for job training or education programs offered through the provider or other organizations; and obtaining or sustaining safe housing. Working directly with the beneficiary to improve their skills to be healthy and thrive in their community and connecting them to identified medical services and nonmedical supports. Documenting care coordination activities including new goals and barriers/ successes experienced by the beneficiary. 	<p>supervision of the Division of Youth Services as verified by Arkansas Department of Human Services</p> <ul style="list-style-type: none"> Between nineteen (19) and twenty-four (24) years of age and has been previously placed under the supervision of the Arkansas Department of Correction, as verified by the Arkansas Department of Correction Between nineteen (19) and twenty-seven (27) years of age and has been previously placed under the supervision of the Division of Children and Family Services; as verified by Arkansas Department of Human Services. Between nineteen (19) and thirty (30) years of age and is a veteran verified by Arkansas Veterans Administration. 	the individual remains eligible for Medicaid.	portion of referrals will come from the state agencies that serve eligible beneficiaries.

Attachment H
Life360 HOME Service Details (RESERVED)

Attachment I
Protocol for Assessment of Beneficiary Eligibility and Needs, Infrastructure Planning, and
Provider Qualifications (RESERVED)