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

APR 12 2019

Jim Jones
Medicaid Director
State of Wisconsin, Department of Health Services
1 West Wilson Street
Room 350; P.O. Box 309
Madison, WI 53701-0309

Dear Mr. Jones:

The Centers for Medicare & Medicaid Services (CMS) is pleased to inform you that Wisconsin's request to extend its section 1115 demonstration, entitled "Wisconsin SeniorCare" (Project Number: 11-W-00149/5) has been approved. CMS' approval of this demonstration extension is granted under the authority of section 1115(a) of the Social Security Act (the Act) and is effective as of the date of this letter through December 31, 2028.

Originally implemented September 1, 2002, this longstanding demonstration will continue to provide a comprehensive prescription drug benefit to Wisconsin residents who are age 65 and older with income at or below 200 percent of the Federal poverty level (FPL) and who are not otherwise eligible to receive full Medicaid State Plan benefits. The SeniorCare demonstration has operated consistently since initial implementation with the only substantive change being to provide an optional medication therapy management benefit to support high-risk enrollees effective January 1, 2013. Since implementation, the program has successfully delivered a comprehensive prescription drug benefit to more than 290,000 seniors in the state of Wisconsin through a simplified enrollment process and affordable income-based deductibles and copayments.

Demonstration projects under section 1115 of the Act offer a way to give states more freedom to test and evaluate innovative solutions to improve quality, accessibility, and health outcomes in a budget-neutral manner, provided that, in the judgment of the Secretary, the demonstration is likely to assist with promoting the objectives of Medicaid. Consistent with federal transparency requirements, CMS also considers all public comments received during both the state and federal public input periods when evaluating whether the demonstration project as a whole will likely assist in promoting the objectives of Medicaid.

Wisconsin received approximately 532 public comments during the state's public comment period that were all in support of the continuation of the SeniorCare demonstration. Many commenters shared personal stories of how the cost-effective prescription drug prices provided

by this demonstration were the only way they were able to afford their medications on a fixed income and without having to sacrifice costs for their other daily living needs. CMS received approximately a dozen comments during the federal public comment period that were also all in support of continuing the SeniorCare demonstration as well as three additional letters of support from federal and state-level Wisconsin legislators.

After review of all the materials submitted by the state, as well as all public comments received, CMS determined that the Wisconsin SeniorCare Section 1115 Demonstration should be extended because it is likely to assist with promoting the objectives of title XIX of the Act by providing access to a high-quality pharmaceutical benefit that promotes efficiencies and that supports the sustainability of Wisconsin's Medicaid program for beneficiaries over the long-term.

CMS' approval of this demonstration project is subject to the state's compliance with the enclosed set of STCs and associated expenditure authorities. All Medicaid title XIX requirements as expressed in law, regulation, and policy statement not expressly identified as not applicable in these approval documents shall apply to the Wisconsin SeniorCare demonstration program. The state's authority to deviate from Medicaid requirements is limited to the expenditure authorities and requirements specifically listed as not applicable to such expenditure authorities, as described in the enclosed approval documents, and to the purpose(s) indicated.

This award is subject to your written acknowledgement of the award and acceptance of the STCs and associated expenditure authorities within 30 days of the date of this letter.

Your CMS project officer for this demonstration is Ms. Tonya Moore, who can be contacted to answer any questions concerning the implementation of this demonstration at 410-786-0019 or at Tonya.Moore@cms.hhs.gov. Official communications regarding program matters and correspondence concerning the demonstration should be submitted to her at the following address:

Centers for Medicare & Medicaid Services
Center for Medicaid & CHIP Services
Mail Stop: S2-25-26
7500 Security Boulevard
Baltimore, MD 21244-1850

Official communications regarding this demonstration should be sent simultaneously to Ms. Moore and to Mr. James Scott, Director of Field Operations North. Mr. Scott's contact information is as follows:

Mr. James Scott
Director
Centers for Medicare & Medicaid Services
Richard Bolling Federal Building
601 East 12th Street, Room 355
Kansas City, MO 64106-2808

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

Sincerely,

[redacted]

Chris Traylor
Deputy Administrator and Director

Enclosures

cc: James Scott, Director, Division of Field Operations North

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

DEMONSTRATION NUMBER: 11-W-00149/5

DEMONSTRATION TITLE: Wisconsin SeniorCare Section 1115 Demonstration

DEMONSTRATION AWARDEE: Wisconsin Department of Health Services

Medicaid Costs Not Otherwise Matchable

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by the state for the items identified below (which would not otherwise be included as matchable expenditures under section 1903 of the Act) shall, for the period of this demonstration through December 31, 2028, be regarded as matchable expenditures under the state's (title XIX) Medicaid State Plan.

The expenditure authority listed below promote the objectives of title XIX by improving health outcomes for low-income populations in the state through access to a prescription drug benefit that promotes efficiencies in ensuring Medicaid's sustainability for beneficiaries over the long term.

- **Demonstration-Eligible Population ("SeniorCare Population")** – Expenditures for prescription drug costs and medication therapy management (MTM) services for individuals age 65 or over with income at or below 200 percent of the Federal poverty level (FPL) who are enrolled in the demonstration and who are not receiving full Medicaid benefits under a group covered under the Medicaid State plan.

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 the demonstration population through December 31, 2028.

Title XIX Requirements Not Applicable to the Demonstration-Eligible Population:

1. Notice and Appeals — **Section 1902(a)(3), 42 CFR 431.211, 42 CFR 431.213, 42 CFR 431.206, and 42 CFR 431.220**

To the extent necessary to enable the state to not provide the 10-day required notification prior to termination of eligibility in cases where the demonstration enrollee has clearly notified the Department either orally or in writing that he or she no longer wishes to receive services. Also, to the extent necessary to enable the state to not provide the right to a hearing to demonstration enrollees with respect to denials of claims for benefit payments during any period in which funding for benefit payments under the program has been completely expended.

2. Eligibility Standards and Methodologies **Section 1902(a)(10)(A) and Section 1902(a)(17)**

To the extent necessary to enable the state to expand eligibility for coverage of pharmaceuticals and MTM services to demonstration enrollees with incomes at or below 200 percent of the FPL and to apply different financial eligibility standards and methodologies to the demonstration eligible population than would be applied to other Medicaid recipients. Eligibility will be re-determined and income will be reassessed for demonstration enrollees once every 12 months.

3. Amount, Duration, and Scope **Section 1902(a)(10)(B)**

To the extent necessary to enable the state to offer a different benefit package to the demonstration-eligible population that varies in amount, duration, and scope from the benefits offered under the Medicaid State Plan.

4. Benefits **Section 1902(a)(10)**

To the extent necessary to allow the state, during any period in which funding for benefit payments under the program is completely expended, to not pay pharmacies or pharmacists for prescription drugs sold to program participants or for MTM services. Further, to allow that pharmacies and pharmacists will not be required to sell drugs to demonstration enrollees at the program payment rate nor perform MTM for demonstration enrollees at the program rate; that demonstration enrollees will not be entitled to obtain prescription drugs for the copayment amounts or at the program payment rate nor will they be entitled to obtain MTM services at the program rate; that the state will not collect rebates from manufacturers for prescription drugs purchased by demonstration enrollees; and that the state is required to continue to accept applications and determine eligibility for the program, and must indicate to applicants that the eligibility of demonstration enrollees to purchase prescription drugs and MTM services under the requirements of the program is conditioned on the availability of funding.

5. Cost Sharing **Section 1902(a)(14)**

To the extent necessary to enable the state to impose an annual enrollment fee of $30; establish that demonstration enrollees with income above 160 percent of the FPL and at or below 200 percent of the FPL would pay the first $500 of prescription drug costs and MTM services prior to receiving the benefit of MTM services and obtaining prescription drugs at the copayment levels; and establish copayment amounts that are above Medicaid statutory limits to demonstration enrollees.

6. Ex Parte Eligibility Redetermination and Applicant's Choice of Category **Section 1902(a)(19), 42 CFR 435.902, 42 CFR 435.916, and 42 CFR 435.404**

To allow the state to require that a separate demonstration application be filed by an applicant who is not eligible for Medicaid State Plan coverage in order to be determined eligible for the demonstration program; and to require demonstration applicants to file a separate Medicaid application if they are potentially eligible for Medicaid State Plan benefits.

7. Retroactive Eligibility **Section 1902(a)(34) and 42 CFR 435.914**

To the extent necessary to enable the state to not provide coverage for the demonstration eligible population for any or all of the three months prior to the date of application for demonstration enrollment. Demonstration enrollees may participate in the program on the first day of the first month following the month in which all eligibility criteria are met.

8. Income Eligibility Verification **Section 1902(a)(46), 42 CFR 435.920, and 42 CFR 435.940 through 435.965**

To the extent necessary to enable the state to use all other state and Federal data exchanges under section 1137 of the Act except the Internal Revenue Service's data exchange for income verification for the demonstration-eligible population.

CENTERS FOR MEDICARE & MEDICAID SERVICES
MEDICAID SECTION 1115 DEMONSTRATION
SPECIAL TERMS AND CONDITIONS

DEMONSTRATION NUMBER: 11-W-00149/5

DEMONSTRATION TITLE: Wisconsin SeniorCare Section 1115 Demonstration

DEMONSTRATION AWARDEE: Wisconsin Department of Health Services

I. PREFACE

The following are the Special Terms and Conditions (STCs) for "Wisconsin SeniorCare" section 1115(a) Medicaid demonstration extension (hereinafter referred to as "demonstration") to enable the Wisconsin Department of Health Services (hereinafter referred to as "State") to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authority and associated non-applicable authorities to authorize federal matching of demonstration costs that are not otherwise matchable, and which are separately enumerated. These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS during this demonstration period. These STCs are effective from the date of approval on the accompanying CMS award letter through December 31, 2028.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Eligibility
V. Benefits
VI. Cost Sharing
VII. Delivery System
VIII. General Reporting Requirements
IX. General Financial Requirements
X. Monitoring Budget Neutrality for the Demonstration
XI. Evaluation Plan and Design

Attachment A: Annual Report Format and Content
Attachment B: CMS Evaluation Design Guidance
Attachment C: CMS Approved Evaluation Design (reserved)

II. PROGRAM DESCRIPTION AND OBJECTIVES

On July 1, 2002, CMS approved Wisconsin's SeniorCare Demonstration for an initial five-year period effective September 1, 2002 to offer a comprehensive prescription drug benefit to Wisconsin residents, age 65 and older, with income at or below 200 percent of the Federal

Poverty Level (FPL) and who are not otherwise eligible for full Medicaid State Plan benefits. Individuals that are eligible for low-income Medicare beneficiary programs such as Qualified Medicare Beneficiaries (QMB), Specified Low-Income Medicare Beneficiaries (SLMB), Qualified Individual (QI-1), or Qualified Disabled Working Individuals (QDWI) are not excluded from SeniorCare eligibility because these limited benefit programs only provide Medicaid payment for Medicare Part A and/or Part B monthly premiums and for any applicable cost-sharing (i.e., coinsurance, copayments, deductible) for Medicare-allowed services. Individuals with prescription drug coverage under other commercial health insurance plans may enroll in the SeniorCare demonstration. The state coordinates SeniorCare's benefit coverage with all other health insurance coverage, including Medicare Part D covered drugs, to ensure that SeniorCare is not paying for prescription costs covered by other health insurance plans.

After the initial approval period, the demonstration has been consistently approved for extension by CMS; with the last extension being approved on December 18, 2015 for a three-year period through December 31, 2018. On June 15, 2018, Wisconsin submitted a request to extend its SeniorCare demonstration without any program changes. The SeniorCare demonstration continues to offer coverage of prescription drugs and over-the-counter insulin the same as provided under the Wisconsin Medicaid State Plan. The only substantive program change since demonstration implementation was the addition of Medication Therapy Management (MTM) services that would be offered as an optional service to demonstration enrollees effective January 1, 2013. The demonstration was temporarily extended by CMS for the period of January 1, 2019 through April 30, 2019 while the state and CMS worked together to process a 10-year extension of the demonstration, which these STCs govern.

The demonstration is expected to continue to promote the following goals:

- Keeping Wisconsin seniors healthy by continuing to provide a necessary primary health care benefit;
- Reducing the rate of increase in the use of non-pharmacy related services provided to this population including hospital, nursing facility and other non-pharmacy related medical services; and,
- Helping control overall costs for the aged Medicaid population by preventing or delaying seniors from becoming eligible for Medicaid due to deteriorating health and spending down to Medicaid eligibility levels.

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, the Age Discrimination Act of 1975, and Section 1557 of the Affordable Care Act.

2. **Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program expressed in federal law, regulation, and written policy, not expressly waived or identified as not applicable in the expenditure authority document (of which these

terms and conditions are part), apply to the demonstration.

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

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

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

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

5. **State Plan Amendments.** The state will not be required to submit title XIX State Plan Amendments (SPAs) 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 appropriate State Plan may be required, except as otherwise noted in these STCs. In all such cases, the Medicaid State Plan governs.

6. **Changes Subject to the Amendment Process.** If not otherwise specified in these STCs, demonstration changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid State Plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, whether for administrative or service-based expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7, except as provided in STC 3.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for

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

a. Demonstration Amendment Summary and Objectives. A detailed description of the amendment, including impact on demonstration enrollees and title XIX program eligible beneficiaries, with sufficient supporting documentation; including the Medicaid program objective(s) the amendment is likely to promote and expected program outcomes.

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

c. Waiver and Expenditure Authorities. The specific waiver and expenditure authorities that are being requested for approval or termination, along with the reason why the state believes these authorities are necessary to authorize the amendment.

d. Public Notice. An explanation of the public process used by the state consistent with the requirements of STC 13.

e. Evaluation Design. A description of how the evaluation design will be modified to incorporate the amendment provisions.

8. Extension of the Demonstration. States that intend to request an extension of the demonstration must submit an application to CMS in accordance with the requirements of 42 Code of Federal Regulations (CFR) 431.412(c) from the Governor or Chief Executive Officer of the state. States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs, must submit a transition and phase-out plan consistent with the requirements of STC 9.

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

a. Notification of Suspension or Termination: The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter

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

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

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

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

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

f. Enrollment Limitation during Demonstration Phase-Out: If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be

suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.

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

10. **Temporary Suspension Due to Unavailability of State Funding.** In the event that state funding for the demonstration is unavailable for any period of time, resulting in a temporary suspension of the benefits provided under the demonstration, the state must provide advance notice in writing to CMS at least 60 days prior to the effective date of the temporary suspension of services to demonstration enrollees. The state must publish notice of the temporary suspension of benefits on its Medicaid website for a 30-day public comment period as well as conduct tribal consultation in accordance with STC 13. Once the 30-day public comment and tribal consultation period has ended, the state must provide to CMS a summary of the issues raised during the comment period and how the state considered the comments in its transition planning for the temporary suspension of benefits. The state must comply with all applicable beneficiary notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, 431.211, and 431.213. The state must also provide written notice to CMS, demonstration enrollees, and any other affected parties within 30 days of reinstating demonstration benefits.

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

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

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

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

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

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

15. **Common Rule Exemption**. The state shall ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid program – including procedures for obtaining Medicaid benefits or services, possible changes in or alternatives to Medicaid programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. The Secretary has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(d)(5).

16. **Transformed Medicaid Statistical Information Systems Requirements (T-MSIS)**. The state will comply with the requirements of section 1903(r) of the Act that requires all states with Medicaid programs to have approved mechanized claims processing and information retrieval systems that are compatible with claims processing and information retrieval systems used in the administration of titles XVIII and XIX of the Act. The claims data format for the electronic transmission, called the Transformed Medicaid Statistical Information System (T-MSIS), is specified in the State Medicaid Manual, Part 2, Section 2700. For additional information on how to comply with these requirements, the state should refer to CMS' August 23, 2013 State Medicaid Directors Letter on the Transformed Medicaid Statistical Information System (T-MSIS), which is available online at https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/SMD-13-004.pdf.

IV. ELIGIBILITY

17. **Populations Affected by the Demonstration.** Individuals eligible for the demonstration must meet all of the following eligibility requirements:

    a. Be a Wisconsin resident;
    b. Be at least 65 years of age;
    c. Be a U.S. citizen or have qualifying immigrant status;
    d. Have annual household income that does not exceed 200 percent of the FPL;
    e. Not be eligible to receive full Medicaid State Plan benefits. (This does not include

individuals eligible for low-income Medicare beneficiary programs such as: Qualified Medicare Beneficiaries (QMB), Specified Low-Income Medicare Beneficiaries (SLMB), Qualified Individual (QI-1), or Qualified Disabled Working Individuals (QDWI).); and,

f. Pay a $30 annual enrollment fee.

18. Period of Eligibility. Initial enrollment in the demonstration begins on the first day of the month following the date the enrollee submits a completed application, pays the $30 enrollment fee, and is determined by the state to meet all enrollment requirements. Demonstration enrollees will remain eligible during the 12-month certification period, regardless of income changes, unless the individual:

a. Begins receiving full Medicaid State Plan coverage;
b. No longer resides in the state of Wisconsin;
c. Becomes incarcerated or institutionalized in an Institution for Mental Disease (IMD); or,
d. Is no longer living.

19. Redeterminations of Eligibility. Redeterminations of demonstration eligibility must occur once every 12 months, which is done through the state's central processing center. An enrollee may request a redetermination of eligibility to be performed by the state due to a change in household income or size at any time, and the state must perform such redeterminations upon request. If at redetermination it appears that the individual may be potentially eligible for full Medicaid State Plan benefits, the individual must be provided facilitated access to apply for full-scope Medicaid coverage.

20. Application Processing and Enrollment Procedures. The state will use a targeted demonstration application and enrollment process for the demonstration that will require all applicants to pay a $30 enrollment fee at initial enrollment and for each subsequent 12-month demonstration enrollment period. In addition, individuals will be required to pay a new $30 enrollment fee if they choose to reapply within the 12-month enrollment period due to a change in household income or size. The state will return the full $30 enrollment fee to the applicant if the applicant is determined not eligible to enroll in the demonstration.

21. Coordination with other Insurance Affordability Programs. The state, or its designated representative, must inform all demonstration applicants of their potential eligibility for full-scope Medicaid State Plan coverage and options for the Medicare Part D low-income subsidy prior to enrolling in the demonstration. Information on more comprehensive coverage programs must be given to individuals at application for demonstration enrollment and the state must provide facilitated access to individuals who wish to apply or appear to be potentially eligible for more comprehensive coverage.

V. BENEFITS

22. Benefits for Participants in the Demonstration. Beneficiaries who are eligible for the demonstration as outlined in STC 17 will receive a targeted benefit of prescription drugs and over-the-counter insulin in the same manner as authorized under the Wisconsin Medicaid

State Plan.

Demonstration enrollees are also eligible to receive Medication Therapy Management (MTM) services as an optional demonstration service if they are at a high risk of experiencing medical complications due to their drug regimen. Under the MTM benefit, traditional pharmaceutical services called "intervention-based services" are provided by a pharmacist to the member through a series of private consultations. There is a limit of one initial and three follow-up MTM consultations per year; though pharmacists may request an exemption from these limits. During a MTM consultation, the pharmacist may:

- Obtain the necessary assessments of the enrollee's health status;
- Formulate a medication treatment plan for the member;
- Provide information, support services, and resources designed to enhance enrollee adherence with the member's therapy regimens;
- Document the care delivered and communication of essential information to the enrollee's primary care providers;
- Refer the enrollee to an appropriate health care provider (if necessary); and,
- Coordinate and integrate medication management services within the broader health care system.

23. Minimum Essential Coverage (MEC). This demonstration is limited to the provision of services as described in STC 22 and, consequently, is not recognized as Minimum Essential Coverage (MEC) as outlined in section 5000A(f)(1)(A)(ii) of the Internal Revenue Code of 1986. The state shall adhere to all applicable Internal Revenue Service reporting requirements with respect to MEC for demonstration enrollees.

VI. COST-SHARING

24. Cost-Sharing for Participants in the Demonstration. Demonstration enrollees are subject to the following cost-sharing requirements as a condition of eligibility for the SeniorCare program:

a. Enrollment Fee: All demonstration enrollees are required to pay an annual $30 enrollment fee prior to the initial enrollment and at each annual enrollment for the program. In addition, individuals who choose to reapply if their income changes are required to pay a new $30 enrollment fee. The enrollment fee will be returned if the applicant is not eligible to enroll in the demonstration.

   If upon application and determination of demonstration eligibility, all applicants have the option to decline participation in the SeniorCare program and will obtain a refund of the enrollment fee paid if the applicant notifies the state within the 30-day initial processing period or within 10 days of the date on the enrollment letter, whichever is later.

b. Co-Payments for Services: All enrollees are required to pay co-payments of $5.00 for generic drugs and $15.00 for brand name drugs. There is no copayment for MTM

services.

c. Deductible for Enrollees with Income Above 160 Percent of the Federal Poverty Level (FPL): Demonstration enrollees with income above 160 percent of the FPL and up to 200 percent of the FPL are responsible for the first $500 of prescription drug costs and MTM costs while in the deductible period each year and may pay up to Medicaid rates.

VII. DELIVERY SYSTEM

25. Medicaid Pharmacy Providers. The state will utilize the same pharmacy provider network used for the Wisconsin Medicaid State Plan to provide prescription drugs and MTM services to demonstration enrollees.

VIII. GENERAL REPORTING REQUIREMENTS

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

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

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

28. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may defer payments in accordance with 42 CFR part 430 subpart C, in the amount of $1,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter singularly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the demonstration. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

In the event that either (1) the state has not submitted a written request to CMS for approval of an extension, as described below, within 30 days after a deliverable was due, or (2) the state has not submitted a revised submission or a plan for corrective action to CMS within thirty days after CMS has notified the state in writing that a deliverable was not accepted for being inconsistent with the requirements of this agreement including the information needed to bring the deliverable into alignment with CMS requirements; the following process is triggered:

a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submission of required deliverable(s). For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided.

b. CMS may agree to a corrective action as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.

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

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

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

29. Monitoring Calls. CMS will convene biannual conference calls with the state in addition to ad hoc communications, as needed. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration. Areas to be addressed include, but are not limited to, health care delivery, enrollment, cost-sharing, quality of care, access, the benefit package, audits, lawsuits, financial reporting and budget neutrality issues, progress on evaluation, legislative developments, and any demonstration amendments the state is considering submitting. CMS shall 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. The state and CMS shall jointly develop the agenda for the calls.

30. Annual Monitoring Reports. The state must submit an Annual Monitoring Report by no later than 90 calendar days following the end of each demonstration year (i.e., by March 31). The reports will include all required elements as per 42 CFR 431.428 and as listed below, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The monitoring reports must follow the framework to be provided by CMS, which is subject to change as monitoring systems are developed/evolve, and will be provided in a structured manner that supports

federal tracking and analysis.

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

b. Performance Metrics – The performance metrics will provide data to demonstrate how the state is progressing towards meeting the milestones identified in CMS' framework which includes the following key policies under this demonstration- community engagement. The performance metrics will reflect all components of the state's demonstration, and may include, but are not limited to, measures associated with enrollment, disenrollment by specific demographics and reason, participation in community engagement qualifying activities, access to care, and health outcomes.

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

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

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

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

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

32. Close-Out Report. Within 120 days after the expiration of the demonstration, the state must submit a draft Close-Out Report to CMS for comments. A final report must only be submitted to CMS upon expiration of the demonstration. This provision does not apply if the demonstration is extended for future years.

a. The draft report must comply with the most current guidance from CMS.
b. The state will present to and participate in a discussion with CMS on the Close-Out Report.
c. The state must take into consideration CMS' comments for incorporation into the final Close-Out Report.
d. The final Close-Out Report is due to CMS no later than thirty calendar days after receipt of CMS' comments.
e. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 28.

IX. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

33. General Financial Requirements. The state must comply with all general title XIX financial requirements including reporting requirements related to monitoring budget neutrality as set forth in this section of the STCs.

34. 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. This project is approved for expenditures applicable to services rendered during the demonstration period. CMS shall provide title XIX FFP for allowable demonstration expenditures only as long as they do not exceed the pre-defined limits on the costs incurred as specified in STC 43.

35. Reporting Expenditures under the Demonstration. The following describes the reporting of expenditures subject to the budget neutrality agreement:

a. Tracking Expenditures. In order to track expenditures under this demonstration that are subject to the budget neutrality limit, the state shall 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 subject to the budget neutrality cap shall be reported on separate Forms CMS-64.9 Waiver and/or 64.9P Waiver, identified by the demonstration project number assigned by CMS (including the project number extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made). For monitoring purposes, cost

settlements must be recorded on Line 10.b, in lieu of Lines 9 or 10.C. For any other cost settlements (i.e., those not attributable to this demonstration), the adjustments should be reported on lines 9 or 10.C through 10.F, as instructed in the State Medicaid Manual.

b. Reporting by Demonstration Year by Date of Service. In each quarter, the state must submit separate Forms CMS-64.9 Waiver and/or 64.9P Waiver reporting expenditures (including prior period adjustments), using the waiver name "SeniorCare." Wisconsin must also separately report "Aged Medicaid expenditures" from all other title XIX expenditures and report them separately on the CMS 64.9 Waiver and/or 64.9P Waiver form using the waiver name, "Aged Medicaid."

   The state shall continue to follow the March 1, 2013 CMS approved reporting using the state's Decision Support System or data warehouse enabling the state to report the Medicaid Aged population separately on the CMS 64.9 Waiver and/or 64.9P Waiver form consistent with this STC for the purpose of measuring budget neutrality.

c. Cost Settlements. For monitoring purposes, cost settlements related to expenditures subject to the budget neutrality expenditure limit may be recorded on the appropriate prior period adjustment schedules (Form CMS-64.9P Waiver) for Summary Sheet line 10B, in lieu of lines 9 or 10C. For any other cost settlements not so associated, the adjustments must be reported on lines 9 or 10C, as instructed in the State Medicaid Manual.

d. Premium and Cost-sharing Adjustments. Enrollment fees and other applicable cost sharing contributions from enrollees that are collected by the state under the demonstration must be reported to CMS each quarter on Form CMS-64 Summary Sheet line 9.D, columns A and B. Additionally, the total amounts that are attributable to the demonstration must be separately reported on the CMS-64 Narrative, with subtotals by demonstration year. In the calculation of expenditure subject to the budget neutrality expenditure limit, premium collections applicable to demonstration populations will be offset against expenditures. These section 1115 premium collections will be included as a manual adjustment (decrease) to the demonstration's actual expenditures on a quarterly basis.

e. Manufacturer Rebates. The state has the capacity to use its MMIS system to stratify manufacturer's rebate revenue that should be assigned to net demonstration expenditures. The state will generate a demonstration-specific rebate report to support the methodology used to assign rebates to the demonstration. The State will report rebate revenue on the CMS 64-9. This revenue will be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid. Budget neutrality will reflect the net cost of prescription drugs.

f. Administrative Costs. Administrative costs will not be included in the budget neutrality expenditure limit, but the state must separately track and report additional administrative costs that are directly attributable to the demonstration. All such

administrative costs will be identified on the Forms CMS-64.10 Waiver and/or 64.10P Waiver, using waiver name "SeniorCare."

36. **Standard Medicaid Funding Process**. The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable demonstration expenditures (total computable and Federal share) subject to the budget neutrality expenditure cap and separately report these expenditures by quarter for each Federal fiscal year on the Form CMS-37 for both the Medical Assistance Payments (MAP) and state and Local Administration Costs (ADM). CMS shall make Federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state 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.

37. **Claiming Period**. All claims for expenditures subject to the budget neutrality expenditure limit (including any cost settlements) must be made within two years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state 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.

38. **Extent of Federal Financial Participation (FPP) for the Demonstration**. Subject to CMS approval of the source(s) of the non-Federal share of funding, CMS shall provide FFP for the demonstration at the applicable federal matching rates for the following, subject to the limits described in these STCs.

    a. Administrative costs, including those associated with the administration of the demonstration; and,

    b. Net expenditures and prior period adjustments made in accordance with the approved expenditure authorities described in this Agreement and for the "Aged Medicaid" population described in STC 35 for the purpose of measuring budget neutrality.

39. **Sources of Non-Federal Share**. The state certifies that the source of the non-Federal share of funds for the demonstration is state/local monies. The state further certifies that such funds shall not be used as the non-federal share for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with title XIX of the Social Security Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

    a. CMS shall review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.

b. The state shall provide information to CMS regarding all sources of the non-federal share of funding for any amendments that impact the financial status of the program.

c. Under all circumstances, health care providers must retain 100 percent of the reimbursement amounts claimed by the state as demonstration expenditures. Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state and/or local government to return and/or redirect any portion of the Medicaid or demonstration payments. This confirmation of Medicaid and demonstration payment retention is made with the understanding that payments that are the normal operating expenses of conducting business (such as payments related to taxes (including health care provider-related taxes), fees, and business relationships with governments that are unrelated to Medicaid or the demonstration and in which there is no connection to Medicaid or demonstration payments) are not considered returning and/or redirecting a Medicaid or demonstration payment.

40. Payer of Last Resort. The Medicaid program is the payer of last resort except as expressly provided by the Medicaid statute; that is, all other available third party resources must meet their legal obligation to pay claims before the Medicaid program will pay for the care of an individual eligible for Medicaid. Accordingly, the state must have adequate systems and safeguards in place to provide for coordination of benefits under the demonstration.

X. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

41. Limit on Federal Title XIX Funding. The state will be subject to a limit on the amount of federal title XIX funding that the state may receive for expenditures subject to the budget neutrality agreement during the demonstration approval period. The budget neutrality expenditure limits are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. The data supplied by the state to CMS to set the annual caps is subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit. CMS' assessment of the state's compliance with these annual limits will be done using the Schedule C report from the MBES/CBES CMS-64 consistent with STC 35.

42. Expenditures Subject to the Budget Agreement. Consistent with STC 35, the expenditures subject to the budget neutrality limit include the following:

a. All medical assistance expenditures (including those authorized in the Medicaid State Plan or through section 1915(c) waivers) made on behalf of the Medicaid Aged population as determined by the agreed upon budget neutrality limit outlined in STC 43.

b. All expenditures (net administrative costs) associated with the SeniorCare population.

43. Budget Neutrality Expenditure Cap. Consistent with the August 22, 2018, State Health Official Letter #18-009, this demonstration is subject to an aggregate budget limit that places

a fixed total dollar cap on state expenditures for the demonstration. With this budget neutrality model, the state is at risk for both total demonstration (i.e., SeniorCare) expenditures and total Medicaid State Plan expenditures for the Medicaid Aged Population that is impacted by the demonstration (as described in STC 35).

The following table provides the total computable budget neutrality limit for each demonstration year, which is equal to calendar year as outlined below. The below specified annual budget neutrality limit is the total expenditure limit for both the SeniorCare demonstration population and the state's Medicaid Aged Population that is impacted by the demonstration for purposes of measuring budget neutrality.

Demonstration Year	Budget Neutrality Limit (Total Computable)
Demonstration 18 (Calendar Year 2019)	$2,018,446,473
Demonstration 19 (Calendar Year 2020)	$2,099,365,939
Demonstration 20 (Calendar Year 2021)	$2,185,623,614
Demonstration 21 (Calendar Year 2022)	$2,275,398,553
Demonstration 22 (Calendar Year 2023)	$2,368,833,228
Demonstration 23 (Calendar Year 2024)	$2,466,075,854
Demonstration 24 (Calendar Year 2025)	$2,567,280,616
Demonstration 25 (Calendar Year 2026)	$2,672,607,912
Demonstration 26 (Calendar Year 2027)	$2,782,224,598
Demonstration 27 (Calendar Year 2028)	$2,896,304,254

44. **Composite Federal Share**. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period, as reported on the forms listed in STC 35 above, by total computable demonstration expenditures for the same period as reported on the forms. Should the demonstration be terminated prior to the end of the approval period (see STC 9), the Composite Federal Share will be determined based on actual expenditures for the period in which the demonstration was active. For the purpose of interim monitoring of budget neutrality, a reasonable Composite Federal Share may be used.

45. **Enforcement of Budget Neutrality**. CMS shall enforce budget neutrality over the life of the 10-year demonstration extension period. No later than 90 calendar days following the end of each demonstration year (as part of the Annual Monitoring Report required by STC 30), the state will calculate and report to CMS an annual cumulative expenditure target for the completed year. This amount will be compared with the actual cumulative amount the state has claimed for FFP through the completed year. If cumulative spending exceeds the cumulative target by more than the indicated percentage, the state will submit a corrective action plan to CMS for approval. The state will subsequently implement the approved plan.

Year	Cumulative Target Expenditures	Percentage
DY18	DY18 budget limit plus:	2 percent
DY19	DY18 and DY19 combined budget limit amount plus:	1.75 percent
DY20	DY18 through DY20 combined budget limit amount plus:	1.5 percent

DY21	DY18 through DY21 combined budget limit amount plus:	1.25 percent
DY22	DY18 through DY22 combined budget limit amount plus:	1.0 percent
DY23	DY18 through DY23 combined budget limit amount plus:	0.75 percent
DY24	DY18 through DY24 combined budget limit amount plus:	0.5 percent
DY25	DY18 through DY25 combined budget limit amount plus:	0.25 percent
DY26	DY18 through DY26 combined budget limit amount plus:	0.25 percent
DY27	DY18 through DY27 combined budget limit amount plus:	0 percent

46. **Exceeding Budget Neutrality**. If the budget neutrality expenditure limit has been exceeded at the end of this 10-year demonstration extension period, the excess federal funds shall be returned to CMS. If the demonstration is terminated prior to the end of the budget neutrality agreement, the budget neutrality test shall be based on the time elapsed through the termination date.

47. **Future Adjustments to the Budget Neutrality Expenditure Limit**. CMS reserves the right to adjust the budget neutrality expenditure limit in order to be consistent with enforcement of impermissible provider payments, health care related taxes, new Federal statutes, or with policy interpretations implemented through letters, memoranda, or regulations. CMS reserves the right to make adjustments to the budget neutrality expenditure limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of Section 1903(w) of the Act. Adjustments to the budget neutrality agreement will reflect the phase-out of impermissible provider payments by law or regulation, where applicable.

XI. EVALUATION OF THE DEMONSTRATION

48. **Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state shall cooperate fully and timely with CMS and its contractors' in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents; providing data and analytic files to CMS; entering into a data use agreement that explains how the data and data files will be exchanged; and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state shall include in its contracts with entities that collect, produce or maintain data and files for the demonstration, a requirement that they make data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 28.

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

methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

50. Draft Evaluation Design. The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, by no later than 120 calendar 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.

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

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

53. Evaluation Budget. A budget for the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluation such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.

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

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

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

c. If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted as required by 42 CFR 431.412(c)(2)(vi). If the state made changes to the demonstration in its application for extension, the research questions and hypotheses, and how the design was adapted should be included. If the state is not requesting an extension of the demonstration, an Interim Evaluation Report is due one year prior to the end of the demonstration. For demonstration phase-out 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 by no later than 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.

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

55. Summative Evaluation Report. The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Evaluation Report) of these STCs. The state must submit a draft Summative Evaluation Report for the approved demonstration extension period (i.e., April 12, 2019 through December 31, 2028) within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

a. Unless otherwise agreed upon in writing by CMS, the state shall submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.

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

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

57. State Presentations for CMS. CMS reserves the right to request that the state present and

participate in a discussion with CMS on the Evaluation Design, the Interim Evaluation Report, and/or the Summative Evaluation Report.

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

59. **Additional Publications and Presentations.** For a period of 12 months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration over which the state has control. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

ATTACHMENT A – Developing the Evaluation Design

Introduction

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

Expectations for Evaluation Designs

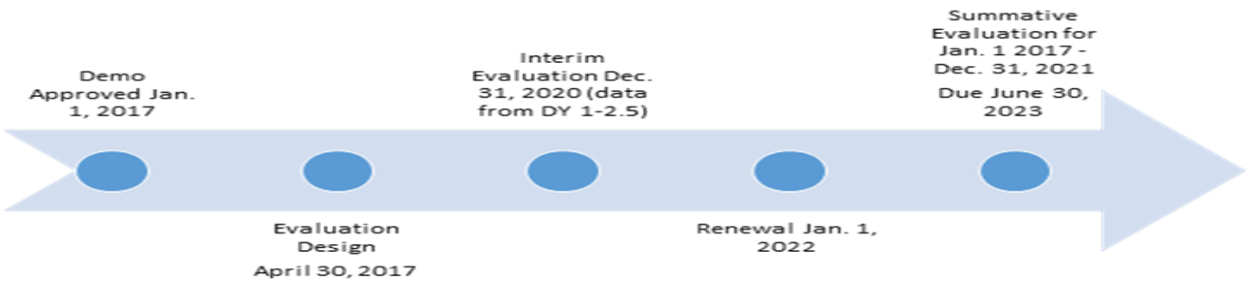
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses,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

The format for the Evaluation Design is as follows:

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

Submission Timelines

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



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

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

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

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

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

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

5) Describe the population groups impacted by the demonstration.

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

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

C. Methodology – In this section, the state is to describe in detail the proposed research methodology. The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references). This section provides the evidence that the demonstration evaluation will use the best available data; reports on, controls for, and makes appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what will be measured and how. Specifically, this section establishes:

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

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

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

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

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

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

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

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

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

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

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

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

E. Special Methodological Considerations – CMS recognizes that there may be certain instances where a state cannot meet the rigor of an evaluation as expected by CMS. In these instances, the state should document for CMS why it is not able to incorporate key components of a rigorous evaluation, including comparison groups and baseline data analyses. Examples of considerations include when the demonstration is considered successful without issues or concerns that would require more regular reporting, such as:

a. Operating smoothly without administrative changes; and
b. No or minimal appeals and grievances; and
c. No state issues with CMS-64 reporting or budget neutrality; and

d. No Corrective Action Plans (CAP) for the demonstration.

F. Attachments

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

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

3) **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(2)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

ATTACHMENT B – Preparing the Evaluation Report

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration 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 need improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Reports

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

Intent of this Attachment

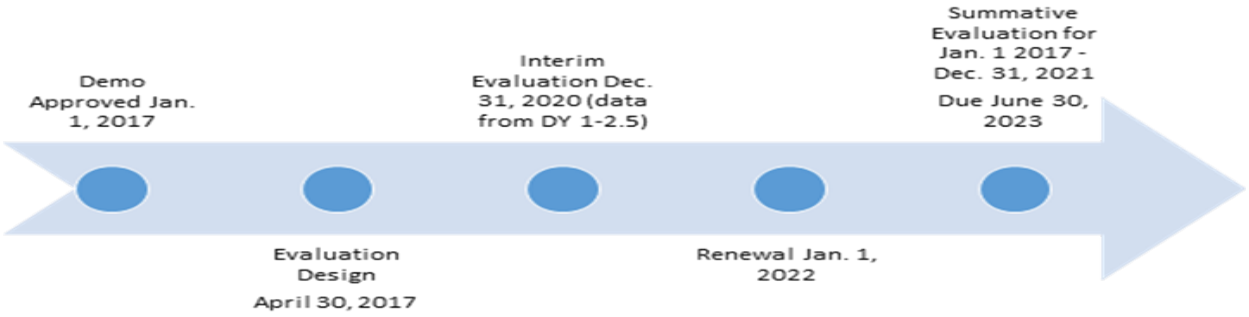
Title XIX of the Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified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

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

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

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

Submission Timelines
There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish the evaluation design and reports to the state's website within 30 days of CMS approval, as per 42 CFR 431.424(d)(2). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of Interim and Summative Evaluation Reports

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

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

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

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

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

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

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

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

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

should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1) *Evaluation Design* – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?

2) *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.

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

4) *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?

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

6) *Analytic methods* – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).

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

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

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

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

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

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

H. Interpretations, Policy Implications and Interactions with Other State Initiatives – In this section, the state will discuss the section 1115 demonstration within an overall

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

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

1) What lessons were learned as a result of the demonstration?

2) What would you recommend to other states which may be interested in implementing a similar approach?

J. Attachment

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

ATTACHMENT C – Approved Demonstration Evaluation Design

(reserved pending CMS approval)