

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



November 02, 2020

Todd Richardson
Director
MO HealthNet Division
Missouri Department of Social Services
P.O. Box 1527
Broadway State Office Building
Jefferson City, MO 65102-1527

Dear Mr. Richardson:

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

For the reasons discussed below, The Centers for Medicare & Medicaid Services (CMS) is approving your request, received on October 30, 2019, to amend Missouri’s section 1115 demonstration project titled, “Missouri Gateway to Better Health” (Project Number: 11-W-00250/7), effective as of the date of this letter. Specifically, approval of this demonstration amendment will enable Missouri to receive FFP to establish and implement a preventative physical function improvement services benefit under the Gateway to Better Health benefit package.

Background on the Gateway to Better Health Demonstration

The Centers for Medicare & Medicaid Services (CMS) first approved the Gateway to Better Health demonstration on July 28, 2010. At the state’s request, CMS approved a series of extensions with the most recent on September 1, 2017, which extended the demonstration through December 31, 2022.

The Gateway to Better Health demonstration covers uninsured individuals, ages 19 through 64, who reside in the St. Louis region (City of St. Louis and St. Louis County), are not eligible for Medicaid under the state plan, and have incomes at or below 100 percent of the federal poverty level (FPL). Individuals have access to limited benefits that include primary care, specialty care, and urgent care through participating providers.

Under the Gateway to Better Health demonstration, the Missouri Department of Social Services is authorized to spend up to \$30 million (total computable) annually to preserve and improve primary and specialty care in the St. Louis region, in lieu of spending that amount on payments to disproportionate share hospitals (DSH). In addition, the demonstration includes an expenditure authority that allows the state to spend a portion of the annual total computable amount of \$30 million on the St. Louis Regional Health Commission (SLRHC) to administer the demonstration (capped at \$4.5 million dollars annually).

Extent and Scope of the Demonstration Amendment

The approval of this demonstration amendment will authorize the state to obtain FFP for expenditures associated with the establishment of a preventative physical function improvement services benefit under the Gateway to Better Health benefits package. The benefit package will cover physical therapy, occupational therapy, chiropractic services, and acupuncture services for Gateway to Better Health beneficiaries with a pain-related diagnosis.

The preventative physical function improvement services benefit will integrate pain relief services into the Gateway to Better Health benefits package. In addition, the benefit offers Gateway to Better Health beneficiaries an alternative to opioid treatment for pain relief and will align with the new Medicaid chronic pain benefit offered by MO HealthNet (Missouri Medicaid). On April 1, 2019, MO HealthNet implemented a new statewide health benefit for their recipients addressing chronic pain. The benefit is coordinated through the patient’s primary care provider and gives patients access to physical therapy, chiropractic therapy, and acupuncture, alongside cognitive-behavioral therapy (CBT) for chronic pain and non-opioid medication therapy.

Determination that the Demonstration Amendment is Likely to Assist in Promoting Medicaid’s Objectives

Under section 1901 of the Act, the Medicaid program provides federal funding to participating states “[f]or the purpose of enabling each state, as far as practicable under the conditions in such state, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care.”

This demonstration amendment continues to offer medical assistance to a population that would not otherwise qualify for Medicaid and provides a rehabilitative services benefit that helps individuals attain or retain capability for independence and self-care.

The approval of this demonstration is also likely to support efforts to combat the national opioid crisis as evidenced by a Gateway to Better Health provider survey, wherein half of the providers reported that they would prescribe fewer controlled substances for pain, such as opioids, if they had greater access to other treatment methods.

In addition, CMS has determined that approval of the Gateway to Better Health preventative physical function improvement amendment is likely to:

- Reduce barriers for beneficiaries in accessing preventative physical function improvement services
- Improve beneficiaries' physical functionality
- Reduce preventable opioid prescriptions for pain management
- Reduce or prevent expensive specialty care visits

For these reasons, CMS has determined that the Gateway to Better Health preventative physical function improvement amendment is likely to promote Medicaid objectives, and the expenditure authority sought is necessary and appropriate to carry out the demonstration amendment.

On August 4, 2020, Missouri passed a ballot initiative to expand Medicaid up to 133 percent of the federal poverty level (FPL). The state is currently evaluating the impact of Medicaid expansion on this demonstration population. CMS will work with the state on a transition plan to ensure demonstration beneficiaries are appropriately transitioned to the new adult group.

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.

As enacted by the Affordable Care Act (ACA), and incorporated under section 1115(d)(2)(A) & (C) of the Act, comment periods should be "sufficient to ensure a meaningful level of public input," but the statute imposed no additional requirement on the states or the Secretary to provide an individualized response to address those comments, as might otherwise be required under a general rulemaking. Accordingly, the implementing regulations issued in 2012 provide that CMS will review and consider all comments received by the deadline, but will not provide individualized written responses to public comments. 42 CFR 431.416(d)(2).

On September 30, 2019, the state opened a public comment period that spanned 30 days from September 30, 2019 through October 30, 2019. The state conducted three public hearings, October 1, 2019, October 3, 2019, and October 7, 2019. The state received only one written comment during the state 30-day public comment period, which was supportive of the amendment. There were no attendees at the two of the public hearings. On October 1, 2019, as a part of the regularly-scheduled Provider Services Advisory Board meeting, which was open to the public and designated as a public forum for providers and community members to provide input on the amendment request, two comments were received during this meeting. One commenter expressed appreciation that an evaluation metric for the amendment focused on patient perception. A second commenter encouraged the state to focus on a home plan, building robust after care, and making this benefit part of an integrated care team. Neither the state nor CMS received any comments opposed to the amendment.

On November 13, 2019, CMS opened a 30-day federal public comment period that extended through December 13, 2019. CMS received 19 comments that expressed overwhelming support for the demonstration amendment. After carefully reviewing the public comments submitted during the federal comment period and the information received from the state public comment period, CMS has concluded that the demonstration is likely to advance the objectives of Medicaid.

Other Information

CMS's approval of this demonstration amendment is subject to the limitation specified in the enclosed authorities and STCs which define 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 they have been specifically listed as waived or not applicable to expenditures or individuals covered by expenditure authority.

This approval is also subject to your written acknowledgement of the award and acceptance of STCs within 30 calendar days of the date of this letter. Please send written acceptance to your project officer, Felix Milburn. Mr. Milburn is available to answer any questions concerning your section 1115(a) demonstration and may be contacted as follows:

Mr. Felix Milburn
Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-25-26
7500 Security Boulevard
Baltimore, MD 21244-1850
Telephone: (410) 786-1315
E-mail: Felix.Milburn@cms.hhs.gov

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

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We look forward to continuing to work with you and your staff.

Sincerely,

A black rectangular redaction box covers the signature of Anne Marie Costello. There are faint blue ink scribbles visible above the redaction.

Anne Marie Costello
Acting Deputy Administrator and Director

Enclosure

cc: Deborah Read, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

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

NUMBER: 11-W-00250/7

TITLE: Gateway to Better Health

AWARDEE: Missouri Department of Social Services

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Missouri for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act, shall, for the period of this demonstration extension, beginning January 1, 2018, through December 31, 2022, be regarded as expenditures under the state's title XIX plan.

The following expenditure authorities shall enable Missouri to implement the Gateway to Better Health Medicaid section 1115 demonstration. In addition to the individual limitation on expenditures under each of these authorities, expenditures under all categories below shall not exceed an amount annually that, when added to the amount of payments made for that year to disproportionate share hospital (DSH) providers, as defined under the state plan in accordance with section 1923(f) of the Act, does not exceed the Missouri state-specific DSH payment allotment for that year, as calculated pursuant to section 1923(f) of the Act.

The expenditure authorities listed below promote the objectives of title XIX in the following ways: by increasing overall coverage of low income individuals and improving health outcomes for low income populations.

The expenditure authorities below shall apply with respect to operation of the Safety Net Pilot Program:

- **Demonstration Population 1:** Expenditures for uninsured individuals, not eligible for Medicaid, who are living in St. Louis City or St. Louis County, and are between the ages of 19 – 64 years of age with income at or below 100 FPL to pay for primary care, specialty care, limited substance use disorder (SUD) services, and preventative physical function improvement services provided by designated primary care providers or designated specialty care providers when referred by a designated primary care provider.
- **Expenditures for Managing the Coverage Model:** Expenditures pursuant to a memorandum of understanding and not to exceed \$4,500,000 annually for costs incurred by the St. Louis Regional Health Commission (SLRHC) for activities related to the continued administration of the coverage model during the extension period.

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly identified as not applicable in the list below, shall apply to all demonstration populations.

Statewideness

Section 1902(a)(1)

To the extent necessary to allow the state to limit enrollment in the demonstration to persons residing in the City of St. Louis and St. Louis County.

Reasonable Promptness

Section 1902(a)(8)

To the extent necessary to enable the state to establish an enrollment target and maintain waiting lists for the demonstration population.

Amount, Duration, and Scope

Section 1902(a)(10)(B)

To the extent necessary to permit the state to offer benefits to the demonstration population that differ from the benefits offered under the Medicaid state plan.

Freedom of Choice

Section 1902(a)(23)(A)

To the extent necessary to enable the state to mandatorily enroll the demonstration population into a delivery system that restricts the free choice of provider.

Retroactive Eligibility

Section 1902(a)(34)

To the extent necessary to enable the state to not provide medical assistance to the demonstration population prior to the date of application for the demonstration benefits.

**Payment for Services by Federally
Qualified Health Centers (FQHCs)**

Section 1902(a)(15)

To the extent necessary to enable the state to make payments to participating FQHCs for services provided to the demonstration population using reimbursement methodologies other than those required by section 1902(bb) of the Act due to the limited nature of the benefits.

Drug formulary and rebate requirements

Section 1902(a)(54)

To the extent necessary to enable the state to offer a limited formulary covering only generic drugs in limited contexts.

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

NUMBER: 11-W-00250/7

TITLE: Gateway to Better Health

AWARDEE: Missouri Department of Social Services

I. PREFACE

The following are the amended special terms and conditions (STCs) for Missouri’s Gateway to Better Health section 1115(a) Medicaid demonstration (hereinafter referred to as “demonstration”). The parties to this agreement are the Missouri Department of Social Services (“state”) and the Centers for Medicare & Medicaid Services (CMS). The STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state’s obligations to CMS during the life of the demonstration. The effective dates of the demonstration are January 1, 2018 through December 31, 2022, unless otherwise stated. The Substance Use Disorder (SUD) component of the demonstration is effective February 1, 2019 through December 31, 2022.

The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description and Objectives
- III. General Program Requirements
- IV. Primary Care Support
- V. Elements of the Demonstration Program for Participating Providers
- VI. Eligibility, Enrollment, and Disenrollment under the Gateway to Better Health
- VII. Demonstration Benefits
- VIII. Cost Sharing Under the Demonstration
- IX. General Reporting Requirements
- X. Monitoring Call and Discussions
- XI. Evaluation of the Demonstration
- XII. Close-Out Reporting
- XIII. General Financial Requirements
- XIV. Monitoring Budget Neutrality for the Demonstration
- XV. Schedule of the State Deliverables during the Demonstration

II. PROGRAM DESCRIPTION AND OBJECTIVES

In July 2010, the demonstration was approved to transition the financial payment structure for five safety net providers in the City of St. Louis to a financial model that links expenditures to coverage. Under the demonstration, the state has been authorized to spend up to \$30 million (total computable) annually to preserve and improve primary and specialty care in the St. Louis region, in lieu of spending that amount of statutorily authorized funding on payments to disproportionate share hospitals (DSHs). The amount of expenditures under this demonstration, when added to

the amount of DSH payments made for the year, shall not exceed the state's DSH allotment calculated in accordance with section 1923 of the Social Security Act (the Act).

The demonstration was amended in June 2012, to implement a pilot program, as described below, whereby it provided health insurance coverage to uninsured individuals residing in St. Louis City and St. Louis County with family income at or below 133 percent of the federal poverty level (FPL). This amendment was effective July 1, 2012.

In addition, under the demonstration, the state has authority to claim as administrative costs limited amounts incurred for functions related to the design, implementation, and the administration of the demonstration pursuant to the Memorandum of Understanding with the St. Louis Regional Health Commission (SLRHC), which is a non-profit, non-governmental organization whose mission is to 1) increase access to health care for people who are medically uninsured and underinsured; 2) reduce health disparities among populations in the St. Louis Region (St. Louis City and County); and 3) improve health outcomes among low income populations in St. Louis Region.

The state also had authority to claim as administrative costs limited amounts incurred by the SLRHC pursuant to an MOU for functions related to emergency room diversion efforts through the Community Referral Coordinator program (CRC). The CRC expenditure authority ended December 31, 2013. The SLRHC continues to perform administrative functions under the demonstration.

On December 26, 2012, the state submitted an extension request. On September 27, 2013, the demonstration was extended for one (1) year to cover uninsured individuals who reside in the St. Louis region with incomes between 0 through 100 percent of the FPL.

In March 2014, the state submitted a renewal application for a two (2) year extension period of the Gateway to Better Health demonstration with no changes. In July 2014, CMS approved a one-year extension of the demonstration to continue health care coverage to Gateway beneficiaries.

On December 31, 2014, the state submitted an extension request for a one (1) year extension of the demonstration. On February 19, 2015, the state submitted an amendment request to offer brand name insulin and inhalers when there is no generic alternative.

In October 2015, CMS approved a one (1) year extension of the current demonstration and the amendment request to provide brand name insulin and inhalers when there is no generic alternative. The state began offering brand name insulin and inhalers starting January 1, 2016, as specified in STC 26.

On December 15, 2015, the state submitted a request for a one (1) year extension of the section 1115 demonstration project, Gateway to Better Health. The extension request had the same program elements as the December 31, 2014 approved extension. On June 17, 2016, CMS approved a one (1) year extension of the demonstration.

On November 9, 2016, the Missouri Department of Social Services (DSS) submitted a section

1115 demonstration extension application to CMS to extend the Gateway to Better Health section 1115 demonstration for one (1) year. The extension did not include any changes to the Gateway to Better Health section 1115 demonstration, as approved for a one (1) year extension on June 17, 2016. On September 1, 2017, CMS approved a five (5) year extension of the demonstration.

On August 31, 2018, DSS submitted an amendment application for the Gateway to Better Health section 1115 demonstration. As approved, the amendment authorizes federal financial participation (FFP) for limited substance use disorder services for the demonstration population and revises the expenditure authorities and STC language to reflect that the requirements in section 1927, as well as the drug manufacturer rebate obligation under that section, do not apply in the case of the limited Gateway to Better Health prescription drug benefit.

On October 30, 2019, DSS submitted an amendment to the Gateway to Better Health section 1115 demonstration. The amendment authorizes the state to offer “preventative physical function improvement services,” which include physical therapy, occupational therapy, chiropractic services, and acupuncture services.

Under this demonstration Missouri expects to achieve the following to promote the objectives of title XIX:

- Preserve and strengthen the St. Louis City and St. Louis County safety net of health care providers available to serve the uninsured.
- Connect the uninsured to a primary care home which will enhance coordination, quality, and efficiency of health care through patient and provider involvement; and
- Maintain and enhance quality service delivery strategies to reduce health disparities.

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, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.
2. **Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly identified as not applicable in the expenditure authority documents (of which these terms and conditions are part), must apply to the demonstration.
3. **Changes in Medicaid Law, Regulation, and Policy.** The state must, within the time frames specified in law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or policy statement, affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is expressly identified as not applicable.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy Statements.**
 - A. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration, as necessary, to comply with such change. The modified budget neutrality agreement will be effective upon the implementation of the change.
 - B. If mandated changes in the federal law require state legislation, the changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law.
5. **State Plan Amendments.** The state shall not be required to submit title XIX state plan amendments for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid state plan is affected by a change to the demonstration, a conforming amendment to the state plan may be required, except as otherwise noted in these STCs.
6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, enrollee 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 changes to these elements without prior approval by CMS. Amendments to the demonstration are not retroactive and FFP will not be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below.
7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the state to submit required reports and other deliverables in a timely fashion according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:
 - A. An explanation of the public process used by the state, consistent with the requirements of STC 14, to reach a decision regarding the requested amendment;
 - B. A data analysis which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include current federal share “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;

- C. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation; and
- D. If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.

8. **Extension of the Demonstration.** The Gateway to Better Health demonstration is not a comprehensive, statewide demonstration; therefore, it may only be renewed under section 1115(a) of the Act. No later than twelve (12) months prior to the expiration date of the demonstration, the governor or chief executive officer of the state must submit to CMS notification that it expects to cover individuals under the Medicaid state plan or through some other type of coverage, a demonstration extension request, or a phase-out plan consistent with the requirements of STC 9

As part of the demonstration extension request, the state must provide documentation of compliance with the transparency requirements at 42 CFR 431.412 and the public notice and tribal consultation requirements outlined in STC 14.

9. **Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.
- A. **Notification of Suspension or Termination:** The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit its notification letter and a draft phase-out plan to CMS no less than five (5) 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 plan for a thirty (30) day public comment period. In addition, the state must conduct tribal consultation in accordance with its approved tribal consultation state plan amendment. Once the thirty (30) day public comment period has ended, the state must provide a summary of each public comment received, the state’s response to the comment and how the state incorporated the received comment into a revised phase-out plan.
 - B. The state must obtain CMS approval of the phase-out plan prior to the implementation of the phase-out activities. Implementation of transition and phase-out activities must be no sooner than fourteen (14) days after CMS approval of the plan.
 - C. **Phase-out Plan Requirements:** The state must include, at a minimum, in its plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary’s appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility for the affected beneficiaries, and ensure ongoing coverage for eligible individuals, as well as any

community outreach activities.

D. **Phase-out Procedures:** The state must comply with all notice requirements found in 42 CFR 431.206, 431.210 and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration participants as outlined in 42 CFR 431.220 and 431.221. If a demonstration participant requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category as discussed in October 1, 2010, state Health Official Letter #10-008.

E. **Federal Financial Participation (FFP):** If the project is terminated or any relevant waivers suspended by the state, FFP shall be limited to normal closeout costs associated with terminating the demonstration including services and administrative costs of disenrolling participants.

10. **CMS Right to Terminate or Suspend.** CMS may suspend or terminate, subject to adequate public notice, 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 will promptly notify the state in writing of the determination and the reasons for the suspension or termination, together with the effective date.

11. **Finding of Non-Compliance.** The state does not relinquish its rights to challenge the CMS finding that the state materially failed to comply.

12. **Withdrawal of Waiver Authority.** CMS reserves the right to withdraw waivers or expenditure authorities at any time it determines that continuing the waivers or expenditure authorities would no longer be in the public interest or promote the objectives of Title XIX. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services and administrative costs of disenrolling participants.

13. **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.

14. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994). The state must also comply with the tribal consultation requirements in section 1902(a)(73) of the Act as amended by section 5006(e) of the American Recovery and Reinvestment Act (ARRA) of 2009, the implementing

regulations for the Review and Approval Process for Section 1115 demonstrations at 42 CFR Section 431.408, and the tribal consultation requirements contained in the state's approved Medicaid state plan, when any program changes to the demonstration, are proposed by the state.

- a. 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 C.F.R. §431.408(b)(2)).
 - b. In states with federally recognized Indian tribes, Indian health programs, and/or Urban Indian organizations, the state is required to submit evidence to CMS regarding the solicitation of advice from these entities prior to submission of any demonstration proposal and/or renewal of this demonstration (42 C.F.R. §431.408(b)(3)).
 - c. The state must also comply with the public notice procedures set forth in 42 C.F.R. 447.205 for changes in statewide methods and standards for setting payment rates.
15. **FFP.** No federal matching for expenditures for this demonstration will take effect until the effective date identified in the demonstration approval letter or as expressly stated within these STCs.

IV. PRIMARY CARE SUPPORT

16. **St. Louis Regional Health Commission (SLRHC).** The SLRHC may assist the state with the administrative functions of the Gateway demonstration.

A. Managing the Coverage Model: The state may claim as administrative costs for expenditures incurred by the SLRHC in support of activities related to the implementation and maintenance of the coverage model subject to the following:

- i. The administrative costs must be claimed by the state at monthly intervals based on the number of individuals who meet criteria for Population 1 as outlined in STC 20 in this demonstration.
- ii. The state must ensure that all administrative expenditures claimed based on SLRHC expenditures are consistent with the cost principles under Office of Management and Budget guidance documents and CMS administrative guiding principles as outlined in Attachment A.
- iii. A memorandum of understanding (MOU) exists between the state and SLRHC outlining the administrative activities that SLRHC will perform on the behalf of the state.

- iv. The state must submit a copy of the MOU for CMS review whenever changes are made.
- v. Costs are not to exceed the limits, as outlined in the chart below, per demonstration year in which the coverage model is operational.

Demonstration Year (DY)	Expenditure Limit per Demonstration Year
DY 5/ FFY 2014 (10/1/2013-09/30/2014) (12 months)	\$4,500,000
DY 6/ FFY 2015 (10/1/2014 – 9/30/2015) (12 months)	\$4,500,000
DY 7/ FFY 2016 (10/1/2015-9/30/2016) (12 months)	\$4,500,000
DY 8/ FFY 2017 (10/1/2016 – 09/30/2017) (12 months)	\$4,500,000
DY 9/ FFY 2018 10/01/2017-09/30/2018 (12 months)	\$4,500,000
DY 10 / FFY 2019 10/01/2018 – 09/30/2019 (12 months)	\$4,500,000
DY-11 / FFY 2020 10/01/2019 – 09/30/2020 (12 months)	\$4,500,000
DY – 12 / FFY 2021 10/01/2020 – 09/30/2021 (12 months)	\$4,500,000
DY – 13 / FFY 2022 10/01/2021 – 09/30/2022 (12 months)	\$4,500,000
DY – 14 / FFY 2023 10/01/2022 – 12/31/2022 (3 months)	\$1,125,000

V. ELEMENTS OF THE SAFETY NET PILOT PROGRAM FOR PARTICIPATING PROVIDERS

This section defines the participating providers in the Pilot Program, payment structures, and associated infrastructure development.

17. Safety Net Pilot Program Providers Defined.

For the purposes of this demonstration, the St. Louis providers eligible for reimbursement under these terms and conditions consist of the following clinics:

- A. CareSTL Health (Formerly known as Myrtle Hilliard Davis Comprehensive Health Centers);
- B. Affinia Healthcare (formerly known as Grace Hill Neighborhood Health Centers);
- C. Betty Jean Kerr People's Health Centers;
- D. Family Health Care Centers; and
- E. St. Louis County Health Centers.

Clinics are reimbursed by an alternate payment methodology established at a 100 percent of the Medicare rate, which will be accepted as payment in full, for assigned enrollees.

18. Specialty Voucher Program Parameters. Demonstration enrollees seen at the facilities listed above who need physician inpatient services or outpatient hospital care, will receive vouchers for such care, as described below and as funding allows. Parameters for the voucher program are as follows:

- A. Utilization managers will not provide vouchers if funding for specialty care services exceeds its estimated annual funding levels.
- B. The providers that participate in the voucher program may include, but are not limited to Barnes-Jewish Hospital, Washington University School of Medicine, St. Louis University School of Medicine, St. Mary's Hospital, Mercy Health System, St. Alexis Hospital, and Eye Associates.
- C. Specialty care providers will be reimbursed at a rate equal to 100 percent of the Medicare rate for each service.

19. Incentive Payments. As part of the payment reform efforts to pay for improved health outcomes, the state may use 7 percent of the provider payment as an incentive to improve provider practices. The provider shall have an opportunity to receive the withheld amount upon demonstrating that the provider has been able to meet measurement targets for improving the health of its enrollees. Any remaining amount will be redirected for services and must not be redirected for administrative or infrastructure payments. Details of the incentive protocol are provided in Attachment D.

- A. The protocol outlines performance metrics that the providers must meet, the schedule on which the providers must submit data, and the date that the state via the SLRHC must make the payment. The state must not claim the federal share of the incentive payments until the actual payments based on provider performance are made.

VI. ELIGIBILITY, ENROLLMENT, AND DISENROLLMENT UNDER THE SAFETY NET PILOT PROGRAM

20. Eligibility.

a. Individuals eligible for the demonstration are described in the table below.

Population Eligible for the Demonstration	
Population 1: Uninsured Individuals receiving primary care, specialty care, urgent care, limited SUD services, and preventative physical function improvement services through the demonstration	This population is limited to those with incomes at or below 100 percent of the FPL. Specialty care services will be provided solely through the specialty voucher program. Individuals are not eligible under the Medicaid state plan, are living in St. Louis City or St. Louis County, and are between the ages of 19-64 years old.

21. **Screening for Eligibility for Medicaid and/or CHIP.** Demonstration applicants for primary care services and specialty care services must be screened for Medicaid or CHIP eligibility before an eligibility determination is made for the demonstration. The state will follow the same enrollment processes as for Medicaid state plan individuals.
22. **Effective Date of Coverage - No Retroactive Eligibility.** Enrollees who qualify for coverage under this demonstration will not receive retroactive coverage. The beginning effective date of coverage under the demonstration will be the first day in which the application was received by the state.
23. **Enrollment Target.** The state generally may cap enrollment to stay within budget neutrality. The state shall set an enrollment target for participants enrolled in the demonstration at 16,000 individuals and will not restrict enrollment if that target has not been met. If the enrollment target has been reached, the state will enroll individuals from the wait list based on available funding and when the number of enrolled individuals drops to 15,951.
24. **Managing the Enrollment Target.** The state or the SLRHC may employ a waiting list to enroll in this demonstration using a “first come – first served” method.
 - A. The state or SLRHC will provide and accept applications for coverage under the demonstration even when enrollment is closed. Applicants will be checked for other categories of Medicaid or CHIP eligibility and will be added to the waiting list if they are not eligible for other coverage.
 - B. The state or SLRHC must provide written notice to CMS at least sixty (60) days prior to changing the enrollment target. The notice to CMS, at a minimum, must include:
 - i. Data on current enrollment levels in the program;
 - ii. An analysis of the current budget neutrality agreement; and

- iii. The projected timeframe for the enrollment target to be in effect or the period for enrollment into Gateway program.
- C. The state or SLRHC will be required to provide written notice to CMS at least thirty (30) days prior to re-establishing program enrollment. The notice to CMS, at a minimum, must include:
- i. Data on current enrollment levels in the program;
 - ii. An analysis of the current budget neutrality agreement; and
 - iii. The projected timeframe for the enrollment target to be in effect or the period for enrollment into Gateway program.

25. **Disenrollment.** Enrollees shall be disenrolled if any of the following circumstances occur: voluntarily withdraw from the program, no longer reside in St Louis City or St. Louis County, obtain other health insurance coverage, become pregnant; attain age 65; or have income that exceeds 100 percent of the FPL, or are deceased.

The state will follow the same disenrollment processes for the demonstration populations as for individuals eligible under the Medicaid state plan. In the event that a waiting list is implemented, the state shall contact enrollees who have not utilized services in a six (6) month period regarding their eligibility status via mail. If any of the reasons for disenrollment apply, the state must also screen individuals for health coverage through Medicaid or CHIP prior to providing notice of disenrollment. The state will reopen enrollment per STC 24.

VII. SAFETY NET PILOT PROGRAM BENEFITS

26. **Benefits.** All enrollees shall receive the following outpatient benefits subject to the applicable limitations noted in the table below:

Benefit	Limits
Preventive	Limited to internal, family practice, gynecology
Well care	
Dental	Limited to diagnostic, periodontal, preventive
Urgent Care	Limited to up to 5 urgent care visits
Durable Medical Equipment	Limited to crutches, walkers, Wound Vac., and supplies for the Wound Vac.
Oncology	
Rheumatology	
Cardiology	
Endocrinology	
Ear, Nose, and Throat	
Gastroenterology	

Internal Medicine	
Neurology	
Ophthalmology	
Orthopedics	
Pulmonology	
Pharmacy	Limited to generics provided through the community health center and brand name insulin and inhalers that are not available in a generic alternative. If other brand name drugs are needed, individuals may apply for coverage under the pharmaceutical manufacturers' Prescription Assistance Program. The state is not required to adhere to the provisions of Section 1927 of the Social Security Act with respect to drugs covered pursuant to the safety net pilot program. The rebates provided for under section 1927 are not available with respect to the drugs covered under the safety net pilot program.
Renal	
Urology	
Non-Emergency Transportation	
Outpatient Surgery	
Radiation therapy	
Laboratory/pathology	
Physical, occupational, or speech therapy	Limited to therapy that is medically necessary after a covered surgery.
Radiology (x-ray, MRI, PET/CT)	
Outpatient Substance Use Disorder (SUD) Services	<p>The Gateway to Better Health outpatient substance use disorder (SUD) benefit offers outpatient SUD treatment services to the Gateway to Better Health demonstration population.</p> <p>The limited outpatient SUD benefit covers screening, evaluation, and assessment; medication assisted treatment (MAT); psychotherapy; group therapy; peer support services; and case management services provided to the demonstration population, as specified in these STCs.</p> <p>Outpatient SUD Treatment Services includes but is not limited to:</p> <ul style="list-style-type: none"> • Alcohol related disorders; • Opioid related disorders;

	<ul style="list-style-type: none"> • Cannabis related disorders; • Sedative, hypnotic, or anxiolytic related disorders; • Cocaine related disorders; • Other stimulant related disorders; • Hallucinogen related disorders; • Nicotine dependence; and • Inhalant related disorders. <p>Outpatient SUD Generic Prescription Drug Benefit includes, but is not limited to:</p> <ul style="list-style-type: none"> • Baclofen; • Buprenorphine (HCl); • Buprobam; • Bupropion HCL, Bupropion HCL SR, Bupropion XI; • Desipramine HCL; • Disulfiram; • Gabapentin; • Mirtazapine; • Naltrexone HCL; • Paroxetine CR, Paroxetine ER, Paroxetine HCL; and • Topiramate.
Preventative Physical Function Improvement Services	<p>Physical Therapy and Occupational Therapy</p> <ul style="list-style-type: none"> • Therapeutic Exercise; • Neuromuscular Re-education; • Gait Training; • Manual Therapy; • Group Therapeutic Procedures; • PT Evaluation: <ul style="list-style-type: none"> -Low Complexity -Moderate Complexity; and -High Complexity. • PT Re-evaluation; • Occupational Therapy: <ul style="list-style-type: none"> -Low Complexity; -Moderate Complexity; and -High Complexity. • Re-evaluation of Occupational Therapy; • Therapeutic Activities; • Self-Care/Home Management Training; • Recurrent Wound Debridement; and • Orthotics Fitting.

	<p>Acupuncture Services</p> <ul style="list-style-type: none"> • Acupuncture, without electrical stimulation; and • Acupuncture, with electrical stimulation. <p>Chiropractic Services</p> <ul style="list-style-type: none"> • Chiropractic Manipulative Treatment; • Traction, Mechanical; • Electrical Stimulation (Unattended); • Application of a modality to one or more areas; and • Ultrasound.
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A. All enrollees are eligible for services through the specialty care voucher program. If persons seen at the facilities listed in STC 17 need physician inpatient services or outpatient hospital care, SLRHC will provide vouchers for such care. In order to access voucher services, a demonstration enrollee must have received care and received a referral from a facility listed in STC 17, within the past twelve (12) months from the date of the request. The service request must be deemed medically necessary by the SLRHC Utilization Management process.

27. **Minimum Essential Coverage.** The Gateway to Better Health demonstration is limited to the provision of primary care and specialty care benefits as described in STC 26; thereby, the demonstration is not recognized as MEC as communicated by CMS in its February 12, 2016 correspondence to the state regarding our designation of MEC for the state’s section 1115 demonstration.

VIII. COST SHARING UNDER THE SAFETY NET PILOT PROGRAM

28. **Cost Sharing.** Cost sharing must be in compliance with Medicaid requirements that are set forth in statute, regulation and policies and be reflected in the state plan. Cost sharing shall not exceed amounts permitted under the federal regulation at 42 CFR §447. Standard Medicaid exemptions from cost-sharing set forth in 42 CFR 447.56 apply to the demonstration.

IX. GENERAL REPORTING REQUIREMENTS

29. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS will issue deferrals in the amount of \$1,000,000 (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. Specifically:

A. Thirty (30) days after the deliverable was due, CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submission of required deliverables.

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

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

31. **Compliance with Federal Systems Innovation.** As federal systems continue to evolve and incorporate additional 1115 waiver reporting and analytics functions, the state will work with CMS to:

- A. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
- B. Ensure all 1115, Transformed Medicaid Statistical Information System (T-MSIS), and other data elements that have been agreed to are provided; and

C. Submit the monitoring reports and evaluation reports to the appropriate system as directed by CMS.

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

This includes, but is not limited to, commenting on design and other federal evaluation documents 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 shall include in its contracts with entities that collect, produce or maintain data and files for the demonstration, that they shall make such data available for the federal evaluation as is required by the state under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 29.

33. **Cooperation with Federal Learning Collaboration Efforts.** The state will cooperate with improvement and learning collaboration efforts by CMS.

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

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

B. Performance Metrics – Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to

beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

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

35. Additional Demonstration Annual Operational Report Requirements. In addition to the components of the Quarterly Reports, the Annual Report must, at a minimum, include the requirements outlined below:

- A. Items included in the Quarterly Reports must be summarized to reflect the operation/activities throughout the DY;
- B. Total annual expenditures for the demonstration population for each DY, with administrative costs reported separately; and
- C. Yearly enrollment reports for demonstration enrollees for each DY (enrollees include all individuals enrolled in the demonstration) that include the member months, as required to evaluate compliance with the budget neutrality agreement.

36. State Data Collection. The state must collect data and information necessary to oversee service utilization and rate setting by provider/plan, comply with the Core Set of Children’s Health Care Quality Measures for Medicaid and CHIP (Child Core Set) and the Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set), collectively referred to as the CMS Child and Adult Core Measure Sets for Medicaid and CHIP, and comply with other existing federal measure sets.

- A. The state will use this information in ongoing monitoring of individual well-being, provider/plan performance, and continuous quality improvement efforts, in addition to complying with CMS reporting requirements.
- B. The state must maintain data dictionary and file layouts of the data collected.
- C. The raw and edited data must be made available to CMS within thirty (30) days of a written request.

X. MONITORING CALLS AND DISCUSSIONS

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

- A. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration.
- B. CMS will provide updates on any amendments or concept papers under review, 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.
- D. Areas to be addressed during the monitoring call include, but are not limited to:
 1. Transition and implementation activities;
 2. Stakeholder concerns;
 3. Operations and performance;
 4. Enrollment;
 5. Cost sharing;
 6. Quality of care;
 7. Beneficiary access;
 8. Benefit package and wrap around benefits;
 9. Audits;
 10. Lawsuits;
 11. Financial reporting and budget neutrality issues;
 12. Progress on evaluation activities and contracts;
 13. Related legislative developments in the state; and
 14. Any demonstration changes or amendments the state is considering.

38. Post Award Forum. Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state shall afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least thirty (30) days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state must also post the most recent annual report on its website with the public forum

announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Quarterly Report associated with the quarter in which the forum was held, as well as in its compiled Annual Report.

XI. EVALUATION OF THE DEMONSTRATION

39. **Independent Evaluator.** At the beginning of the demonstration period, the state must arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The independent party must sign an agreement to conduct the demonstration evaluation in accord with the CMS-approved, Draft Evaluation Design. For scientific integrity, every effort should be made to follow the approved methodology. State evaluation must follow the approved methodology; however, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.
40. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a Draft Evaluation Design with implementation timeline, for the demonstration to CMS no later than 120 days after the effective date of these STCs. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state may choose to use the expertise of the independent party in the development of the Draft Evaluation Design.
41. **Evaluation Design Approval and Updates.** The state's Draft Evaluation Design may be subject to multiple revisions until a format and the content is agreed upon by CMS. The state must submit a revised Draft Evaluation Design within sixty (60) days after receipt of CMS' comments. Upon CMS approval of the Draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the Quarterly Reports and Annual Reports.
42. **Evaluation Questions and Hypotheses.** Consistent with the most recent Guidance as found on Medicaid.gov, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each waiver and expenditure authority should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
43. **Evaluation Budget.** A budget for the evaluation shall be provided with the Draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluation such as any

survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design, if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.

44. **Evaluation Requirements.** The demonstration evaluation will meet the prevailing standards of scientific evaluation and academic rigor, as appropriate and feasible for each aspect of the evaluation, including standards for the evaluation design, conduct, and interpretation and reporting of findings.
- A. The demonstration evaluation will use the best available data; use controls and adjustments for and reporting of the limitations of data and their effects on results; and discuss the generalizability of results.
 - B. The state shall arrange with an independent entity to conduct the evaluation. The evaluation design shall discuss the state’s process for arranging with an independent entity to conduct the evaluation, including a description of the qualifications the entity must possess, how the state will ensure no conflict of interest, and a budget for evaluation activities.
 - C. **Design Requirements.** Please refer to Attachment F for design requirements.
45. **State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the final Evaluation Design, the interim evaluation, and/or the summative evaluation.
46. **State Must Separately Evaluate Components of the Demonstration.** The outcomes from each evaluation component must be integrated into one programmatic summary that describes whether the state met the demonstration goal, with recommendations for future efforts regarding all components.
- A. At a minimum, the Draft Evaluation Design must include a discussion of the goals, objectives, and specific hypotheses that are being tested, including those outlined in STC 46.A. The draft design will discuss:
 - i. The outcome measures to be used in evaluating the impact of the demonstration during the period of approval, particularly among the target population;
 - ii. The data sources and sampling methodology for assessing these outcomes; and
 - iii. A detailed analysis plan that describes how the effects of the demonstration are isolated from other initiatives occurring in the state.
47. **Draft Interim Evaluation Reports.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent

renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Report should be posted to the state's website with the application for public comment. Also refer to Attachment F for additional information on the Interim Evaluation Report

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

48. **Summative Evaluation Report.** The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within eighteen (18) months of the end of this approval period. The draft Summative Evaluation Report must include the information in the approved Evaluation Design. Refer to Attachment F for additional information on the evaluation report.

- A. Unless otherwise agreed upon in writing by CMS, the state shall submit the final Summative Evaluation Report within sixty (60) days of receiving comments from CMS on the draft.

XII. CLOSE OUT REPORTING

49. **Close out Reports.** Within 120 days prior to the expiration of the demonstration, the state must submit a Draft Final Operational Report to CMS for comments.

- A. The draft final reports must comply with the most current Guidance from CMS.
- B. The state will present to and participate in a discussion with CMS on the Close-Out reports.
- C. The state must take into consideration CMS' comments for incorporation into the final Close-Out Report.
- D. The Final Close-Out Report is due to CMS no later than thirty (30) days after receipt of CMS' comments.
- E. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 29.

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

- A. For a period of twenty-four (24) months following CMS approval of the final reports, CMS will be notified prior to the public release or presentation of these reports and related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles and other publications, CMS will be provided a copy including any associated press materials. CMS will be given thirty (30) days to review and comment on publications before they are released. CMS may choose to decline some or all of these notifications and reviews.

XIII. GENERAL FINANCIAL REQUIREMENTS

51. **Quarterly Expenditure Reports.** The state must provide quarterly expenditure reports using Form CMS-64 to separately report total expenditures for services provided through this demonstration under section 1115 authority that are subject to budget neutrality. This project is approved for expenditures applicable to services rendered during the demonstration period. CMS shall provide FFP for allowable demonstration expenditures only as long as they do not exceed the pre-defined limits on the costs incurred as specified in section XI (Monitoring Budget Neutrality). At the end of each quarter:

- a. The state will run a summary report identifying the total expenditures to be claimed under the demonstration. The documentation in support of the summary report will be the individual claims paid by the state during the quarter. The state will be able to produce the details of the individual claims upon request.
- b. The state will produce reports from the State Accounting System (SAMII) as supporting documentation for the state’s expenditures. These reports will identify the amount paid from state appropriations (General Revenue equivalent, Federal Reimbursement Allowance Fund, and federal funds) to Gateway providers.
- c. The signed certification of expenditures from the City of St. Louis will be the documentation used by the state to support the amount of local expenditures paid by the city.
- d. The signed certification of expenditures from St. Louis County will be the documentation used by the state to support the amount of local expenditures paid by the county.

- e. The total computable amount will be claimed on the appropriate CMS 64 Waiver forms. The total computable amount claimed for a quarter will not exceed the aggregate amount paid by the state, the City of St. Louis, and St. Louis County.
- f. The documentation will be maintained at the offices of state and will be made available for review by CMS reviewers, as part of the quarterly review of expenditures, or other federal reviewers or auditors.
- g. The Certification of Expenditures by the City of St. Louis and St. Louis County meets the Missouri Partnership Plan (MPP) requirement in Attachments B and C of the MPP since the city of St. Louis and St. Louis County are purchasing services rather than providing services. No further approved protocol is necessary. For example:
- h.

Total computable expenditures	\$7,500,000 (supported by MMIS reports)
Total paid by state	\$6,062,500 (supported by MMIS reports)
Total paid by the City of St. Louis	\$1,250,000 (supported by MMIS reports)
Total paid by St. Louis County	\$187,000 (supported by MMIS reports)
Total	\$7,500,000

52. **Expenditures Subject to the Title XIX Budget Neutrality Expenditure limit.** All expenditures to support the administrative costs of the SLRHC (all years of the demonstration) and the Safety Net Provider Network for primary care and specialty care for demonstration participants are subject to the budget neutrality expenditure limit.

53. **Reporting Expenditures Subject to the Title XIX Budget Neutrality Expenditure Limit.** The following describes the reporting of expenditures subject to the budget neutrality limit:

- a. In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in section 2500 of the state Medicaid Manual. All demonstration expenditures claimed under the authority of title XIX of the Act and subject to the budget neutrality expenditure limit must be reported each quarter on separate Forms CMS-64.9 Waiver and/or 64.9P Waiver, identified by the demonstration project number (11-W-00250/7) assigned by CMS, including the project number extension, which indicates the DY in which services were rendered.
- b. To simplify monitoring of both demonstration expenditures and remaining DSH payments, DYs will be aligned with federal fiscal years (FFYs). DY 1 is defined as the period from July 28, 2010 (date of the original approval letter) through September 30, 2010. DYs 2 through 14 will coincide with FFYs 2011 through 2023. DY 14 will begin October 1, 2022 and end December 31, 2022.

- c. **DSH Expenditures.** To facilitate monitoring of budget neutrality and compliance with the DSH allotment, the rules below will govern reporting of DSH expenditures for the demonstration. All DSH expenditures are subject to the DSH allotments defined in section 1923(f) of the Act.
 - i. All DSH expenditures for FFYs 2011 through 2022 are demonstration expenditures subject to the budget neutrality, and must be reported on Forms CMS-64.9 Waiver and CMS-64.9P Waiver for the DY corresponding to the FFY.
 - ii. Missouri must report DSH expenditures that are subject to FFY 2023 DSH allotment on CMS-64.9 Waiver and CMS-64.9 until such expenditures equal one-quarter of the DSH allotment minus \$7.5 million (total computable), which is the amount to be spent on the Expansion Population for that year. For FFY 2023, demonstration expenses and actual DSH expenditures must not exceed the state DSH allotment.
 - iii. All DSH expenditures reported on Forms CMS-64.9 Waiver or CMS-64.9P Waiver must be reported using the waiver name “Residual DSH.”
 - iv. All DSH expenditures reported on Forms CMS-64.9 Waiver or CMS-64.9P Waiver must be reported using the waiver name “Residual DSH.”
 - v. All DSH expenditures are subject to the auditing and reporting requirements under section 1923(j) of the Act.
- d. **Reporting of Premiums.** If applicable, the state must report premiums on Forms CMS-64.9 Waiver and CMS-64.9P Waiver, using Line 18A.
- e. **Cost Settlements.** For monitoring purposes, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (Form CMS-64.9P Waiver) for the Summary Sheet Line 10B, in lieu of Lines 9 or 10C. For any cost settlements not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the state Medicaid Manual.
- f. **Use of Waiver Forms.** The following five (5) waiver forms CMS-64.9 Waiver and/or 64.9P Waiver must be submitted each quarter (when applicable) to report title XIX expenditures for individuals enrolled in the demonstration and for residual DSH. The expression in quotation marks are the waiver names to be used to designate the waiver form in the MBES/CBES system.
 - i. “Grace Hill” expenditures
 - ii. “Myrtle Davis” expenditures
 - iii. “Contingency Provider Network” expenditures
 - iv. “Voucher” expenditures

- v. “Residual DSH” expenditures
- g. **Title XIX Expenditures Subject to the Budget Neutrality Expenditure Limit.** For purposes of this section, the term “expenditures subject to the budget neutrality cap” refers to all title XIX expenditures made to support the providers on behalf of individuals who are enrolled in this demonstration, as defined in STC 20, including all service expenditures net of premium collections and other offsetting collections. DSH expenditures (“Residual DSH”) are also subject to the budget neutrality limit. Total expenditures must not exceed the state’s annual DSH allotment. All title XIX expenditures that are subject to the budget neutrality expenditure limit are considered demonstration expenditures and must be reported on Forms CMS-64.9 Waiver and/or CMS-64.9P Waiver.
- h. **Title XIX Administrative Costs.** The following provisions govern reporting of administrative costs during the demonstration.
 - i. The administrative costs associated with support of the SLRHC program are subject to the budget neutrality limit and must be reported on Forms CMS-64.10 Waiver and/or 64.10P Waiver, identified by the demonstration project number assigned by CMS, including the project number extension, which indicates the DY for which the administrative services were paid. A separate form must be submitted, using the waiver name “**SLRHC Adm**” to report expenses related to administrative support of the SLRHC.
 - ii. Administrative costs that are directly attributable to the demonstration that are not described in this STC must be reported under waiver name “Gateway.” These expenses are not subject to the budget neutrality limit, but the state must separately track and report administrative costs that are directly attributable to the demonstration. Directly attributable administrative costs for this demonstration include eligibility determinations made by state staff. All administrative costs will be identified on the Forms CMS-64.10 Waiver and/or 64.10P Waiver.
 - iii. **Claiming Period.** All claims for expenditures subject to the budget neutrality expenditure limit (including any cost settlements) must be made within two (2) years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including any cost settlements) must be made within two (2) years after the conclusion or termination of the demonstration. During the latter two (2) year period, the state must continue to identify separately net expenditures related to dates of service during the operation of the section 1115 demonstration on the CMS-64 waiver forms, in order to properly account for these expenditures in determining budget neutrality.

54. Standard Medicaid Funding Process. The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable Medicaid expenditures

on the quarterly Form CMS-37. In addition, the estimate of matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each FFY on the Form CMS-37 (narrative section) 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 thirty (30) days after the end of each quarter, the state must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter just ended. CMS shall reconcile expenditures reported on the 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.

55. Extent of Federal Financial Participation for the Demonstration. Subject to CMS approval of the source(s) of the non-federal share of funding, CMS shall provide FFP at the applicable federal matching rates for the demonstration as a whole as outlined below, subject to the budget neutrality limits described in section XIX.

- a. Administrative costs, including those associated with the administration of the demonstration; and
- b. Net expenditures and prior period adjustments, made under approved Expenditure Authorities granted through section 1115(a)(2) of the Act, with dates of service during the operation of the demonstration.

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

- a. CMS may review at any time the sources of the non-federal share of funding for the demonstration. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.
- b. Any amendments that impact the financial status of the program shall require the state to provide information to CMS regarding all sources of the non-federal share of funding.
- c. The state assures that all health care related taxes comport with section 1903(w) of the Act and all other applicable federal statutory and regulatory provisions as well as the approved Medicaid state plan.
- d. The non-federal share of the total computable expenditures certified as the basis for federal funds are quarterly medical service demonstration expenditures incurred by the City of St. Louis or St. Louis County as documented through the Quarterly Expenditure Reconciliation process and the Certification of

Expenditures Statement. The amounts represented on the Certification of Expenditures Statement are expressed in total computable (state and federal) costs incurred by the City of St. Louis or St. Louis County for eligible and paid medical waiver claims reported to the MMIS for the reporting period. The incurred costs represent medical provider demonstration service claims reimbursed at the rates established through the demonstration. One hundred percent of the total computable service rate payments are paid to and retained by eligible demonstration providers. The non-federal share for all other demonstration service claims are satisfied through the state appropriations to the single state Medicaid agency. The source of non-federal share funds utilized shall not include federal funds or revenue from provider taxes or donations that do not comport with federal requirements at section 1903(w) of the Social Security Act, implementing regulations and applicable policy guidance.

- e. On a quarterly basis, the appropriate executive official of the City of St. Louis will sign the certification statement on the Certification of Expenditures (Attachment B) form. The document presents the total computable quarterly service expenditures incurred by the City of St. Louis for eligible paid waiver claims for which the city funds the non-federal match associated with the payments.
- f. On a quarterly basis, the appropriate executive official of St. Louis County will sign the certification statement on the Certification of Expenditures (Attachment C) form. The document presents the total computable quarterly service expenditures incurred by St. Louis County for eligible paid waiver claims for which the county funds the non-federal match associated with the payments.
- g. As defined in the Quarterly Expenditure Reconciliation, the quarterly calculation of documented waiver claims is derived from MMIS paid claims reports within the quarter.

57. Monitoring the Demonstration. Unless the timeframe is extended by CMS, the state must respond within thirty (30) days to all CMS requests regarding information to effectively monitor the demonstration.

58. Program Integrity. The state must have processes in place to ensure that there is no duplication of federal funding for any aspect of the demonstration. The state must 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.

XIV. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

59. Limit on Title XIX Funding. The state shall be subject to a limit on the amount of federal Title XIX funding that the state may receive on selected Medicaid expenditures during the period of approval of the demonstration. The budget neutrality expenditure targets are set

on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. Actual expenditures subject to the budget neutrality expenditure limit shall be reported by the state using the procedures described in STC 37.

60. **Risk.** The state shall be at risk for both the number of enrollees in the demonstration, as well as the per capita cost for demonstration-eligible under this budget neutrality agreement.
61. **Budget Neutrality Expenditure Limit.** The following table gives the budget neutrality limit for each DY. The limits are expressed in terms of FFP (i.e., federal share).

DY	Budget Neutrality Limit
DY 1	¼ of the FFY 2010 DSH allotment
DYs 2 through 13	Corresponding FFY DSH allotment
DY 14	¼ of the FFY 2023 DSH allotment

For purposes of illustration, the annual expenditure authority cap is shown in the table below.

DY/ FFY	Dates	Annual Expenditure Authority Cap (Total Computable)
DY 1/ FFY 2010	07/28/2010 to 09/30/2010	\$7.5 million
DY 2/ FFY 2011	10/01/2010 to 09/30/2011	\$30 million
DY 3/ FFY 2012	10/01/2011 to 09/30/2012	\$30 million
DY 4/ FFY 2013	10/01/2012 to 09/30/2013	\$30 million
DY 5/ FFY 2014	10/01/2013 to 9/30/2014	\$30 million
DY 6/ FFY 2015	10/01/2014 to 09/30/2015	\$30 million
DY 7/ FFY 2016	10/01/2015 to 09/30/2016	\$30 million
DY 8/ FFY 2017	10/01/2016 to 09/30/2017	\$30 million
DY 9/ FFY 2018	10/01/2017 to 09/30/2018	\$30 million
DY 10/ FFY 2019	10/01/2018 to 09/30/2019	\$30 million
DY 11/ FFY 2020	10/01/2019 to 09/30/2020	\$30 million
DY 12/ FFY 2021	10/01/2020 to 09/30/2021	\$30 million
DY 13/ FFY 2022	10/01/2021 to 09/30/2022	\$30 million
DY 14/ FFY 2023	10/01/2022 to 12/31/2022	\$7.5 million
Cumulative Total		\$375 million

62. **Future Adjustments to the Budget Neutrality Expenditure Limit.** CMS reserves the right to adjust the budget neutrality expenditure limit to be consistent with enforcement of impermissible provider payments, health care related taxes, new federal statutes, or policy interpretations implemented through letters, memoranda, or regulations with respect to the provision of services covered under the demonstration.

63. **Enforcement of Budget Neutrality.** CMS shall enforce budget neutrality on an annual basis. If the state exceeds the annual budget neutrality expenditure limit in any given DY, the state must submit a corrective action plan to CMS for approval and will repay (without deferral or disallowance) the federal share of the amount by which the budget neutrality agreement has been exceeded.

XV. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

Date – Specific	Deliverable	STC Reference
120 days after approval December 30, 2017	Submit revised Evaluation Design	Section XII, STC 48
09/01/2022	Submit Draft Final Report	Section IX, STC 34

	Deliverable	STC Reference
Annual	By February 1 st - Draft Annual Report	STC 34
Annual	Within 30 days of receipt of CMS comments – Final Annual Report	STC 34
Quarterly	Quarterly Progress Reports	STC 34

Attachment A

Administrative Cost Claiming Rules and Protocol

I. Preface

As part of the total amount payable under the demonstration authority granted under section 1115(a)(2) of the Social Security Act (the Act) by the Centers for Medicare and Medicaid Services (CMS) to the Gateway for Better Health (GBH), federal financial participation (FFP) as authorized by 42 Code of Federal Regulations (CFR) 433.15 is available to GBH at the 50 percent rate for administrative costs required for "proper and efficient" administration of the demonstration subject to the limitations outlined below.

The following guidance and protocols are based on and in response to information submitted in writing or otherwise communicated to CMS and are provided to inform the state and assist the state in its efforts to comply with the rules and protocols regarding claiming for FFP for administrative expenditures incurred by the state and/or its contractors under this demonstration.

a. General Requirements

The state must comply with all federal statute, regulations and guidance for all claims for FFP.

In order for the costs of administrative activities to be claimed as Medicaid administrative expenditures at the 50 percent FFP rate, the following requirements must be met:

- Costs must be “necessary for the proper and efficient administration of the Medicaid state plan” (Section 1903(a)(7) of the Act).
- If applicable, costs must be allocated in accordance with the relative benefits received by all programs, not just Medicaid.
- Claims for costs must not duplicate costs that have been, or should have been, paid through another source.
- State or local governmental agency costs must be supported by an allocation methodology under the applicable approved public assistance Cost Allocation Plan (42 CFR 433.34).
- Costs must not include funding for a portion of general public health initiatives that are made available to all persons, such as public health education campaigns.
- Costs must not include the overhead costs of operating a provider facility or otherwise include costs of a direct service to beneficiaries (these should be claimed as service costs, not plan administration).
- Costs must not duplicate activities that are already being offered or should be provided by other entities, or through other programs.
- Costs must be supported by adequate source documentation.
- Costs must not be federally-funded or used for any other federal matching purposes.

b. Interagency Agreements/Memorandum of Understanding (MOU)

Because only the state Medicaid agency may submit a claim to CMS to receive FFP for allowable and properly allocated Medicaid costs, every participating entity that is performing administrative activities on behalf of the Medicaid program must be covered, either directly or indirectly, through an interagency agreement. These agreements must be in effect before the Medicaid agency may claim federal matching funds for any administrative activities conducted by the St. Louis Regional Health Commission (SLRHC) as detailed in the agreement with the Medicaid agency.

In order to provide a basis for FFP to be claimed, the agreement must describe and define the relationships between the state Medicaid agency and the SLRHC and must document the scope of the activities being performed by the SLRHC. The interagency agreement must include:

- Mutual objectives of the agreement;
- Responsibilities of all the parties to the agreement;
- Activities or services each party to the agreement offers and under what circumstances;
- Cooperative and collaborative relationships at the state and local levels;
- Specific administrative claiming time study activity codes which have been approved by CMS, by reference or inclusion;
- Specific methodology which has been approved by CMS for computation of the claim, by reference or inclusion;
- Methods for reimbursement, exchange of reports and documentation, and liaison between the parties, including designation of state and local liaison staff.

The interagency agreement should address the Medicaid administrative claiming process, identify the services the state Medicaid agency will provide for the local entity, including any related reimbursement and funding mechanisms, and define oversight and monitoring activities and the responsibilities of all parties. All participation requirements the state Medicaid agency determines to be mandatory for ensuring a valid process should be detailed in the agreement. Maintenance of records, participation in audits, designation of local project coordinators, training timetables and criteria, and submission of fiscal information are all important elements of the interagency agreement. Also, the specific methodologies, which may include a standardized claim form, the mechanism for filing the claim, and the approved allocation methodology that may include use of a time study by the local entity, are valid agreement elements.

Many interagency agreements require the governmental agency that performs the administrative activities to provide the required state match for Medicaid administrative claiming. As always, the non-federal share of the Medicaid payments must comply with the requirements of section 1903(w) of the Act, federal regulations and policy such as being derived from permissible sources (e.g., appropriations, Intergovernmental transfers, certified public expenditures, broad-base health care related taxes).

c. Identification, Documentation and Allocation of Costs

All administrative costs (direct and indirect) are normally charged to federal grant awards such as Medicaid through the state's public assistance Cost Allocation Plan (CAP). Federal regulations (42 CFR 433.34) require that under the Medicaid state plan, the single state agency

have an approved public assistance CAP on file with the Division of Cost Allocation in the U.S. Department of Health and Human Services that meets certain regulatory requirements, which are specified at Subpart E of 45 CFR part 95 and referenced in OMB Circular A-87. There are certain items that must be in the public assistance CAP which a state Medicaid agency must submit before providing FFP for administrative claiming. The public assistance CAP must make explicit reference to the methodologies, claiming mechanisms, interagency agreements, and other relevant issues pertinent to the allocation of costs and submission of claims by the participating entities.

Documentation for administrative activities must clearly demonstrate that the activities directly support the administration of the Medicaid program. In accordance with the statute, the regulations, and the Medicaid state plan, the state is required to maintain/retain adequate source documentation to support Medicaid payments. The basis for this requirement can be found in statute and regulations. See section 1902(a)(4) of the Act and 42 CFR 431.17; see also 45 CFR 92.20(b) and 42 CFR 433.32(a) (requiring source documentation to support accounting records) and 45 CFR 92.42 and 42 CFR 433.32(b and c) (retention period for records). The records must be made available for review by state and federal staff upon request during normal working hours (section 1902(a) (4) of the Act, implemented at 42 CFR 431.17).

When states submit claims for FFP for Medicaid administration, only costs directly related to Medicaid administration are allowable and these costs must be allocated according to accepted cost principles. Since most administrative activities are provided both to Medicaid and non-Medicaid eligible individuals, the costs applicable to these activities must be allocated to both groups.

d. Administrative FFP for Skilled Professional Medical Personnel

In addition to the 50 percent federal Medicaid administrative matching rate, Section 1903(a)(2) of the Act provides for FFP at 75 percent for expenditures attributable to the compensation and training of skilled professional medical personnel (SPMP) of the state agency (See also 42 CFR 432.2, 432.45, 432.50 and 433.15.)

The state has not identified to CMS any activities under this demonstration that are reimbursable at the enhanced 75 percent SPMP matching rate.

Note: Administrative costs incurred that are an integral part of, or an extension of, the provision of services by medical providers, are to be included in the rate paid by the state or its fiscal agent for the medical service. There is no additional FFP available.

II. General Conditions

Under the Gateway to Better Health, the state must:

1. Obtain prior approval from CMS for any changes to the methodology used to capture or claim FFP for administrative costs associated with the demonstration

2. Describe how it will offset other revenue sources for administrative expenditures associated with the demonstration, if applicable.
3. Detail the oversight and monitoring protocol to oversee administrative claiming for the demonstration.
4. Obtain prior approval for any new categories of administrative expenditures to be claimed under the demonstration.
5. Agree to permit CMS to review any forms and/or documents that are subsequently developed for use by this program, prior to modification or execution.
6. Submit all necessary changes to the Medicaid administrative claiming plan to CMS for review and approval prior to implementation.

Attachment B

**Certification of Expenditures
By St. Louis City
For the Missouri Gateway to Better Health Waiver**

I certify that:

1. I am the executive officer of St. Louis City or his/her designate authorized by the City to submit this form.
2. This certification only includes expenditures that are allowable in accordance with the approved Gateway to Better Health waiver.
3. The expenditures included in this report are based on actual recorded expenditures for the period _____ through _____, and are not based on estimates.
4. The city funds in the amount of \$ _____ were paid for primary or specialty care and were used to match the allowable waiver expenditures for the same time period referenced above, and were in accordance with all applicable federal requirements for the non-federal share of expenditures.
5. The information shown above is correct to the best of my knowledge and belief.

Name

Title

Signature

Date

Attachment C

**Certification of Expenditures
By the County of St. Louis
For the Missouri Gateway to Better Health Waiver**

I certify that:

1. I am the executive officer of the county of St. Louis or his/her designate authorized by the county to submit this form.
2. This certification only includes expenditures that are allowable in accordance with the approved Gateway to Better Health waiver.
3. The expenditures included in this report are based on actual recorded expenditures for the period _____ through _____, and are not based on estimates.
4. The county funds in the amount of \$_____ were paid for primary or specialty care and were used to match the allowable waiver expenditures for the same time period referenced above, and were in accordance with all applicable federal requirements for the non-federal share of expenditures.
5. The information shown above is correct to the best of my knowledge and belief.

Name

Title

Signature

Date

Attachment D Incentive Payment Protocol

Incentive Payments

The state will withhold 7 percent from payments made to the primary care health centers (PCHC) through December 31, 2022 and the amount withheld will be tracked on a monthly basis. The SLRHC will be responsible for monitoring the PCHC performance against the pay-for-performance metrics outlined below.

Pay-for-performance incentive payments will be paid out at six (6) month intervals of the Pilot Program based on performance during the reporting period. The state must not claim the federal share of the incentive payments until the actual payments based on provider performance are made.

Reporting Periods:

- July 1, 2012 – December 31, 2012
- January 1, 2013 – June 30, 2013
- July 1, 2013 – December 31, 2013
- January 1, 2014 – June 30, 2014
- July 1, 2014 – December 31, 2014
- January 1, 2015 – June 30, 2015
- July 1, 2015 – December 31, 2015
- January 1, 2016 – June 30, 2016
- July 1, 2016 - December 31, 2016
- January 1, 2017 – June 30, 2017
- July 1, 2017 – December 31, 2017
- January 1, 2018 – June 30, 2018
- July 1, 2018 – December 31, 2018
- January 1, 2019 – June 30, 2019
- July 1, 2019 – December 31, 2019
- January 1, 2020 – June 30, 2020
- July 1, 2020 - December 31, 2020
- January 1, 2021 – June 30, 2021
- July 1, 2021 – December 31, 2021
- January 1, 2022 – June 30, 2022
- July 1, 2022 – December 31, 2022

SLRHC will calculate the funds due to the providers based on the criteria and methodologies described below and report the results to the state. The state will disburse funds within the first quarter following the end of the reporting period. PCHC are required to provide self-reported data within thirty (30) days of the end of the reporting period.

Primary Care Health Center Pay-for-Performance Incentive Eligibility

Below are the criteria for the PCHC first incentive payments to be paid within the first quarter following the end of the reporting period:

TABLE 1

Pay-for-Performance Incentive Criteria	Threshold	Weighting	Source
All Newly Enrolled Patients Minimum of at least 1 office visit within 1 year (6 months before/after enrollment date)	80%	20%	EHR data
Patients with Diabetes, Hypertension, Congestive Heart Failure or chronic obstructive pulmonary disease – Minimum of at least 2 office visits within 1 year (6 months before/after reporting period start date)	80%	20%	EHR Data
Patients with Diabetes – Have one HgbA1c test within 6 months of reporting period start date	85%	20%	EHR data
Patients with Diabetes – Have a HgbA1c less than or equal to 9 percent on most recent HgbA1c test within the reporting period	60%	20%	EHR Data
Hospitalized Patients - Among enrollees whose primary care home was notified of their hospitalization by the Gateway Call Center, the percentage of patients who have been contacted (i.e. visit or phone call for status/triage, medical reconciliation, prescription follow up, etc.) by a clinical staff member from the primary care home within 7 days after hospital discharge.	50%	20%	Self-reported by health centers and AHS Call Center Data
TOTAL POSSIBLE SCORE		100%	

Objective measures may be changed for the subsequent reporting period. Any changes or additions will be approved by the Pilot Program Planning Team managed by the SLRHC at least sixty (60) days in advance of going into effect. At no time will changes to the measures go into effect for a reporting period that has already commenced. (Note: the health centers and state are represented on the Pilot Program Planning Team.) Any changes to the measures will be included in an updated protocol and subject to CMS review.

Any remaining funds will be disbursed based on the criteria summarized below and will be paid within the first quarter following the end of the reporting period:

TABLE 2

Pay-for-Performance Incentive Criteria	Threshold	Weighting	Source
Rate of Referral to Specialist among Demonstration Enrollees	680/1,000 analysis	100%	Referral data

The primary care providers will be eligible for the remaining funds based on the percentage of Demonstration Population 1 individuals enrolled at their health centers. For example, if Grace Hill has 60 percent of the primary care patients and Myrtle Hilliard Davis 40 percent, they would

each qualify up to that percentage of the remaining funds. Payments will not be redirected for administrative or infrastructure payments.

Within the first quarter following the end of the reporting period, the state will issue incentive payments to the health centers. Incentive payments will be calculated based on the data received and the methodology described below.

Primary Care Health Center (PCHC) Calculations

Step 1: Calculate the PCHC Incentive Pool (IP) for each PCHC.

- $IP = \text{PCHC Payments Earned} \times 7 \text{ percent}$

Step 2: Calculate the Incentive Pool Earned Payment (IPEP) that will be paid to each PCHC.

- Identify which performance metrics were achieved
- Determine the total Incentive Pool Weights (IPW) by adding the weights of each performance metric achieved
- *Example:* If the PCHC achieves 3 of the 5 performance metrics, then: $IPW = 20 \text{ percent} + 20 \text{ percent} + 20 \text{ percent} = 60 \text{ percent}$
- $IPEP = IP \times IPW$

Step 3: Calculate the Remaining Primary Care Incentive Funds (RPCIF) that are available for performance metrics not achieved.

- Add the IP for each PCHC to derive the Total IP
- Add the IPEP for each PCHC to derive the Total IPEP
- $RPCIF = \text{Total IP} - \text{Total IPEP}$

Step 4: Calculate member months (MM) per reporting period for each PCHC (CMM) and in total (TMM).

- $CMM = \text{Total payments earned by each PCHC during the reporting period} / \text{Rate}$
- $TMM = \text{Total payments earned by all PCHC during the reporting period} / \text{Rate}$

Step 5: Calculate the Proportionate Share (PS) of the RPCIF that is available to each PCHC.

- $PS = RPCIF \times (CMM/TMM)$

Step 6: Calculate the Remaining Primary Care Incentive Fund Payment (RPCIFP) for each PCHC.

Example: If the PCHC achieves the specialty referral performance metrics, then:
 $IPW = 100 \text{ percent (effective 01/01/2014 through 12/31/2016)}$

- $RPCIFP = PS \times IPW$

The following scenarios illustrate the calculations for Step 3 through Step 6 explained above as well as the final amounts withheld and paid to each PCHC based on the assumptions of these

scenarios. These scenarios are provided for illustrative purposes only and are not a prediction of what may actually occur.

SCENARIO 1

Key assumptions:

- \$40,000 remains in the primary care incentive pool after the first round of disbursements based on the criteria listed in Table 1.
- Each PCHC met the performance metric for specialty referrals based on the criteria listed in Table 2.

	7% Withheld	Earned	Remaining (Unearned)
Grace Hill	\$ 200,000	\$200,000	\$ -
Myrtle Hilliard	\$ 100,000	\$ 75,000	\$ 25,000
Family Care	\$ 20,000	\$ 20,000	\$ -
BJK People's	\$ 50,000	\$ 40,000	\$ 10,000
St. Louis County	\$ 50,000	\$ 45,000	\$ 5,000
Total	\$ 420,000	\$380,000	\$ 40,000

Remaining Primary Care Incentive Funds

Table 1B - Identifies each PCHC proportionate share of the remaining incentive funds.

	STEP 4		STEP 5	
	Gross Earnings	# of Member Months	% of Member Months	PCHC Proportionate Share
Grace Hill	\$ 2,857,143	54,966	48%	\$ 19,200
Myrtle Hilliard	\$ 1,428,571	27,483	24%	\$ 9,600
Family Care	\$ 285,714	5,497	4%	\$ 1,600
BJK People's	\$ 714,286	13,742	12%	\$ 4,800
St. Louis County	\$ 714,286	13,742	12%	\$ 4,800
Total	\$ 6,000,000	115,430	100%	\$ 40,000

Table 1C - Computes the remaining primary care incentive fund payment (RPCIFP) for each PCHC assuming the performance metrics for specialty referral metrics are met (Table 2).

	Step 6		
	PCHC Proportionate Share	IPW	RPCIFP
Grace Hill	\$ 19,200	100%	\$ 19,200
Myrtle Hilliard	\$ 9,600	100%	\$ 9,600
Family Care	\$ 1,600	100%	\$ 1,600
BJK People's	\$ 4,800	100%	\$ 4,800
St. Louis County	\$ 4,800	100%	\$ 4,800
Total	\$ 40,000		\$ 40,000

Table 1D - Shows the total withheld, earned and paid for each PCHC.

7% Withheld	Earned	RPCIFP	Total Paid
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Table 1D - Shows the total withheld, earned and paid for each PCHC.

	7% Withheld	Earned	RPCIFP	Total Paid
Grace Hill	\$ 200,000	\$200,000	\$ 19,200	\$ 219,200
Myrtle Hilliard	\$ 100,000	\$ 75,000	\$ 9,600	\$ 84,600
Family Care	\$ 20,000	\$ 20,000	\$ 1,600	\$ 21,600
BJK People's	\$ 50,000	\$ 40,000	\$ 4,800	\$ 44,800
St. Louis County	\$ 50,000	\$ 45,000	\$ 4,800	\$ 49,800
Total	\$ 420,000	\$380,000	\$ 40,000	\$ 420,000

SCENARIO 2

Key assumptions:

- \$40,000 remains in the primary care incentive pool after the first round of disbursements based on the criteria listed in Table 1.
- Some PCHC do not meet both performance metrics for emergency room and specialty referrals based on the criteria listed in Table 2.

Table 2A - Identifies the remaining incentive funds to be disbursed to PCHC.

	7% Withheld	Earned	STEP 3 Remaining (Unearned)
Grace Hill	\$ 200,000	\$200,000	\$ -
Myrtle Hilliard	\$ 100,000	\$ 75,000	\$ 25,000
Family Care	\$ 20,000	\$ 20,000	\$ -
BJK People's	\$ 50,000	\$ 40,000	\$ 10,000
St. Louis County	\$ 50,000	\$ 45,000	\$ 5,000
Total	\$ 420,000	\$380,000	\$ 40,000

Remaining Primary Care Incentive Funds

Table 2B - Identifies each PCHC proportionate share of the remaining incentive funds.

	STEP 4		STEP 5	
	Gross Earnings	# of Member Months	% of Member Months	PCHC Proportionate Share
Grace Hill	\$ 2,857,143	54,966	48%	\$ 19,200
Myrtle Hilliard	\$ 1,428,571	27,483	24%	\$ 9,600
Family Care	\$ 285,714	5,497	4%	\$ 1,600
BJK People's	\$ 714,286	13,742	12%	\$ 4,800
St. Louis County	\$ 714,286	13,742	12%	\$ 4,800
Total	\$ 6,000,000	115,430	100%	\$ 40,000

Table 2C - Computes the remaining primary care incentive fund payment (RPCIFP) for each PCHC assuming that some providers did not meet both performance metrics for emergency department utilization and/or specialty referrals.

Step 6

	PCHC		RPCIFP	Unused Funding for Medical Services
	Proportionate Share	IPW		
Grace Hill	\$ 19,200	100%	\$ 19,200	\$ -
Myrtle Hilliard	\$ 9,600	70%	\$ 6,720	\$ 2,880
Family Care	\$ 1,600	100%	\$ 1,600	\$ -
BJK People's	\$ 4,800	30%	\$ 1,440	\$ 3,360
St. Louis County	\$ 4,800	0%	\$ -	\$ 4,800
Total	\$ 40,000		\$ 28,960	\$ 11,040

Table 2D - Shows the total withheld, earned and paid for each PCHC.

	7% Withheld	Earned	RPCIFP	Total Paid
Grace Hill	\$ 200,000	\$ 200,000	\$ 19,200	\$ 219,200
Myrtle Hilliard	\$ 100,000	\$ 75,000	\$ 6,720	\$ 81,720
Family Care	\$ 20,000	\$ 20,000	\$ 1,600	\$ 21,600
BJK People's	\$ 50,000	\$ 40,000	\$ 1,440	\$ 41,440
St. Louis County	\$ 50,000	\$ 45,000	\$ -	\$ 45,000
Total	\$ 420,000	\$ 380,000	\$ 28,960	\$ 408,960

The state will determine with the SLRHC where the demand exists in the demonstration (primary care or specialty care) to determine where to apply the remaining funds. Payments will not be redirected for administrative or infrastructure payments.

Attachment E: Developing the Evaluation Design

Introduction

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

Expectations for Evaluation Designs

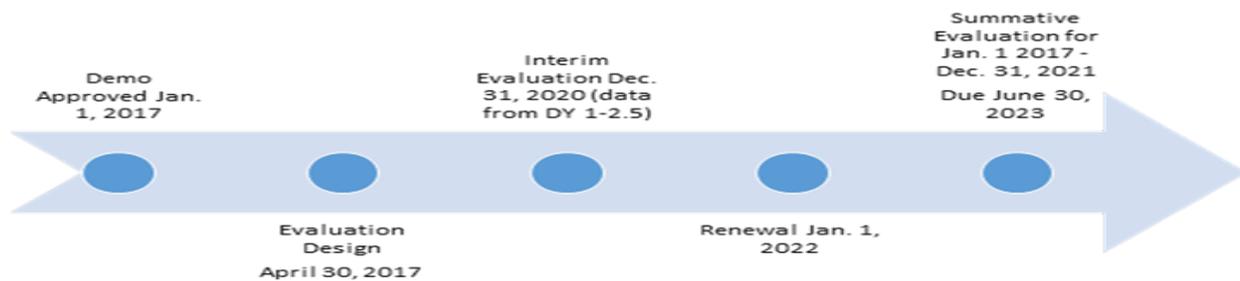
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals.

The format for the Evaluation Design is as follows:

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

Submission Timelines

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



Required Core Components of All Evaluation Designs

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

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

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

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

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

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

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

- 1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?
- 2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.
- 3) *Evaluation Period* – Describe the time periods for which data will be included.

- 4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by “owning”, defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:
- a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
 - b. Qualitative analysis methods may be used, and must be described in detail.
 - c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
 - d. Proposed health measures could include CMS’s Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
 - e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
 - f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.
- 5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

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

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

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

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

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

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

- 1) When the state demonstration is:
 - a. Long-standing, non-complex, unchanged, or
 - b. Has previously been rigorously evaluated and found to be successful, or
 - c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)
- 2) When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
 - a. Operating smoothly without administrative changes; and
 - b. No or minimal appeals and grievances; and
 - c. No state issues with CMS-64 reporting or budget neutrality; and
 - d. No Corrective Action Plans (CAP) for the demonstration.

E. Attachments

A. Independent Evaluator. The process the state will use for obtaining an independent entity to conduct the analysis and write the Evaluation Report, including a description

of the qualifications the entity must possess. As soon as known, this section should be updated to include:

- a. Information about the organization conducting the evaluation;
- b. Contact information for the organization, including how to obtain a copy of the evaluation;
- c. The name and contact information of the Principal Investigator; and
- d. Curriculum Vitae of the Principal Investigator.

- B. No Conflict of Interest.** Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. This includes “No Conflict of Interest” signed conformation statements.
- C. Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.
- D. Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

Attachment G: Preparing the Interim and Summative Evaluation Reports

Introduction

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

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. As these valid analyses multiply (by a single state or by multiple states with similar demonstrations) and the data sources improve, the reliability of evaluation findings will be able to shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

Intent of this Guidance

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

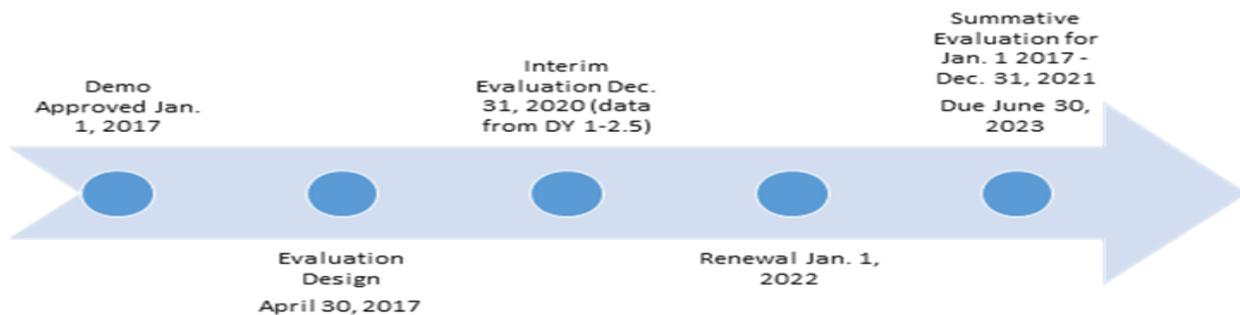
The format for the Interim and Summative Evaluation reports is as follows:

- F. Executive Summary;
- G. General Background Information;
- H. Evaluation Questions and Hypotheses;
- I. Methodology;

- J. Methodological Limitations;
- K. Results;
- L. Conclusions;
- M. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
- N. Lessons Learned and Recommendations; and
- O. Attachment(s).

Submission Timelines

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



Required Core Components of Interim and Summative Evaluation Reports

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

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

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

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

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

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

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

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

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

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

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

A. Methodological Limitations

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

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

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

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

B. Interpretations, Policy Implications and Interactions with Other State Initiatives – In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long range planning. This should include interrelations of the demonstration with other aspects of the state’s Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health

outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretation of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

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

D. Attachment

Evaluation Design: Provide the CMS-approved Evaluation Design