DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop: S2-25-26
Baltimore, Maryland 21244-1850

State Demonstrations Group

June 25, 2025

Bill Hanna
State Medicaid Director
Wisconsin Department of Health Services
1 W. Wilson St.
Madison, WI 53701

Dear Director Hanna:

The Centers for Medicare & Medicaid Services (CMS) is updating the section 1115 demonstration monitoring approach to reduce state burden, promote effective and efficient information sharing, and enhance CMS's oversight of program integrity by reducing variation in information reported to CMS.

Federal section 1115 demonstration monitoring and evaluation requirements are set forth in section 1115(d)(2)(D)-(E) of the Social Security Act (the Act), in CMS regulations in 42 CFR 431.428 and 431.420, and in individual demonstration special terms and conditions (STCs). Monitoring provides insight into progress with initial and ongoing demonstration implementation and performance, which can detect risks and vulnerabilities to inform possible course corrections and identify best practices. Monitoring is a complementary effort to evaluation. Evaluation activities assess the demonstration's success in achieving its stated goals and objectives.

Key changes of this monitoring redesign initiative include introducing a structured template for monitoring reporting, updating the frequency and timing of submission of monitoring reports, and standardizing the cadence and content of the demonstration monitoring calls.

Updates to Demonstration Monitoring

Below are the updated aspects of demonstration monitoring for the Wisconsin Senior Care (Project Number 11-W-00149/5) demonstration.

Reporting Cadence and Due Date

CMS determined that, when combined with monitoring calls, an annual monitoring reporting cadence will generally be sufficient to monitor potential risks and vulnerabilities in demonstration implementation, performance, and progress toward stipulated goals. Thus, pursuant to CMS's authority under 42 CFR 431.420(b)(1) and 42 CFR 431.428, and in alignment with SeniorCare's demonstration STCs, CMS is retaining the cadence for this demonstration to

annual monitoring reporting (see also section 1115(d)(2)(D)-(E) of the Act). However, CMS is extending the due date of the annual monitoring report from 90 days to 180 days after the end of each demonstration year to balance Medicaid claims completeness with the state's work to draft, review, and submit the report timely.

CMS might increase the frequency of monitoring reporting if CMS determines that doing so would be appropriate. The standard for determining the frequency of monitoring reporting will ultimately be included in each demonstration's STCs. CMS expects that this standard will permit CMS to make on-going determinations about reporting frequency under each demonstration by assessing the risk that the state might materially fail to comply with the terms of the approved demonstration during its implementation and/or the risk that the state might implement the demonstration in a manner unlikely to achieve the statutory purposes of Medicaid. *See* 42 CFR 431.420(d)(1)-(2).

The next annual monitoring report for the Wisconsin SeniorCare demonstration will be due on June 29, 2026, which reflects the first business day following 180 calendar days after the end of the current demonstration year. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect the new reporting cadence and due date.

Structured Monitoring Report Template

As noted in STC 30, "Monitoring Reports," monitoring reports "must follow the framework provided by CMS, which is subject to change as monitoring systems are developed / evolve and be provided in a structured manner that supports federal tracking and analysis." Pursuant to that STC, CMS is introducing a structured monitoring report template to minimize variation in content of reports across states, which will facilitate drawing conclusions over time and across demonstrations with broadly similar section 1115 waivers or expenditure authorities. The structured reporting framework will also provide CMS and the state opportunities for more comprehensive and instructive engagement on the report's content to identify potential risks and vulnerabilities and associated mitigation efforts as well as best practices, thus strengthening the overall integrity of demonstration monitoring.

This structured template will include a set of base metrics for all demonstrations. For demonstrations with certain waiver and expenditure authorities, there are additional policy-specific metrics that will be collected through the structured reporting template.

Demonstration Monitoring Calls

As STC 29 "Monitoring Calls" describes, CMS may "convene periodic conference calls with the state," and the calls are intended "to discuss ongoing demonstration operation, including (but not limited to) any significant actual or anticipated developments affecting the demonstration." Going forward, CMS envisions implementing a structured format for monitoring calls to provide consistency in content and frequency of demonstration monitoring calls across demonstrations. CMS also envisions convening quarterly monitoring calls with the state and will follow the structure and topics in the monitoring report template. We anticipate that standardizing the

expectations for and content of the calls will result in more meaningful discussion and timely assessment of demonstration risks, vulnerabilities, and opportunities for intervention. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect that monitoring calls will be held no less frequently than quarterly.

CMS will continue to be available for additional calls as necessary to provide technical assistance or to discuss demonstration applications, pending actions, or requests for changes to demonstrations. CMS recognizes that frequent and regular calls are appropriate for certain demonstrations and at specific points in a demonstration's lifecycle.

In the coming weeks, CMS will reach out to schedule a transition meeting to review templates and timelines outlined above. As noted above, the pertinent Wisconsin Senior Care section 1115 demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect these updates.

If you have any questions regarding these updates, please contact Danielle Daly, Director of the Division of Demonstration Monitoring and Evaluation, at Danielle.Daly@cms.hhs.gov.

Sincerely,

[redacted]

Karen LLanos
Acting Director

Enclosure
cc: Mai Le-Yuen, State Monitoring Lead, Medicaid and CHIP Operations Group

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 promotes the objectives of title XIX by providing coverage for a targeted benefit package of prescription drugs, medication therapy management services, and vaccinations to a population of certain adult Wisconsin residents age 65 and over.

- **Demonstration-Eligible Population ("SeniorCare Population")** – To the extent necessary, expenditures for the coverage of prescription drugs, vaccinations recommended for adults age 65 or over by the Advisory Committee on Immunization Practices (ACIP), 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), and who are not eligible for enrollment in any group covered under the Medicaid state plan other than one of the following groups: the limited-benefit Medicaid state plan eligibility group that receives medical assistance only for tuberculosis-related benefits, the limited-benefit Medicaid state plan eligibility group that receives medical assistance only for family planning benefits, or one of the limited-benefit Medicaid state plan eligibility groups that receives medical assistance only for payment of Medicare premiums and/or cost-sharing. To the extent necessary, the expenditure authority for vaccinations also applies, notwithstanding section 1903(b)(1) of the Act and implementing regulations at 42 CFR 431.625(d)(3), to state payments to providers for ACIP-recommended vaccinations that could have been paid for under Medicare Part B, but were not, because the beneficiary was eligible for enrollment in Medicare Part B but was not enrolled in Medicare Part B.

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, MTM services, and vaccinations to demonstration enrollees with income 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 demonstration enrollees, and also to not pay for MTM services and vaccinations provided to demonstration enrollees. 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 receive MTM services and vaccinations 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.

9. Coordination of Medicaid with Medicare Part B — **Section 1903(b)(1), 42 CFR 431.625(d)(3)**

Pertaining to the expenditure authority for vaccination coverage, to the extent necessary to permit federal financial participation (FFP) to be provided in state expenditures for payments to providers for ACIP-recommended vaccinations that could have been paid for under Medicare Part B, but were not, because the beneficiary was eligible for enrollment in Medicare Part B but was not enrolled in Medicare Part B.

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 June 6, 2022, the date of approval on the accompanying CMS award letter, through December 31, 2028.

The STCs have been arranged into the following subject areas:

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). To be eligible to enroll in SeniorCare, otherwise eligible individuals must not be eligible under the Medicaid state plan, with a few limited exceptions for certain limited-benefit state plan eligibility groups. First, otherwise eligible individuals may enroll in SeniorCare even if they are also eligible for enrollment in one of the limited-benefit Medicaid state plan eligibility groups that receives medical assistance only for payment of Medicare premiums and/or cost-sharing. In other words, otherwise eligible persons who are eligible for enrollment in a Medicare Savings Program as Qualified Medicare Beneficiaries, Specified Low-Income Medicare Beneficiaries, Qualifying Individuals, or Qualified Disabled Working Individuals may enroll in the SeniorCare demonstration. Second, otherwise eligible individuals may enroll in SeniorCare even if they are also eligible for enrollment in the limited-benefit state plan eligibility group that receives medical assistance only for tuberculosis-related benefits, as described in sections 1902(a)(10)(A)(ii)(XII) and 1902(z)(1) of the Act. Third, otherwise eligible individuals may enroll in SeniorCare even if they are also eligible for enrollment in the limited-benefit state plan eligibility group that receives medical assistance only for family planning benefits, as described in sections 1902(a)(10)(A)(ii)(XXI) and 1902(ii) of the Act. Individuals with commercial health insurance may also enroll in the SeniorCare demonstration if all other eligibility criteria are met.

Accordingly, the demonstration serves as supplemental drug coverage for persons who are enrolled in the demonstration and who do not have Medicare Part D or other coverage for prescription drugs that pays primary to Medicaid. For SeniorCare enrollees who have Medicare Part D or other coverage that pays primary to Medicaid, the demonstration also fills a gap in coverage for any prescription drugs not covered under the enrollee's other coverage.

Consistent with federal law, Wisconsin ensures that SeniorCare pays last for services covered under the demonstration whenever Medicaid is the payer of last resort. Special Term and Condition (STC) 40 of the Wisconsin SeniorCare demonstration reflects this assurance, and coordination of benefits is implemented through "other insurance" or "cost-avoidance" rules that have been programmed into Wisconsin's mechanized claims processing and information retrieval system for Medicaid. The system can thus identify when a SeniorCare enrollee has coverage that should pay primary to Medicaid, such as Medicare or commercial insurance, and bills these payers first, before claims are submitted under the Wisconsin SeniorCare demonstration.

After the initial approval period, the demonstration has been consistently approved for extension by CMS; with the last extension being approved on April 12, 2019, without any program changes, for a 10-year period through December 31, 2028.

In April 2020, the Wisconsin legislature passed 2019 Wisconsin Act 185 to amend the definition of "prescription drug" under the SeniorCare program to include vaccinations recommended by the Advisory Committee on Immunization Practices (ACIP) for adults. The state identified a coverage gap for SeniorCare enrollees that do not have vaccination coverage under the state plan, Medicare Part B, Medicare Part D, or other coverage that pays primary to Medicaid. Accordingly, Wisconsin submitted an amendment request on November 19, 2020, which CMS approved on June 6, 2022, to add coverage of ACIP-recommended vaccinations for adults age 65 or over under the SeniorCare demonstration, without enrollee cost-sharing requirements. The

vaccination coverage will include both the vaccines themselves (if not federally purchased), and their administration. With this amendment, the state will provide supplemental coverage of vaccinations, to the extent necessary, to persons enrolled in the demonstration who do not have this coverage under the Medicaid state plan, Medicare Part B, Medicare Part D, or other coverage that pays primary to Medicaid. To the extent necessary, the amended expenditure authority also applies, notwithstanding section 1903(b)(1) of the Act and implementing regulations at 42 CFR 431.625(d)(3), to state payments to providers for ACIP-recommended vaccinations that could have been paid for under Medicare Part B, but were not, because the beneficiary was eligible for enrollment in Medicare Part B but was not enrolled in Medicare Part B.

The SeniorCare demonstration is expected to promote the following goals:

- Keeping Wisconsin seniors healthy by providing 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 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 state wide 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 for coverage under the Medicaid state plan, except as described below:
    i. Eligible individuals may enroll in SeniorCare even if they are also eligible for enrollment in one of the following limited-benefit Medicaid state plan eligibility groups:
        1. A group that receives medical assistance only for payment of Medicare premiums and/or cost-sharing (i.e., persons eligible for enrollment in a Medicare Savings Program as Qualified Medicare Beneficiaries, Specified Low-Income Medicare Beneficiaries, Qualifying Individuals, or Qualified Disabled Working Individuals);
        2. The group that receives medical assistance only for tuberculosis-related benefits, as described in sections 1902(a)(10)(A)(ii)(XII) and 1902(z)(1) of the Act; or
        3. The group that receives medical assistance only for family-planning benefits, as described in sections 1902(a)(10)(A)(ii)(XXI) and 1902(ii) of the Act; 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. Becomes eligible under the Medicaid state plan other than as described in STC 17;
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 under the Medicaid state plan other than as described in STC 17, the individual must be provided facilitated access to apply for 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 coverage under the Medicaid state plan other than as described in STC 17 and options for enrollment into Medicare Part B and/or the Medicare Part D low-income subsidy program 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: (1) prescription drugs, including over-the-counter insulin, in the same manner as authorized under the Wisconsin Medicaid state plan; (2) Medication Therapy Management (MTM) services as described in the following paragraph; and (3) Vaccinations that are recommended for adults age 65 and over by the Advisory Committee on Immunization Practices (ACIP).

    - Medication Therapy Management (MTM) Services. Demonstration enrollees are 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 an 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 demonstration 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 or for ACIP-recommended vaccinations.

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. Vaccination costs are excluded from the deductible period, and demonstration enrollees are eligible to receive ACIP-recommended vaccinations, without cost-sharing, while in the deductible period.

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, Transformed Medicaid Statistical Information System (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.

Wisconsin ensures that the SeniorCare demonstration pays last whenever Medicaid is the payer of last resort through "other insurance" or "cost avoidance" rules that have been programmed into Wisconsin's mechanized claims processing and information retrieval system for Medicaid, called the Medicaid Management Information System (MMIS). The system identifies when a SeniorCare enrollee has coverage that should pay primary to Medicaid, such as commercial insurance or Medicare Parts B or D; this "coordination of benefit segment" will review and deny any claim submitted under the SeniorCare demonstration that does not have the results of billing the enrollee's primary coverage.

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 Interim and Summative Evaluation Reports) 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 Reports. The state must submit two Interim Evaluation Reports for the completed years of the demonstration, as specified in subparagraph c, including one for a subsequent extension of the demonstration, in alignment with 42 CFR 431.412(c)(2)(vi). When submitting an application for extension, the most recently completed Interim Evaluation Report should be posted to the state 's website with the application for public comment.

a. The Interim Evaluation Reports 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 Reports must include an evaluation of the authority as approved by CMS.

c. The state must provide a draft Interim Evaluation Report for the corresponding years described below. The state must submit a revised Interim Evaluation Report within calendar 60 days after receipt of CMS' comments on the corresponding draft Interim Evaluation Report. Once CMS approves each Interim Evaluation Report, the state must post it on the state's Medicaid website within 30 days of approval by CMS.
    i. A draft Interim Evaluation Report for the period from January 2019 through December 2022 will be due no later than December 31, 2023.
    ii. A draft Interim Evaluation Report for the period from January 2019 through December 2026 will be due no later than December 31, 2027.

d. If the state is seeking to extend the demonstration, the draft Interim Evaluation Report, representing January 2019 through December 2026, is due when the application for extension is submitted as required by 42 CFR 431.412(c)(2)(vi).

e. If the state is not requesting an extension of the demonstration, the second 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.

f. The Interim Evaluation Reports 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 Interim and Summative Evaluation Reports) 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

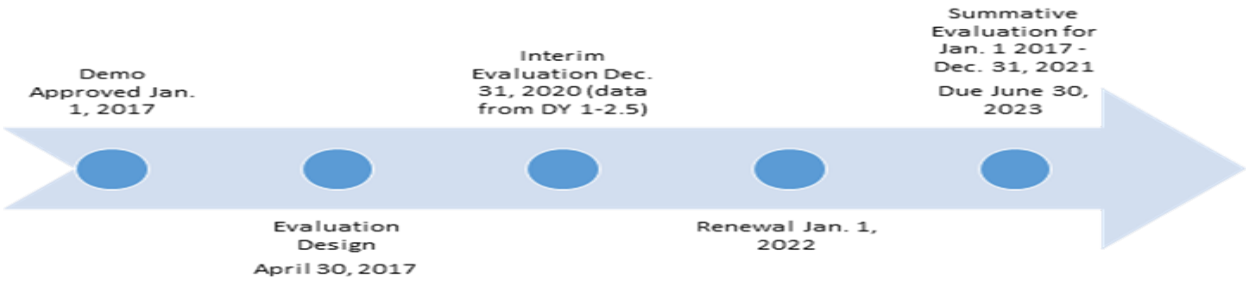
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, 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 Interim and Summative Evaluation Reports

Introduction

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

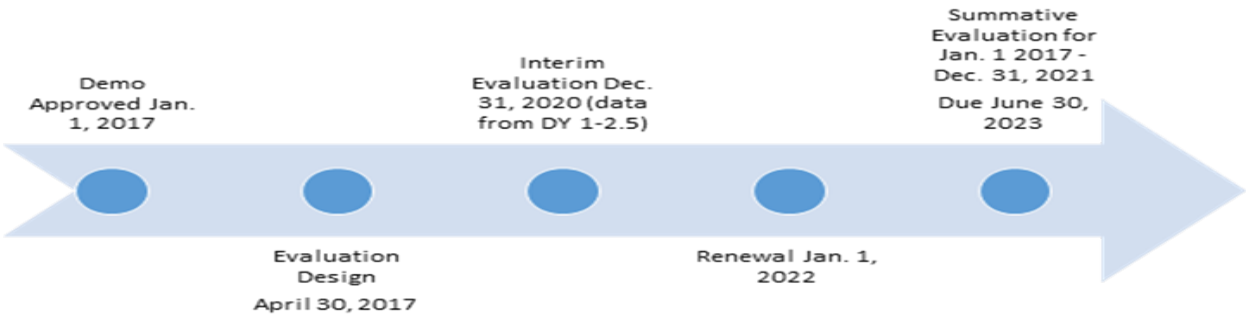
Title XIX of the Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state 's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified 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

Wisconsin's SeniorCare Pharmaceutical Benefit for Low-Income Seniors CMS Section 1115 Waiver Project, 2019 Renewal

Evaluation Design

ABBREVIATIONS & GLOSSARY OF TERMS

CCW	Chronic Conditions Data Warehouse
CMS	Centers for Medicare and Medicaid Services
CMR/A	Comprehensive Medication Review and Assessment
EBD	Elderly, Blind, and Disabled
FDA	Food and Drug Administration
FPL	Federal Poverty Level
GLM	Generalized Linear Model
LIS	Low-Income Subsidy
MMIS	Medicaid Management Information System
MTM	Medication Therapy Management
SNAP	Supplemental Nutrition Assistance Program
TANF	Temporary Assistance for Needy Families
WIR	Wisconsin Immunization Registry

I. EXECUTIVE SUMMARY

The University of Wisconsin-Madison (UW) will evaluate the State of Wisconsin's SeniorCare Pharmaceutical Benefit for Low-Income Seniors, as approved by the federal Centers for Medicare and Medicaid Services (CMS) under a § 1115 waiver. The waiver was approved for a ten-year period, from 2019-2028, and this proposed evaluation is designed to answer hypotheses using data from the first five-year period, from 2019-2023. (Note: After five years of operating and evaluating the waiver evaluation, DHS will assess the program, the observed outcomes, and the environment, to consider new hypotheses and evaluation questions for the second five-year period.) This evaluation will involve a range of health services and econometric methods, and relies on state and national administrative claims data. The evaluation will address the following three hypotheses and associated research questions, along with relevant data and analytic methods:

Hypothesis 1: SeniorCare will have a positive effect on member medication use and financial hardship.

Q1-1: How does the SeniorCare population compare to older adults enrolled in Medicare Part D?

- Descriptive statistics and statistical tests using enrollment and claims data from SeniorCare and Medicare. Comparisons will be made between SeniorCare members and similar Part D enrollees.

Q1-2: How do annual trends in drug utilization and expenditures in SeniorCare compare to older adults enrolled in Medicare Part D?

- Descriptive statistics and regression analysis using enrollment and claims data from SeniorCare and Medicare. Comparisons will be made between SeniorCare and similar Part D enrollees. Outcomes will be assessed in detail for important drug types and therapeutic classes.

Q1-3: How does the prevalence of financial hardship among SeniorCare members compare to similar populations of older adults?

- Descriptive statistics and regression analysis using enrollment and claims data from SeniorCare and Medicare. Comparisons will be made between SeniorCare members and similar Part D enrollees.

Hypothesis 2: SeniorCare will have a positive effect on the health outcomes of Wisconsin seniors.

Q2-1: How does the quality of medication use (medication safety, adherence and appropriate use) in SeniorCare compare to older adults enrolled in Medicare Part D?

- Descriptive statistics and regression analysis using enrollment and claims data from SeniorCare and Medicare. Various quality measures endorsed by CMS and the PQA will be applied for analyses of drug utilization of certain drug therapeutic classes and chronic conditions. Comparisons will be made between SeniorCare members and similar Part D enrollees.

Q2-2: How does the health status of SeniorCare members compare to older adults enrolled in Medicare Part D?

- Descriptive statistics and regression analysis using enrollment and claims data from SeniorCare and Medicare. Comparisons will be made between SeniorCare members and similar Part D enrollees.

Q2-3: How do annual trends in health care services utilization and expenditures in the SeniorCare population compare to older adults enrolled in Medicare Part D?

- Descriptive statistics and regression analysis using enrollment and claims data from SeniorCare and Medicare. Comparisons will be made between SeniorCare members and similar Part D enrollees.

Q2-4: What are annual trends in Comprehensive Medication Review and Assessment (CMR/A) utilization and expenditures in SeniorCare?

- Descriptive statistics and statistical tests using enrollment and claims data from SeniorCare.

Q2-5: Are there changes in adherence to recommended vaccine schedules among SeniorCare members after the initiation of SeniorCare vaccination coverage?

- Descriptive statistics and statistical tests using enrollment and claims data from SeniorCare and Wisconsin Immunization Registry (WIR) data.

Hypothesis 3: SeniorCare will reduce the likelihood of Medicaid entry and provide cost savings to the Wisconsin Medicaid program.

Q3-1: How does SeniorCare enrollment impact an individual's likelihood of Medicaid entry?

- Descriptive statistics and regression analysis, using enrollment and claims data from SeniorCare, Medicare, and Medicaid

Q3-2: How does SeniorCare enrollment impact an individual's use of Medicaid-funded nursing home care?

- Descriptive statistics and time-to-event models using SeniorCare enrollment data and Medicaid enrollment and nursing home claims

Q3-3: What would Medicaid expenditures be in the absence of the SeniorCare program?

- Cost modeling using a generalized linear model (GLM), using SeniorCare enrollment and claims, Medicare enrollment and claims, and Medicaid claims data

II. DEMONSTRATION WAIVER AND EVALUATION BACKGROUND

The UW Institute for Research on Poverty (IRP) is conducting an evaluation of the Wisconsin SeniorCare Pharmaceutical Benefit for Low-Income Seniors, as proposed by the Wisconsin Department of Health Services (DHS) and approved by the federal Centers for Medicare and Medicaid Services (CMS).

A. Waiver Overview and Target Populations

The Wisconsin Department of Health Services has received a CMS-approved Section 1115 demonstration waiver to continue its longstanding SeniorCare Prescription Drug Assistance Program. The newly approved waiver authorizes an additional ten-year period for the program, from January 1, 2019, to December 31, 2028. The demonstration-eligible population includes individuals age 65 or over with income at or below 200% of the federal poverty level (FPL), who are otherwise not receiving full Medicaid benefits.

A1. Background

On July 1, 2002, the Department received the necessary waiver approvals from CMS to operate a portion of SeniorCare, a prescription drug benefit for seniors, as a five-year demonstration project. The SeniorCare waiver extends Medicaid eligibility through Title XIX to cover prescription drugs as a necessary primary health care benefit. The target population for services under the SeniorCare waiver program is seniors who are age 65 or older with income at or below 200% FPL.

Under the terms of the waiver, SeniorCare has complied with federal and state laws and regulations (except those for which a specific waiver is requested) for Medicaid eligibility, benefits, and administration, including application processing, claims processing, federal reporting, and safeguards for fraud and abuse.

As of 2019, Wisconsin has a CMS-approved 10-year section 1115 waiver to continue operating the SeniorCare program, and to receive Medicaid federal matching funds for individuals who qualify for SeniorCare. Wisconsin will continue to provide the SeniorCare prescription drug benefit to low-income seniors.

Under the continuation waiver, Wisconsin residents who are ages 65 or older, not currently eligible for Medicaid benefits, and whose income does not exceed 200% FPL are eligible for coverage of legend drugs and over-the-counter insulin as currently provided under the Wisconsin Medicaid State plan. Those seniors with prescription drug coverage under other plans are also eligible to enroll, with SeniorCare covering eligible costs not covered under other plans. There is no asset test.

Members pay an annual $30 enrollment fee. Individuals with income at or below 160% FPL are responsible for a copayment of $15 for each brand name prescription and $5 for each generic prescription. Individuals with an income above 160% and less than 200% FPL are also responsible for the first $500 of prescription drug costs each year at the SeniorCare rate.

Members may begin participation in the program on the first day of the month following the month in which all eligibility criteria are met. Once determined eligible for the SeniorCare program, an individual may remain eligible for 12 months from the date of initial enrollment, regardless of changes in income.

SeniorCare, similar to Medicaid, must coordinate eligibility across programs and coordinate with benefits covered by other insurers.

A2. SeniorCare Objectives

The CMS-approved 2019 waiver identifies the program provisions, objectives, and Special Terms and Conditions, included here in Attachment A.

The demonstration waiver 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.

A3. Eligibility Requirements

To be eligible for prescription drug services under the SeniorCare waiver program, individuals must meet all of the following requirements:

1. Wisconsin resident;
2. U.S. citizen or have qualifying immigrant status;
3. Not Medicaid enrolled other than as a low-income Medicare beneficiary (QMB, SLMB, QI-1 or QDWI);
4. Age 65 or older;
5. Household income at or below 200% FPL; and
6. Payment of the applicable annual enrollment fee of $30 per person.

Individuals with a household income above 200% FPL receive program benefits after they have met

program requirements for deductible and spenddown, if required. Income is calculated as follows:

- A gross income test is used, except in cases of self-employment income. The standard Elderly, Blind or Disabled (EBD) Medicaid deductions and other deductions are not applied.
- In cases of self-employment income, current policy for Medicaid EBD is followed. Therefore, deductions for business expenses, losses and depreciation are permitted for individuals with self-employment income.
- Income is determined on a prospective basis, annually.
- A fiscal test group that is consistent with current Medicaid EBD policy is used. Thus, individual income is used for a married person not living with his or her spouse, and joint income is used for a married person living with his or her spouse. These income amounts are compared to the FPL for a group size of one if counting only the income of the individual, or for a group size of two if counting the income of the applicant and his or her spouse.
- There is no asset test related to eligibility for the SeniorCare waiver program.

A4. Application Process for SeniorCare Benefits

The application process for eligible seniors involves the following components:

- The senior completes the simple, short application.
- The senior submits the application by regular mail.
- The application is processed by a central unit administered by the Department.
- Near the end of the individual's year of eligibility, the Department notifies him or her of the need for an annual re-determination of his or her eligibility. The Department provides the individual with a pre-printed renewal form containing some of the information provided in the previous year. To continue coverage, the form must be filed in a timely manner and receive approval. The individual must also pay the annual enrollment fee.
- Upon enrollment, the SeniorCare waiver program member receives an identification card distinct from the current ForwardHealth card. Members must present the identification card to the pharmacy or pharmacist when purchasing prescription drugs.

A5. Enrollment Periods

Enrollment periods for eligible members are as follows:

- Once determined eligible for the SeniorCare waiver program, an individual may remain eligible for 12 months from the date of initial enrollment, regardless of changes in income. However, if a person permanently leaves Wisconsin or becomes deceased, he or she is no longer eligible for the SeniorCare waiver program.
- Members may reapply if their income decreases. For example, if an individual with income at or above 165% FPL subsequently loses a part-time job resulting in income below 160% FPL, the individual may reapply. In this situation, the individual would no longer be required to pay the first $500 in prescription drug costs but would need to pay a new $30 enrollment fee to establish a

new 12-month benefit period.

- An individual is able to begin participation in the program on the first day of the month following the month in which all eligibility criteria are met.
- Eligibility for benefits is prospective only. There is no retroactive eligibility.

A6. Coordination of Benefits

The SeniorCare waiver program extends coverage only to legend (prescription) drugs and to over-the-counter insulin; these are drugs that are currently covered by the Wisconsin Medicaid State plan. SeniorCare is the payer of last resort for covered services; coordination of benefits is applied in a manner similar to the Medicaid program. The SeniorCare waiver program uses a combination of automated, pre-payment cost avoidance within the point of service (POS) system and, where necessary, will bill liable third parties after the payment is made.

If a person is eligible to receive medication therapy management (MTM) services through commercial insurance and/or Medicare, the pharmacist is required to submit the MTM claims to other payers.

A7. Cost Sharing

SeniorCare members are required to comply with cost-sharing provisions that vary by income level. The following describes the cost-sharing features in more detail.

Annual Enrollment Fee

All SeniorCare members are required to pay an annual enrollment fee of $30. Once determined eligible for SeniorCare, an applicant will receive a letter notifying him or her of the eligibility and cost-sharing requirements. All applicants have the option to decline participation if they notify the Department within the 30-day processing period or within 10 days of the date on the letter, whichever is later. If an individual declines participation within this time period, the Department will refund the enrollment fee paid for that benefit period. If an individual has paid the annual enrollment fee with his or her application and is determined ineligible for the program, the Department will refund the paid enrollment fee.

Annual Costs for Members

- SeniorCare members with income between 160% and 200% FPL are responsible for the first $500 of prescription drug costs per year. The first $500 will be paid by the member at the SeniorCare rate.
- If SeniorCare members chooses to receive MTM services and their income is between 160% and 200% FPL, they are responsible for paying Medicaid rates for the MTM services while in the $500 deductible period. Member payments toward MTM services will count toward the member's deductible.
- SeniorCare members with income at or below 160% FPL are not required to pay a $500 deductible for prescription drug costs or MTM services.

Co-Payments

For SeniorCare members with income above 160% FPL who have met the $500 annual deductible, and for members with income at or below 160% FPL, a copayment is-required for each prescription drug for the remainder of that 12-month period. The following copayments apply:

- $15 copayment per prescription for brand name drugs.
- $5 copayment per prescription for generic drugs.

There is no copayment for MTM services.

A8. Coordination with Other Medicaid Programs

The following are stipulations regarding coordination between the Medicaid program and the SeniorCare waiver program:

- SeniorCare members whose income decreases to allowable Medicaid eligibility levels and who want to receive full Medicaid benefits must apply for and be determined eligible for full-benefit Medicaid through the normal Medicaid application process.
- Except during the 30-day initial processing period, the enrollment fee is not refundable to SeniorCare members who, during their 12-month benefit period, become eligible for full Medicaid benefits. However, SeniorCare will remain open to these individuals. Thus, if they subsequently become ineligible for full Medicaid benefits during the 12 months, they will automatically be able to receive SeniorCare benefits for the remainder of the 12-month period without having to pay another $30 fee.
- SeniorCare members who are terminated from the SeniorCare program or who fail to re-enroll will not be reviewed for eligibility for other Medicaid programs prior to termination.

A9. Benefits

Pharmaceuticals

Wisconsin Medicaid covers legend drugs and over-the-counter insulin prescribed by a licensed physician, dentist, podiatrist, nurse prescriber, or ophthalmologist as currently provided under the Wisconsin Medicaid State plan. In addition, physicians may delegate prescription authority to a nurse practitioner or physician assistant.

Wisconsin Medicaid has an open drug formulary. This means that legend drugs or over-the-counter insulin are covered if they meet all of the following criteria:

- The drug is Food and Drug Administration (FDA)-approved;
- The manufacturer signed a rebate agreement with CMS; and
- The manufacturer has reported data and prices to First DataBank (a national drug database).

SeniorCare statutes define prescription drugs as prescription drugs covered by Wisconsin Medicaid and for which the drug manufacturers enter into a rebate agreement with the state. However, like Wisconsin Medicaid, SeniorCare extends coverage to over-the-counter insulin.

Medication Therapy Management (MTM)

The Medication Therapy Management (MTM) benefit consists of private consultations between a pharmacist and a member to review the member's drug regimen, as currently provided under the Wisconsin Medicaid State plan.

Comprehensive Medication Review and Assessment (CMR/A) allow specially trained pharmacists to review a member’s drug regimen. Members who are at a high risk of experiencing medical complications due to their drug regimen are eligible for this service. During the CMR/A, the pharmacist may:

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

There is a limit of one initial and three follow-up CMR/As per year. Pharmacists may request an exemption from these limits.

Vaccinations

Beginning in 2021, SeniorCare will cover all vaccinations recommended for older adults by the federal Centers for Disease Control and Prevention. This coverage is authorized by 2019 Wisconsin Act 185, enacted on April 16, 2020.[1] DHS will provide payments to pharmacies that administer the vaccinations and submit claims for payment in the manner required. Additionally, DHS may provide payment for a vaccination only after deducting the amount of any payment for the vaccination available from other sources.

B. Evaluation Team Background and Qualifications

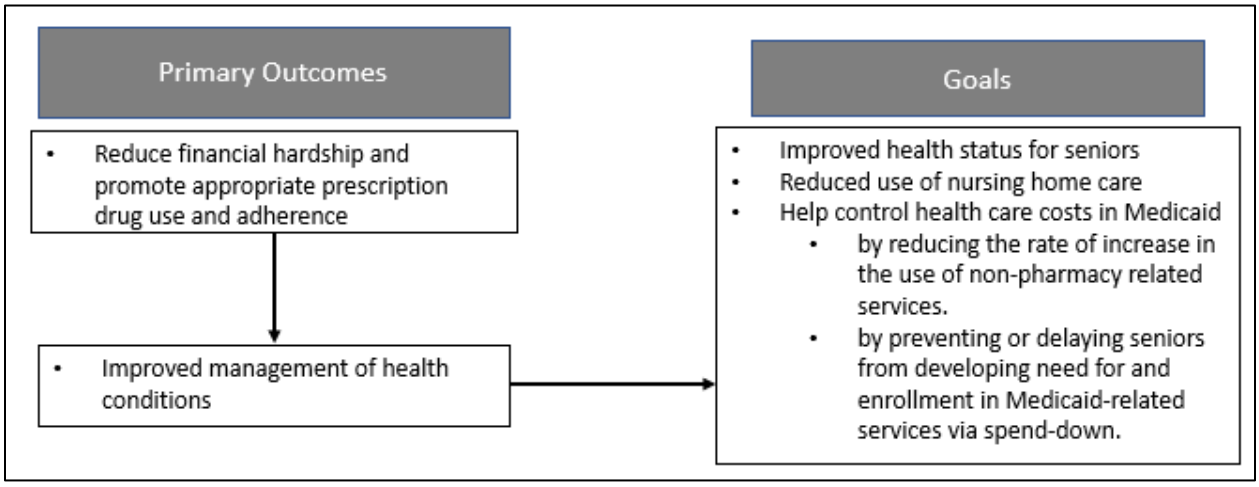
Our team has conducted and published studies on a broad range of prescription-drug and Medicaid-related evaluation and research topics. Sponsors of this team's work include the state and federal governments, foundations, and private sector concerns. We conducted the evaluation of Wisconsin's SeniorCare prescription drug program under the 2016-18 demonstration waiver project period, and we have contributed to the CMS-required evaluation of Wisconsin's BadgerCare § 1115 waiver during the 2014-2018 project period. The team is based at the UW-Madison, with collaborating faculty investigators at the UW School of Pharmacy and at the Medical College of Wisconsin, supported by research and data programming staff based at the UW Institute for Research on Poverty.

[1] For background, see: https://docs.legis.wisconsin.gov/misc/lc/information_memos/2020/im_2020_05

III. EVALUATION QUESTIONS AND HYPOTHESES

A. Driver Diagram

Figure III.A.1. Driver Diagram for SeniorCare Pharmaceutical Benefit



B. Waiver Goals: Relationship to Hypotheses and Questions

CMS, within the waiver approval Special Terms and Conditions document, has identified the following goals for the SeniorCare demonstration waiver:

- Keep Wisconsin seniors healthy by continuing to provide a necessary primary health care benefit;
- Reduce the rate of increase in the use of non-pharmacy related services provide to this population, including hospital, nursing facility and other non-pharmacy related medical services; and
- Help 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.

The hypotheses and research questions articulated here grow directly from these goals and drive the evaluation plan:

Hypothesis 1: SeniorCare will have a positive effect on member medication use and financial hardship.

Q1-1: How does the SeniorCare population compare to older adults enrolled in Medicare Part D?

Q1-2: How do annual trends in drug utilization and expenditures in SeniorCare compare to older adults enrolled in Medicare Part D?

Q1-3: How does the prevalence of financial hardship among SeniorCare members compare to similar populations of older adults?

Hypothesis 2: SeniorCare will have a positive effect on the health outcomes of Wisconsin seniors.

Q2-1: How does the quality of medication use (medication safety, adherence and appropriate use) in SeniorCare compare to older adults enrolled in Medicare Part D?
Q2-2: How does the health status of SeniorCare members compare to older adults enrolled in Medicare Part D?
Q2-3: How do annual trends in health care services utilization and expenditures in the SeniorCare population compare to older adults enrolled in Medicare Part D?
Q2-4: What are annual trends in Comprehensive Medication Review and Assessment (CMR/A) utilization and expenditures in SeniorCare?
Q2-5: Are there changes in adherence with recommended vaccine schedules among SeniorCare members after the initiation of SeniorCare vaccination coverage?

Hypothesis 3: SeniorCare will reduce the likelihood of Medicaid entry and provide cost savings to the Wisconsin Medicaid program.

Q3-1: How does SeniorCare enrollment impact an individual's likelihood of Medicaid entry?
Q3-2: How does SeniorCare enrollment impact an individual's use of Medicaid-funded nursing home care?
Q3-3: What would Medicaid expenditures be in the absence of the SeniorCare program?

IV. METHODOLOGY

A. Evaluation Design Summary

The best available data will be used to evaluate the demonstration project using the prevailing standards of scientific and academic rigor. Each of the hypotheses depend on different data sources and require different analytic methods, which will be used to provide a comprehensive assessment of the evaluation questions. The evaluation design includes the analysis of existing secondary data (e.g., enrollment and claims data). Given the longitudinal nature of the SeniorCare program, multiple cross-sectional and longitudinal analyses will be conducted to assess the evaluation measures and changes in these measures over time. Comparable data on appropriate comparison groups composed of similar populations of low-income seniors will be included whenever possible to enhance the rigor of the analyses.

The Design Table (Table IV.A.1.) summarizes the key features of the evaluation design, including the primary research questions for each hypothesis, example outcome measures, target populations, data sources, and analytic methods for each question. The narrative that follows provides more detail about each of these items.

The target population of this evaluation is the entire SeniorCare population covered by the section 1115 waiver. In order to make relevant and meaningful comparisons, the evaluation will focus on key subgroups of SeniorCare members, such as SeniorCare members who are subject to a deductible (160-200% FPL) and those that have a copayment only (<160% FPL). We will also compare study outcomes to Medicare Part D members who do not have SeniorCare or other sources of prescription drug coverage (e.g., Part D only) and if feasible, the subgroup of Part D enrollees that are Low-Income Subsidy recipients. Propensity score matching will be used whenever possible for constructing the most comparable group of Part D enrollees to the SeniorCare population. More details on the study populations are available in section B. Target and Comparison Populations.

Table IV.A.1. Evaluation Design Table

Research Question	Outcome Measures	Population	Data Sources	Analytic Methods
Hypothesis 1: SeniorCare will have a positive effect on member medication use and financial hardship				
Q1-1: How does the SeniorCare population compare to older adults enrolled in Medicare Part D?	-Demographic characteristics (e.g., age, gender, race/ethnicity) -Socioeconomic status (e.g., annual income)	-Entire SeniorCare population -Comparison group of older adults with Part D -Subgroups of interest (e.g., by waiver and cost sharing status)	-SeniorCare enrollment data -Medicare enrollment data	-Descriptive statistics -Comparisons between SeniorCare members and Medicare Part D enrollees (e.g., chi-squared test, student t-test, etc.) -Stratified analyses comparing subgroups
Q1-2: How do annual trends in drug utilization and expenditures in SeniorCare compare to older adults enrolled in Medicare Part D?	-Trends in drug utilization (e.g., number of drug fills, proportion of enrollees with any drug fills, etc.) -Likelihood of having drug claims -Trends in expenditures (e.g., total drug costs, SeniorCare drug costs, member out-of-pocket costs, drug costs by other payers, etc.) -Trends in utilization and expenditures for brand and generic drugs -Trends in utilization and expenditures for specialty and non-specialty drugs -Trends in utilization and expenditures for common therapeutic drug classes	-Entire SeniorCare population -Comparison group of older adults with Part D -Subgroups of interest (e.g., by waiver and cost sharing status)	-SeniorCare enrollment and drug claims data -Medicare enrollment and Part D drug claims data	-Descriptive statistics -Multiple logistic regression -Time-series models -Comparisons between SeniorCare and Medicare Part D enrollees -Stratified analyses comparing subgroups
Q1-3: How does the prevalence of financial hardship among SeniorCare members compare to	-Trends in the prevalence of claims-based measures of financial burden (e.g., total out-of-pocket costs, ratio of out-of-pocket costs to income exceeding 5% or 10%, etc.) -Likelihood of having high financial burden	-Entire SeniorCare population -Comparison group of older adults with Part D -Subgroups of interest (e.g., by waiver and cost sharing status)	-SeniorCare enrollment and claims data -Medicare enrollment and Part D drug claims data	-Descriptive statistics -Multiple logistic regression -Time-series models -Comparisons between SeniorCare and non-SeniorCare enrollees

similar populations of older adults?			-US Census data	-Stratified analyses comparing subgroups

Hypothesis 2: SeniorCare will have a positive effect on the health outcomes of Wisconsin seniors				
Q2-1: How does the quality of medication use (medication safety, adherence and appropriate use) in SeniorCare compare to older adults enrolled in Medicare Part D?	-Adherence to medications for chronic conditions (e.g., Diabetes All Class, Statins, Renin Angiotensin System Antagonists, etc.) -Statin use in persons with diabetes -Use of high-risk medications in the elderly (e.g., opioids, benzodiazepines, polypharmacy, etc.) -Likelihood of having high quality medication use	-Entire SeniorCare population -Comparison group of older adults with Part D -Subgroup of SeniorCare members with select chronic conditions -Subgroups of interest (e.g., by waiver and cost sharing status)	-SeniorCare enrollment and drug claims data -Medicare enrollment, Part D drug claims, and fee-for-service (Parts A and B) health claims data -Pharmacy Quality Alliance (PQA) performance measures and value sets	-Descriptive statistics -Time-series models with control groups -Comparisons between SeniorCare and Medicare Part D enrollees -Stratified analyses comparing subgroups
Q2-2: How does the health status of SeniorCare members compare to older adults enrolled in Medicare Part D?	-Number and type of chronic health conditions -Claim-based measures of health status (e.g., Charlson Comorbidity Index, Elixhauser Index, or Rx-Risk Comorbidity Index) -Likelihood of having poor member health	-Entire SeniorCare population -Comparison group of older adults with Part D -Subgroups of interest (e.g., by waiver and cost sharing status)	-SeniorCare enrollment and drug claims data -Medicare enrollment, Part D drug claims, and fee-for-service (Parts A and B) health claims data -Medicare Chronic Conditions and Other Chronic or Potential Disabling Conditions files	-Descriptive statistics -Multiple logistic regression -Time-series models -Comparisons between SeniorCare and Medicare Part D enrollees -Stratified analyses comparing subgroups
Q2-3: How do annual trends in health care services utilization and expenditures in the SeniorCare population compare to older adults enrolled in Medicare Part D?	-Trends in utilization of health care services (e.g., inpatient, outpatient, emergency department visits, etc.) -Trends in costs for health care services -Cumulative probability of remaining outside the hospital -Likelihood of hospital admission or	-Entire SeniorCare population -Comparison group of older adults with Part D -Subgroups of interest (e.g., by waiver and cost	-SeniorCare enrollment and claims data -Medicare enrollment and fee-for-service (Parts A and B) health claims data	-Descriptive statistics -Multiple logistic regression -Time-series models -Regression models such as Cox proportional hazard or competing risks model

	emergency department use	sharing status)		-Comparisons between SeniorCare and Medicare Part D enrollees -Stratified analyses comparing subgroups
Q2-4: What are annual trends in Comprehensive Medication Review and Assessment (CMR/A) utilization and expenditures in SeniorCare?	-Utilization of CMR/A services (e.g., number of CMR/A claims, members who received CMR/A, etc.) -Expenditures for CMR/A services (e.g., annual total costs for CMR/A, annual SeniorCare and member costs, mean costs per member, etc.)	-Entire SeniorCare population -Subgroups of interest (e.g., by waiver and cost sharing status)	-SeniorCare enrollment, drug claims, and MTM claims data	-Descriptive statistics -Stratified analyses comparing subgroups
Q2-5: Are there changes in adherence with recommended vaccine schedules among SeniorCare members after the initiation of SeniorCare vaccination coverage?	-Utilization of vaccinations (e.g., number of vaccinations, members who had vaccinations, etc.) -Expenditures for vaccinations (e.g., total costs, SeniorCare program costs, and member out-of-pocket costs)	-Entire SeniorCare population -Subgroups of interest (e.g., by waiver and cost sharing status) -Elderly Medicaid beneficiaries	-SeniorCare enrollment and vaccination claims data -Medicaid EBD enrollment and vaccination claims data -Wisconsin Immunization Registry (WIR) data	-Descriptive statistics -Pre-post comparison after implementation of vaccination coverage -Comparisons between SeniorCare and elderly Medicaid beneficiaries -Stratified analyses comparing subgroups

Hypothesis 3: SeniorCare will reduce the likelihood of Medicaid entry and provide cost savings to the Wisconsin Medicaid program.				
Q3-1: How does SeniorCare enrollment impact an individual's likelihood of Medicaid entry?	-Cumulative rate of Medicaid entry	-Entire SeniorCare population -Comparison group of older adults with Part D -Subgroup of SeniorCare members with Part D	-SeniorCare enrollment data -Medicaid enrollment data -Medicare enrollment data	-Descriptive statistics -Regression models such as Cox proportional hazard or competing risks model-Comparisons between SeniorCare and Medicare Part D enrollees
Q3-2: How does SeniorCare enrollment impact an individual's use of Medicaid-funded	-Utilization of nursing home care -Costs for nursing home care	-SeniorCare members who used nursing home care -Medicare Part D	-SeniorCare enrollment data -Medicaid EBD enrollment and nursing home claims data -Medicare enrollment data	-Descriptive statistics -Comparisons between SeniorCare and non-SeniorCare enrollees -Multiple logistic regression

nursing home care?	-Cumulative probability of remaining outside a nursing home[2] -Likelihood of transitioning to a nursing home	beneficiaries who used nursing home care		-Time-to-event models (discrete time hazard models using a logistic regression and/or a Cox proportional hazard model)
Q3-3: What would Medicaid expenditures be in the absence of the SeniorCare program?	-Estimated Medicaid costs for SeniorCare members	-Entire SeniorCare population	-SeniorCare enrollment and drug claims data -Medicare enrollment, Part D drug claims, and fee-for-service (Parts A and B) health claims data -Medicaid claims data	-Cost modeling using a GLM with appropriate link and family selected using a modified Park test -Predicted spending adjusted using marginal standardization

[2] Soumerai SB, Ross-Degnan D, Avorn J, McLaughlin TJ, Choodnovskiy I. 1991. Effects of Medicaid drug-payment limits on admission to hospitals and nursing homes. New England Journal of Medicine 325(15):1072-1077. https://www.nejm.org/doi/full/10.1056/NEJM199110103251505

B. Target and Comparison Populations

Analyses will be conducted from a variety of perspectives to provide a comprehensive understanding of the impact of the SeniorCare program. The target population consists of all members enrolled in the SeniorCare waiver program during the evaluation period. Program-level analyses of the entire SeniorCare population will be conducted to understand broad characteristics of the program and how it interacts with other public insurance programs (i.e., Medicare and Medicaid). Additional member-level analyses will be conducted to provide a more detailed understanding of these outcomes, as well as the impact of the SeniorCare program on member medication use, expenses, and health outcomes.

The program-level analyses will primarily include all SeniorCare members enrolled in the waiver program during the evaluation period. Certain longitudinal member-level analyses will focus on the continuously enrolled population, as the most complete information is available for these members. Subgroups of interest for stratified analyses include SeniorCare members with varying cost sharing arrangements (i.e., <160% FPL and 160-200% FPL subgroups), supplemental drug coverage (e.g., both SeniorCare and Part D), rural and urban populations, members with chronic conditions, and members receiving MTM services. Annual or monthly measures will be used whenever possible for the evaluation measures; if there is insufficient sample size for the subgroups, pooled analyses over larger time periods will be used to ensure statistically reliable sample sizes are available.

Multiple comparison groups consisting of similar populations of low-income older adults will be used whenever possible to enhance the rigor of the analyses and better identify the impact of the SeniorCare program. The selection of an appropriate comparison group will vary for each evaluation measure, and the decision will be based on the comparability, feasibility, and availability of data for the various groups.

The feasibility of using the Medicare low-income subsidy (LIS) population as a comparison group will be checked in two aspects. First, we will examine the adequacy of the sample size of LIS recipients, as the income and resource eligibility criteria for LIS is more restrictive than for SeniorCare waiver enrollment. Potential comparison groups of LIS recipients include Qualified Medicare Beneficiaries (QMBs) and Specified Low-Income Medicare Beneficiaries (SLMBs) that are not receiving full Medicaid benefits, as well as Part D LIS applicants. Although these groups are most similar to the SeniorCare population based on income, individuals in the QMB and SLMB populations have income levels lower than SeniorCare waiver enrollees on average (QMB: ≤100% FPL, SLMB: 100-120% FPL) and limited assets. However, according to CMS data, there would be no more than 20,000 non-disabled QMBs, SLMBs, and LIS applicants in stand-alone PDPs in Wisconsin, which would likely result in insufficient sample size for use as a comparison group.[3]

Second, we will consider the different levels of premium subsidy and copayment reductions among LIS recipients and check the feasibility of making comparisons with the SeniorCare waiver population. The level of LIS support is determined based on the recipient's income and available financial resources. The variability in subsidy amounts among LIS recipients may make the sample size even smaller or confound our ability to make comparisons with SeniorCare enrollees. We will check the common level of subsidy that LIS recipients in our sample receive and consider them when constructing comparison groups.

[3] CMS.gov. Total Medicare Enrollment. https://www.cms.gov/research-statistics-data-systems/cms-program-statistics/2019-medicare-enrollment-section

Apart from the potential use of the Medicare LIS group, our primary comparison group will be non-disabled Wisconsin Medicare beneficiaries enrolled in a Medicare Part D stand-alone prescription drug plan (PDP), who are not receiving the low-income subsidy (LIS) and were not enrolled in SeniorCare at any point during the evaluation period. This population was selected because Wisconsin Part D plans are the most logical alternative source of prescription drug insurance coverage for SeniorCare members. Stand-alone PDPs have similar structure to SeniorCare (i.e., state -wide coverage with an open pharmacy network). Beneficiaries enrolled in Medicare Advantage prescription drug plans (MA-PDs) will be excluded due to structural differences in these plans (i.e., regional plans with restricted pharmacy networks) and limited data availability. Propensity score matching will be used to identify Medicare beneficiaries that are as similar to SeniorCare members as possible, and to ensure the distribution of observed covariates will be the same between the SeniorCare and Part D populations. More details on our approach to propensity score matching are available in Section D.

Our secondary comparison group will be the non-waiver SeniorCare population with income >200% FPL that are not dually enrolled in Part D. This group was selected because they are the only population for whom we will have identical data availability as for the waiver population. As described in Section C, data availability between the Medicare and SeniorCare populations; therefore, we will use Part D beneficiaries as a comparison group for all available years of data, and the non-waiver SeniorCare population as a comparison group only for years in which Medicare data are unavailable. It should also be noted that these analyses will only incorporate outcomes related to prescription drug use within the SeniorCare program, as the Medicare data are the only source of health care utilization.

Evaluation Period

Data from January 1, 2016 to December 31, 2023 will be used to address the evaluation measures. This period includes 3 years prior to and the first half of the approved waiver period (calendar years 2019-2023). The time period will vary for each evaluation measure and upon data availability from vendors. Data from the Wisconsin Department of Health Services on the SeniorCare and Medicaid populations are typically available on a regular and timely basis; in contrast, external data sources (i.e., Medicare data) typically have a lag of 14 months for data collection, cleaning, and imputation of missing data. Therefore, some analyses may consist of a cross-section in time, several years of data, or the entire evaluation period.

C. Data Sources and Outcome Measures

Table IV.A.1, above, displays the outcome measures for each question. This evaluation will involve multiple data sources, including state and national administrative data. They are noted in Table IV.C.1, along with the hypotheses for which these data will be used. Whenever possible, validated or commonly used measures will be utilized to allow for comparisons between the SeniorCare population and other older adult populations in the literature. The following narrative provides more information on each of the data sources that will be used to conduct the evaluation.

The evaluation plan was designed to incorporate multiple data sources that allow us to begin addressing the evaluation hypotheses and research questions for the SeniorCare program in year 01. We have incorporated limited historical data (calendar years 2016-2018) to help address lags in data availability for our Medicare Part D comparison group. This will also allow for longitudinal analyses of the outcomes to see whether our findings reflect the pre-waiver period trend or the changes associated with the current waiver period. This trend analysis is particularly important given the potential for the COVID-19 pandemic to have incurred major changes to beneficiary health status and health care utilization. In addition, historical data will allow us to incorporate characteristics of beneficiary demographics and medication use into our analyses.

Table IV.C.1. Data Sources and Associated Hypotheses

Data Sources	Hypotheses
SeniorCare Data	H1, H2, H3
Medicaid Data	H3
Medicare Data	H1, H2, H3
Wisconsin Immunization Registration Data	H2

SeniorCare Data: SeniorCare administrative, enrollment, and claims data over the entire waiver period will be used to obtain information on program enrollment, prescription drug utilization, and expenditures. These data will be used to obtain information on the target population (SeniorCare waiver members) as well as the SeniorCare non-waiver comparison group. The enrollment data reside in the Wisconsin CARES system, a state -operated data warehouse that includes all eligibility-related information pertaining to members of Medicaid and SeniorCare. Claims data reside in the state ’s Medicaid Management Information System (MMIS). These data are available with a lag period of approximately three months, and provide detailed and complete information on all drug claims paid by the SeniorCare program. The evaluation will incorporate SeniorCare data for the entire waiver period (2019-2028) and for a limited historical period prior to the waiver period (2016-2018).

Although these data provide limited information on paid amounts from other payers, they do not provide detailed information on the identities of other payer(s) or drugs obtained from sources other than the SeniorCare benefit (e.g., through other insurance or obtaining a drug without using insurance). These data also do not provide information on what happens to disenrolled members after they leave SeniorCare. In addition, because the SeniorCare benefit only provides prescription drug insurance to members, there is no information on health care utilization.

Medicaid Data: Medicaid administrative, enrollment, claims, and encounter data over the entire waiver period will be used to obtain data for the older adult Medicaid EBD population (i.e., elderly beneficiaries with full-benefit Medicaid). Wisconsin CARES is the state 's online eligibility and enrollment portal for public benefits, including Medicaid, TANF, and FoodShare (SNAP). We will use data from CARES to obtain longitudinal administrative data pertaining to enrollment. Demographic information includes age, sex, educational attainment, county of residence, income, and income sources. Wisconsin Medicaid claims and encounter data come from the State 's MMIS claims database. These data contain detailed information on diagnoses, procedure, and billing codes from which we will construct outcome measures of health care use, as well as paid amounts for covered services. These data are available with a lag period of approximately three months.

The Medicaid data will be used to assess the use of nursing home and long-term care services by those enrolled in SeniorCare, and to identify individuals that transitioned between SeniorCare and Medicaid (Hypothesis 3). These data provide detailed and complete information on all claims paid by the Medicaid program, which is the primary payer of nursing home care in the US.[4] If feasible, these data will be used to construct a comparison group of elderly Medicaid beneficiaries to examine the impact of implementing coverage for vaccinations (Question 2-5). However, these data do not provide detailed information from other payer(s), which is particularly relevant for dual-eligibles covered by both Medicare and Medicaid.

Medicare Data: Medicare administrative, enrollment, and claims data will be obtained for Medicare Parts A, B, and D. These data be used to construct our primary comparison group of individuals enrolled in Medicare Part D for prescription drug insurance coverage. Medicare data will be obtained for a 100% sample of Wisconsin Medicare beneficiaries in addition to a 5% national sample of Medicare beneficiaries over a 6-year period. Medicare is the primary provider of health insurance coverage for SeniorCare members; therefore, these data will be used to obtain information on the use of inpatient and outpatient health services covered by traditional fee-for-service Medicare (Parts A and B). Medicare Part D data will be used to supplement the SeniorCare claims and obtain more detailed information on drug use for SeniorCare members enrolled in both programs.

The Medicare data will be used to construct appropriate comparison groups to the SeniorCare waiver population of older adults who have Medicare Part D as their primary source of prescription drug insurance coverage as outlined in Section B: Target and Comparison Populations. The Medicare data will be obtained from the CMS Chronic Conditions Data Warehouse (CCW), which provides researchers with Medicare and Medicaid beneficiary, claims, and assessment data linked by beneficiary across the continuum of care. The CCW is a research database designed to make Medicare, Medicaid, and Part D Prescription Drug Event data more readily available to support research designed to improve the quality of care and reduce costs and utilization. Medicare data are purchased from the data vendor (ResDAC) following CMS review and approval. These data are available with an approximately 14-month time lag,

[4] Kaiser Family Foundation. 2017. "Medicaid's Role in Nursing Home Care." Kaiser Family Foundation Infographic. Issued June 20, 2017. www.kff.org/infographic/medicaids-role-in-nursing-home-care/

plus any additional time for review and approval of the request. There is additional lag time due to the time needed for the UW IRP to obtain the data from ResDAC and for the evaluation team to clean and analyze the data. In total, there is an approximately two calendar year lag in Medicare data availability. Thus, although the waiver period ends in calendar year 2028, Medicare data will only be available for inclusion through calendar year 2026 due to this lag. We will also use limited historical data (calendar years 2016-2018) to help address this lag in data availability, which will also allow us to incorporate characteristics of pre-waiver beneficiary demographics and medication use into our analyses.

The Medicare data provide detailed and complete information on all claims paid by the Medicare program, which is the primary source of health insurance coverage for older adults in the US. These data can also be linked to state Medicaid data to allow for tracking of these individuals across multiple programs (i.e., SeniorCare, Medicaid, and Medicare). However, these data are only available for individuals enrolled in traditional fee-for-service Medicare (Parts A, B, and D) and are not available for individuals enrolled in Medicare Advantage managed care plans (Part C). Thus, complete information may not be available for all SeniorCare members. In 2018, around 34% of total Medicare beneficiaries were enrolled in Part C.[5]

Wisconsin Immunization Registry Data[6]: The Wisconsin Immunization Registry (WIR) is a computerized internet database maintained by the Wisconsin DHS to record and track immunization records for Wisconsin residents. It allows health care providers to record and track patients' vaccine records and make sure they receive vaccines on time according to recommended schedules. Patients also can look up their own or their children's immunization records.

Although it is not mandatory for all health care providers that administer vaccines to use the WIR, approximately 3,700 providers and 2,400 schools and school districts across Wisconsin have implemented the WIR.[7] In addition, pharmacists are required under Wisconsin statutes to report immunizations in WIR for immunizations administered to individuals aged 6-18 years within 7 days of administration. As one of the initiatives to encourage adoption and meaningful use of electronic health records, CMS has established an incentive program for health care providers and hospitals to connect their electronic health records with immunization information systems such as the WIR.[8] According to a study comparing medical records with WIR records among children born in 2009, the WIR record showed good completeness and accuracy; 97% of the vaccinations were documented in the WIR, 99% had the same administration date, and 96% had the same trade name.[9]

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[5] Kaiser Family Foundation. An Overview of Medicare. Issued Feb 13, 2019 https://www.kff.org/medicare/issue-brief/an-overview-of-medicare/

[6] See https://www.dhs.wisconsin.gov/immunization/wir-healthcare-providers.htm

[7] See https://www.dhs.wisconsin.gov/publications/p02451.pdf

[8] Engstrom, et al. Timeliness of data entry in Wisconsin Immunization Registry by Wisconsin pharmacies. J Am Pharm Assoc (2003) . Jul-Aug 2020;60(4):618-623. https://pubmed.ncbi.nlm.nih.gov/31953117/

[9] Ruth et al. Completeness and Accuracy of the Wisconsin Immunization Registry: An Evaluation Coinciding With the Beginning of Meaningful Use. J Public Health Manag Pract. May-Jun 2015;21(3):273-81. https://www.medicine.wisc.edu/sites/default/files/completeness_and_accuracy_of_wisconsin_conway.pdf

The WIR receives demographic information and vaccination records from multiple sources: Wisconsin Divisions of Public Health Vital Records Office, manual data entry into the WIR database, electronic health records, and billing systems. WIR may also receive immunization record from patients even when their providers did not submit data to the WIR.[8]

As multiple options are available to SeniorCare members for vaccination coverage (e.g., Medicare Part B, C, or D), SeniorCare data will not provide complete information on all vaccinations administered to members. The WIR data can provide dates and names of vaccinations administered to Wisconsin residents, regardless of the types of providers or insurance coverage. It can also provide the immunization data in near real-time with a relatively short time lag (e.g., around 7 days). However, the WIR data does not have payer information, such as source of coverage, covered amount, and copay amount.

D. Analytic Methods

An overview of the primary analytic methods for each hypothesis and research question are included in the Design Table IV.A.1, along with example outcome measures, target and comparison populations, and data sources. The following section provides a more detailed overview for each individual hypothesis and research question.

The evaluation of the demonstration waiver will involve a variety of analytic approaches. Descriptive analyses will be used for all analyses to provide cross-sectional snapshots and longitudinal trends in the outcomes for the SeniorCare population. Whenever possible, one or more comparison groups will be used to allow for more rigorous analytic techniques, and multivariate analyses will be used to control for potential confounders. Sensitivity analyses will be performed for all analyses to assess the responsiveness of the results to changes in the assumptions used in the primary analyses.

As described below, several analyses will incorporate propensity-score matched comparison groups to optimize the similarity of the treatment and comparison groups, and to allow for comparisons between the SeniorCare waiver population and a comparable population of Medicare Part D enrollees. While the Medicare data are quite informative, they do not provide beneficiary income, which is the primary determinant of eligibility for the SeniorCare program. Therefore, we will use propensity scores to reweight the comparison group to achieve balance on key beneficiary characteristics such as beneficiary demographics (age, gender and race), comorbidity burden, and drug spending in the prior 12 months. Using the output of the propensity score model, we will create standardized inverse treatment probability weights (IPTW) to compare between groups. We will stabilize the propensity score weights by multiplying the IPTW weights by the marginal prevalence of the being in the SeniorCare population, providing an estimate of the effect of being in SeniorCare. An alternative approach will consider generating the propensity scores by zip code and comparing SeniorCare members and Part D beneficiaries within each zip code if feasible.

Hypothesis 1: SeniorCare will have a positive effect on member medication use and financial hardship

Q1-1: How does the SeniorCare population compare to older adults enrolled in Medicare Part D?

Medicare Part D was implemented on January 1, 2006 as a voluntary prescription drug insurance benefit for older adults in the Medicare program. SeniorCare is considered creditable coverage, which means it is considered to be as good as the standard Medicare Part D plan. However, older adults in Wisconsin have the opportunity to enroll in one or both programs given their individual needs and preferences. Given the possibility of self-selection into these programs, it is important to understand the different populations covered by the two programs and how they compare in terms of demographic and socioeconomic characteristics. In addition, previous evaluations of the SeniorCare program have found increasing use of SeniorCare as supplementary coverage to other sources of drug coverage. Therefore, we will also evaluate the subgroup of SeniorCare members who are also enrolled in Medicare Part D.

Outcomes

We will assess and compare annual trends in program enrollment and beneficiary characteristics for SeniorCare, Medicare Part D, and dually enrolled members. Annual trends in SeniorCare program enrollment and beneficiary socioeconomic and demographic characteristics will be assessed to identify changes in the composition of the SeniorCare program over time.

Data

SeniorCare and Medicare eligibility and enrollment data will be used to obtain information on the demographic and socioeconomic status of enrollees in the two programs.

Statistical Analysis

Descriptive statistics will be used to summarize the characteristics of each study group for various time periods. Comparisons between the various populations (SeniorCare only, Medicare Part D only, SeniorCare + Part D) will be made using appropriate statistical tests such as chi-squared tests, t-tests, ANOVA, and/or ANCOVA. Stratified analyses will compare the waiver and non-waiver populations, as well as the subgroups of waiver enrollees subject to a copayment only (≤160% FPL) and those subject to a deductible (160-200% FPL). We will also identify and compare beneficiary characteristics of the SeniorCare and Medicare Part D populations to identify whether there are systematic differences between the two populations.

Q1-2: How do annual trends in drug utilization and expenditures in SeniorCare compare to older adults enrolled in Medicare Part D?

When Medicare Part D was implemented on January 1, 2006 additional prescription drug coverage options became available to SeniorCare members. SeniorCare is considered creditable coverage, which means it is considered to be as good as the standard Medicare Part D plan. However, it is unknown how the SeniorCare and Medicare Part D programs compare on a variety of domains related to the utilization of and expenditures for prescription drugs. Analyzing and comparing trends in the use of various types of drugs (e.g., brand, generic, specialty, etc.) and the associated expenditures will improve our understanding of how the program has performed over time, and can inform policies and programs promoting cost-effective drug use.

Outcomes

Trends (e.g., annual and monthly) in drug utilization will be evaluated, including outcomes such as total drug fills, mean drug fills, and 30-day adjusted drug fills to account for differences in drug supply (e.g., 90-day fills). Additional outcomes to be assessed include the ratio of enrollees to drug claims, the proportion of enrollees with at least one drug fill, and the likelihood of having drug claims. Drug expenditures will be determined using total annual drug costs, mean annual drug costs, and mean drug costs per claim.

Drug expenditures will be evaluated from multiple perspectives, including total expenditures from all sources of payment, SeniorCare program expenditures, and member out-of-pocket costs. Drug utilization and expenditures will also be assessed in detail for a variety of important drug types, including brand name vs. generic drugs, specialty vs. non-specialty drugs, and drugs from common therapeutic categories. Specialty drug classification will be determined using the Wisconsin Medicaid specialty pharmacy drug classification, and a sensitivity analysis will be conducted using the Medicare Part D classification for specialty drugs.

Data

We will use enrollment and drug claims data for SeniorCare and Medicare Part D to measure and assess the outcomes. These data contain detailed information on all drugs obtained by enrollees, including drug name, type (e.g., brand vs generic), therapeutic class, and source of payment. Medicare fee-for-service health claims (i.e., Parts A and B) will be used to identify health status characteristics of SeniorCare and Medicare beneficiaries.

Statistical Analysis

Descriptive statistics will be used to identify trends in the outcomes and comparisons will be made between the SeniorCare and Medicare Part D programs. We will include both graphical analyses and tabulations. Multiple logistic regression will be used to identify factors associated with outcomes of interest. Time-series models will be used to longitudinally assess and compare drug utilization and expenditures between the two programs over time. These models will control for important beneficiary characteristics, as well as seasonal variations in the outcomes and autocorrelation. Propensity score matching may be used to select the most comparable subgroup of Part D enrollees to the SeniorCare population. Stratified analyses will compare the waiver and non-waiver populations, as well as the subgroups of waiver enrollees subject to a copayment only (≤160% FPL) and those subject to a deductible (160-200% FPL).

Q1-3: How does the prevalence of financial hardship among SeniorCare members compare to similar populations of older adults?

SeniorCare was implemented on September 1, 2002 as an affordable prescription drug insurance benefit with predictable cost sharing. This is proposed to reduce the out-of-pocket costs and financial hardship as low-income older adults manage their medications. Evaluation of this component is particularly relevant given that similar populations of older adults in the Medicare Part D program experience significant levels of financial burden due to the high levels of variability in cost sharing for medications.[10]

[10] See, for example: Doshi JA, Li P, Pettit AR, Dougherty JS, Flint A, Ladage VP.2017. Reducing out-of-pocket cost barriers to specialty drug use under Medicare Part D: addressing the problem of "too much too soon". Am J Manag Care. 23(3 Suppl):S39-S45.

Outcomes

This outcome will be assessed by adapting claims-based measures of financial burden used in the literature. The ratio of total annual out-of-pocket costs for drugs to annual household income will be calculated for SeniorCare members, and the threshold of greater than 5% (or 10%) will be used to define having high financial burden for drugs.[11] Other outcomes include total member out-of-pocket drug costs and the ratio of member out-of-pocket costs to total drug costs.

Data

SeniorCare enrollment data will be used to obtain annual household income for SeniorCare members. As the Medicare data do not contain this information, an alternative approach will use US Census data to assign mean zip code or county income to Medicare beneficiaries. Drug claims data for SeniorCare and Medicare Part D will be used to obtain member out-of-pocket drug spending. We will also identify factors associated with high financial burden.

Statistical Analysis

Descriptive statistics will be used to identify trends in the outcomes and comparisons will be made between the SeniorCare and Medicare Part D programs using appropriate statistical tests such as chi-squared tests, t-tests, ANOVA, and/or ANCOVA. Multiple logistic regression will be used to identify factors associated with financial burden. Time-series models will be used to longitudinally assess and compare the prevalence of medication-related financial hardship between the two programs over time, and will be adjusted to control for important beneficiary characteristics. Propensity score matching may be used to select the most comparable subgroup of Part D enrollees to the SeniorCare population. Stratified analyses will compare the waiver and non-waiver populations, as well as the subgroups of waiver enrollees subject to a copayment only (≤160% FPL) and those subject to a deductible (160-200% FPL).

[11] Walid FG et al. 2012. The Financial Burden From Prescription Drugs Has Declined Recently For The Nonelderly, Although It's Still High For Many. Health Aff (Millwood).31(2): 408–416.

Hypothesis 2**: SeniorCare will have a positive effect on the health outcomes of Wisconsin seniors**

Q2-1: How does the quality of medication use (i.e., medication safety, adherence and appropriate use) in SeniorCare compare to older adults enrolled in Medicare Part D?

High quality medication use is believed to lead to positive health outcomes. In order to assess the quality of medication use in the SeniorCare program, we will apply a variety of commonly used quality measures endorsed by CMS (e.g., Medicaid Adult Core Set), and other national quality organizations (e.g., National Quality Forum, or NQF, Pharmacy Quality Alliance, or PQA, National Committee for Quality Assurance, or NCQA).[12] These organizations work in partnership with CMS to develop medication use measures and measures for Medicare Part D star ratings.[13] This analysis builds on Hypothesis 1 by providing more specific analyses of drug utilization for certain therapeutic classes or chronic conditions among members in the SeniorCare program. To better understand the quality of medication use in the SeniorCare program, we will utilize a comparison group of older adults with Medicare Part D.

Outcomes

We will apply a wide range of validated, commonly used quality measures in order to provide a comprehensive evaluation of the quality of medication use in the SeniorCare program. This will allow for direct comparisons with existing estimates in the literature. Our analyses will incorporate measures that are used to calculate Medicare Part C or Part D Star Ratings, as well as display measures that are not part of the Star Ratings; these display measures may have been transitioned from the Star Ratings or are new measures being tested before inclusion into the Star Ratings.[14] Example measures include but are not limited to the following:

> Proportion of Days Covered: Diabetes All Class (PDC-DR), Proportion of Days Covered: Statins (PDC-STA), and Proportion of Days Covered: Renin Angiotensin System Antagonists (PDC-RASA); Statin use in persons with diabetes (NQF #2712); use of high-risk medications in the elderly (PQA HRM); use of benzodiazepine sedative hypnotic medications in the elderly (PQA BSH); polypharmacy: use of multiple anticholinergic medications in older adults (PQA POLY-ACH); polypharmacy: use of multiple CNS-active medications in older adults (PQA POLY-CNS); concurrent use of opioids and benzodiazepines (NQF #3389); use of opioids at high dosage in persons without cancer (NQF #2940); use of opioids from multiple providers in persons without cancer (NQF #2950); and use of opioids at high dosage and from multiple providers in persons without cancer (NQF #2951).

Additional outcomes will be considered for inclusion as approved by national quality organizations. We will also identify factors associated with high quality medication use.

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[12] 2019 Adult Core Set available here: https://www.medicaid.gov/medicaid/quality-of-care/downloads/performance-measurement/2019-adult-core-set.pdf
PQA adherence measures available here: www.pqaalliance.org/adherence-measures.

[13] Available at https://www.pqaalliance.org/assets/Measures/2019_PQA_Measure_Overview.pdf

[14] "Medicare 2021 Part C & D Display Measure Technical Notes" located under 2021 Display Measures on CMS.gov: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData

Data

We will use enrollment and claims data from the SeniorCare and Medicare Part D programs to define the sample for each measure and evaluate the quality of medication use. Medicare fee-for-service health claims (i.e., Parts A and B) will be used as needed to identify the target populations. The technical specifications for each measure will be obtained from the appropriate agencies (e.g., PQA performance measures and value sets) and used or adapted to current best practices in quality measurement.

Statistical Analysis

Descriptive statistics will be used to identify trends in the outcomes and comparisons will be made between the SeniorCare and Medicare Part D programs using appropriate statistical tests such as chi-squared tests, t-tests, ANOVA, and/or ANCOVA. Multiple logistic regression will be used to identify factors associated with outcomes indicating high-quality drug use. Time-series analysis will be used to assess changes in the level and slope of the outcomes over time between the two groups, and will be adjusted to control for important beneficiary characteristics.

The sample will be identified separately for each quality measure by following the inclusion and exclusion criteria defined for each measure. For example, some of the quality measures focus on patients who have specific chronic conditions or use certain types of medications; therefore, such measures will be evaluated amongst the appropriate subgroups of treatment and control group members. Stratified analyses will compare the waiver and non-waiver populations, as well as the subgroups of waiver enrollees subject to a copayment only (≤160% FPL) and those subject to a deductible (160-200% FPL).

Q2-2: How does the health status of SeniorCare members compare to older adults enrolled in Medicare Part D?

It is believed that by making medications more affordable for Wisconsin seniors, the SeniorCare program will keep members healthier longer. Therefore, it is important to understand the health status of the SeniorCare population and how it changes over time. Given the possibility of self-selection into the SeniorCare and Medicare Part D programs, it is important to understand the different populations covered by the two programs and how they compare on health status.

Outcomes

Claims-based measures of health status will be used to assess trends in health status. This includes the number and type of chronic health conditions, as well as the use of validated measures such as the Charlson Comorbidity Index,[15] Elixhauser Index,[16] or Rx-Risk Comorbidity Index.[17] These indices are widely used to measure comorbidities affecting health status and predict mortality. Using claims-based measures is an efficient way of measuring health status for large populations such as SeniorCare and

[15] Charlson ME, Pompei P, Ales KL, MacKenzie CR. 1987. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis 40(5):373-83.

[16] Elixhauser A, Steiner C, Harris DR, Coffey RM. 1998. Comorbidity measures for use with administrative data. Med Care 36(1):8-27.

[17] Pratt L, et al. The validity of the Rx-Risk Comorbidity Index using medicines mapped to the Anatomical Therapeutic Chemical (ATC) Classification System (https://bmjopen.bmj.com/content/8/4/e021122)

Medicare Part D enrollees. We will also evaluate if there are any differences in health outcomes attributable to length of time enrolled in SeniorCare, as well as factors associated with poor member health.

Data

The analysis will utilize enrollment and health claims data for SeniorCare and Medicare fee-for-service health claims (e.g., Parts A and B). The Medicare Chronic Conditions and Other Chronic or Potentially Disabling Conditions files will also be used to identify Medicare beneficiaries with common chronic conditions.

Statistical Analysis

Descriptive statistics will be used to identify trends in the outcomes and comparisons will be made between the SeniorCare and Medicare Part D programs using appropriate statistical tests such as chi-squared tests, t-tests, ANOVA, and/or ANCOVA. Multiple logistic regression will be used to identify factors associated with poor member health. Time-series regression analysis will be used to assess changes in the level and slope of the outcomes over time between the groups, and will be adjusted to control for important beneficiary characteristics. Propensity score matching may be used to select the most comparable subgroup of Part D enrollees to the SeniorCare population. Stratified analyses will compare the waiver and non-waiver populations, as well as the subgroups of waiver enrollees subject to a copayment only (≤160% FPL) and those subject to a deductible (160-200% FPL).

Q2-3: How do annual trends in health care services utilization and expenditures in the SeniorCare population compare to older adults enrolled in Medicare Part D?

The Wisconsin SeniorCare drug assistance program was implemented on September 1, 2002 and in 2006 Medicare Part D expanded the coverage options available to seniors. SeniorCare is considered creditable coverage, which means it is considered to be as good as the standard Medicare Part D plan. However, it is unknown how SeniorCare enrollment impacts an individual's use of health services, or how SeniorCare members compare to individuals enrolled in Medicare Part D on important domains such as health services use and costs. Medicare is the primary source of health insurance coverage for older adults in the United States, including SeniorCare members. Thus, it is important to assess the impact of SeniorCare coverage on the Medicare program. In addition, comparing these outcomes to a comparable group of older adults in the Medicare Part D program can help us better understand the role that SeniorCare plays in supporting the health of its members.

Outcomes

Annual trends in health care utilization and costs will be assessed for services such as inpatient, outpatient, and emergency department visits. In addition, we will estimate the cumulative probability of remaining outside the hospital, as well as the likelihood of hospital admission or emergency department use to identify differences between SeniorCare members and Medicare Part D enrollees.

Data

We will link SeniorCare and Medicare data to assess the use and costs of health care services for SeniorCare members. We will use SeniorCare enrollment and claims data, as well as Medicare enrollment and fee-for-service (i.e., Parts A and B) inpatient, and outpatient claims data to measure the outcomes for SeniorCare members. Medicare enrollment, inpatient, and outpatient claims data will be used to measure the outcomes for the comparison group composed of older adults enrolled in Medicare Part D.

Statistical Analysis

Descriptive statistics will be used to identify trends in the outcomes and comparisons will be made between the SeniorCare and Medicare Part D programs. We will include both graphical analyses and tabulations. Multiple logistic regression will be used to identify factors associated with outcomes of interest. Time-series models will be used to longitudinally assess and compare health services utilization and expenditures between the two programs over time, and will be adjusted to control for important beneficiary characteristics, as well as seasonal variations in the outcomes and autocorrelation.

Propensity score matching may be used to select the most comparable subgroup of Part D enrollees to the SeniorCare population. The likelihood of hospital admission or emergency department use will be assessed using time-to-event models for SeniorCare and non-SeniorCare enrollees. Appropriate model choices could include discrete time hazard models and/or Cox proportional hazard models. Stratified analyses will compare the waiver and non-waiver populations, as well as the subgroups of waiver enrollees subject to a copayment only (≤160% FPL) and those subject to a deductible (160-200% FPL).

Q2-4: What are annual trends in Comprehensive Medication Review and Assessment (CMR/A) utilization and expenditures in SeniorCare?

Comprehensive Medication Review and Assessment (CMR/A) is a type of MTM service, which includes private consultations between a SeniorCare member and a pharmacist to discuss and review that member's entire medication regimen. These consultations may include a variety of consultative, analytical, and educational services, with the goal of preventing complications, increasing adherence, and controlling costs. It also allows a patient to take more initiative in health management and facilitates partnership between a patient, pharmacist, and physician. SeniorCare members who meet the eligibility criteria may receive CMR/A services from a participating pharmacy provider; similarly, eligible older adults in the Medicare Part D program may also receive these services. Analyzing and comparing trends in the use of CMR/As and the associated expenditures will improve our understanding of how the program has performed over time, and can inform policies and programs promoting the use of these services.

Outcomes

Utilization will be measured using the annual numbers and types of CMR/A services provided to SeniorCare members. Expenditures will be evaluated overall and on a per-member basis by source of payment, including total costs, SeniorCare program costs, and member out-of-pocket costs.

Data

We will use SeniorCare enrollment, prescription drug, and MTM data for SeniorCare enrollees.

Statistical Analysis

Descriptive statistics will be used to identify annual trends in the outcomes. Statistical tests (e.g., chi-squared tests, t-tests, ANOVA, and ANCOVA) will be used to assess changes in CMR/A receipt over time. Stratified analyses will compare the waiver and non-waiver populations, as well as the subgroups of waiver enrollees subject to a copayment only (≤160% FPL) and those subject to a deductible (160-200% FPL).

Q2-5: Are there changes in adherence to recommended vaccine schedules among SeniorCare members after the initiation of SeniorCare vaccination coverage?

SeniorCare will cover vaccinations recommended to older adults by the Centers for Disease Control and Prevention, beginning January 2021 or following approval and implementation of the benefit. Two different categories of vaccine are recommended: 1) vaccines for all older adults aged 65 years or more, and 2) vaccines for older adults with medical conditions or other indications.[18] The first category includes influenza, pneumococcal, diphtheria, tetanus, pertussis, and shingles vaccines. The second category includes meningococcal, hepatitis A and B, and varicella zoster (chicken pox) vaccines. SeniorCare may pay the entire costs for a vaccination if the member has met their required deductible and spenddown, or the remaining part of the costs if a member had other insurance sources that paid some amount of the costs.

The evaluation will assess the role of SeniorCare in supporting older adult's vaccination rates, through analysis and comparison of trends in the vaccine utilization. Wisconsin Immunization Registry (WIR) data will be used to identify vaccine utilization outside the SeniorCare program in order to obtain a complete picture of vaccine use among SeniorCare members, and to determine whether SeniorCare coverage of vaccines acts as a replacement or supplement to other sources of vaccination coverage (e.g. Medicare). If feasible, vaccine utilization among SeniorCare members will be compared with older adults in the Medicaid EBD population that were never enrolled in SeniorCare.

Outcomes
Annual vaccination rates and vaccine expenditures within SeniorCare will be evaluated overall and on a per-member basis, including total costs, SeniorCare program costs, and member out-of-pocket costs.

Data
We will use SeniorCare enrollment and vaccination claims for SeniorCare enrollees. We will also use WIR data to identify vaccine utilization outside the SeniorCare program in order to obtain a complete picture of vaccine use among SeniorCare members.

Statistical Analysis
Descriptive statistics will be used to identify changes in the outcomes, before and after implementation of vaccination coverage. Statistical tests (e.g., chi- squared tests, t-tests, ANOVA, and ANCOVA) will be used to assess changes in the outcomes. Stratified analyses will compare the waiver and non-waiver populations, as well as the subgroups of waiver enrollees subject to a copayment only (≤160% FPL) and those subject to a deductible (160-200% FPL).

[18] U.S. CDC. Recommended Adult Immunization Schedule for ages 19 years or older. United State s 2020. https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf?fbclid=IwAR3CgLKmaTUNPFTWXVCWZRDxxFGULVT-CSg51lWptMZxgU08M6TVLPwgVok

Hypothesis 3**: SeniorCare will reduce the likelihood of Medicaid entry and provide cost savings to the Wisconsin Medicaid program.**

Question 3-1: How does SeniorCare enrollment impact an individual's likelihood of Medicaid entry?

SeniorCare could produce cost savings to the Medicaid program if, by providing access to medications that help control and prevent adverse health conditions, it reduces the likelihood of Medicaid entry. In addition, SeniorCare can help maintain better health status, which will save Medicaid costs after a member transitions to Medicaid. To evaluate these questions, we will compare the incidence of Medicaid entry between SeniorCare and Medicare Part D populations.

Outcomes

We will assess the rate of Medicaid entry among SeniorCare and Medicare Part D populations and compare the rates between the two groups.

Data

Eligibility and enrollment data for SeniorCare, Medicare, and Medicaid will be used to identify an individual's entry into Medicaid.

Statistical Analysis

Descriptive analyses and statistical comparisons will be conducted to compare the incidence of Medicaid entry among the SeniorCare and Medicare Part D populations. Regression models such as Cox proportional hazard or competing risks model will be used to control for potential confounding factors.

Question 3-2: How does SeniorCare enrollment impact an individual's use of Medicaid-funded nursing home care?

Medicaid is the largest payer for nursing home care in the United States.[19] It is believed that SeniorCare will reduce the need for Medicaid-funded nursing home care among older adults, thus reducing Medicaid costs for these services. To evaluate this assumption, we will identify SeniorCare members who receive Medicaid-funded nursing home care and assess the utilization and costs of this care, which will be compared to other older adults in the Medicaid EBD population that were never enrolled in SeniorCare (e.g., that were enrolled in Medicare Part D). We will also compare the cumulative probability of remaining outside a nursing home between these two groups.

Outcomes

We will link SeniorCare, Medicare, and Medicaid enrollment and claims data to longitudinally assess the health status, utilization of nursing home care, and costs for SeniorCare and Medicare Part D members before and after first entry into the Medicaid EBD population. This will allow for pre-post comparisons to identify changes in the outcomes over time, as well as comparisons between the two groups. In

[19] Kaiser Family Foundation. 2017. "Medicaid's Role in Nursing Home Care." Kaiser Family Foundation Infographic. Issued June 20, 2017. www.kff.org/infographic/medicaids-role-in-nursing-home-care/

addition, we will estimate the likelihood of transitioning to a nursing home, the cumulative probability of remaining outside a nursing home, and associated factors to identify differences between SeniorCare members and other older adult Medicaid EBD enrollees.

Data

SeniorCare enrollment data will be used to identify former SeniorCare enrollees, and Medicare enrollment data will be used to identify former Medicare Part D enrollees. Medicaid enrollment and nursing home data will be used to identify individuals that transitioned to the Medicaid EBD population and assess the outcomes. Due to the potential for churning in Medicaid programs, our analysis will utilize Medicaid data after an individual's first transition to Medicaid.

Statistical Analysis

Descriptive analyses will be conducted to describe population-level measures of nursing home care among former SeniorCare members in the Medicaid EBD population and a comparison group of older adults in the Medicaid EBD population never enrolled in SeniorCare (e.g., Medicare Part D). Outcomes include the proportion of patients with nursing home use and mean length of stay. Additional outcomes based on the existing Medicaid literature[20] will be used to describe nursing home care, including the monthly proportion of individuals residing in nursing homes and the cumulative probability of remaining outside a nursing home. In addition, the likelihood of transitioning to a nursing home will be assessed using time-to-event models for SeniorCare and non-SeniorCare enrollees. Appropriate model choices could include discrete time hazard models and/or Cox proportional hazard models.

Question 3-3: What would Medicaid expenditures be in the absence of the SeniorCare program?

It is believed that SeniorCare will save the Wisconsin Medicaid program money by reducing the likelihood of Medicaid entry, keeping members healthier longer, and mitigating costs related to receiving Medicaid benefits. Thus, it is important to understand how changes to the SeniorCare program might impact Medicaid expenditures. Therefore, we will use cost modeling to estimate how changes to the SeniorCare program might impact Medicaid expenditures.

Outcomes

The main outcome of interest is Medicaid expenditures for SeniorCare members in the absence of the SeniorCare program. We will measure health care expenditures at the annual level (i.e., summing reimbursements for all services received within 12 months). Additional secondary outcomes (e.g., expenditures by service type) will be assessed to identify specific factors contributing to Medicaid expenditures.

Data

[20] For example, see Soumerai SB, Ross-Degnan D, Avorn J, McLaughlin TJ, Choodnovskiy I. 1991. Effects of Medicaid drug-payment limits on admission to hospitals and nursing homes." New England Journal of Medicine 325(15):1072-7.

SeniorCare enrollment and claims data will be used to identify current patterns in the utilization of prescription drugs among SeniorCare enrollees, and Medicare fee-for-service (i.e., Parts A and B) enrollment and claims data will be used to identify the use of other health services. Medicaid claims data will be used to obtain Medicaid payment amounts for these services, which will be used to project the estimated Medicaid costs for SeniorCare members.

Statistical Analysis

First, current patterns of health services use will be identified for SeniorCare members, as well as the likelihood of Medicaid entry. Next, Medicaid payment amounts for these services will be applied. We will identify Medicaid costs using GLMs with clustered standard errors to determine the Medicaid expenditures in the absence of SeniorCare. From these models we will calculate the predicted reimbursement with the marginal standardization form of predictive margins. For all models, we will adjust for demographics and comorbidity. Additionally, we will include fixed effects for the metropolitan statistical area and services used, which directly adjusts for regional differences in reimbursement and service use mix. We will combine the predicted values for health service use and spending to generate the differences in Medicaid expenditures in the absence of the SeniorCare program. We will use bootstrapping across these models to generate the standard errors and confidence intervals. The sensitivity of the estimates will be tested using alternative model specifications, such as varying the model assumptions (i.e., a hurdle model) and parameters.

V. METHODOLOGICAL LIMITATIONS

The evaluation will use numerous data elements from a variety of sources, each with its own strengths and weaknesses. By working across and combining data sources, we can get a comprehensive look at the SeniorCare population and comparable older adult populations. However, there are important methodological limitations that should be taken into consideration and may have an impact on the evaluation findings.

First, linking different data sources may lead to multiple limitations. When working across multiple data sources, caution should be used when making direct comparisons between the data elements contained in these files. For example, variables may be collected or stored differently, even when the data appear to contain similar elements (e.g., actual vs imputed costs, age as of January 1 vs December 31, etc.). Each data element used in the evaluation will be screened for potential issues of completeness, accuracy, and comparability across data sources, and identical data elements will be used whenever possible to strengthen confidence in the findings. In addition, all data elements will be screened for potential issues with missing or invalid data, and appropriate action will be taken to maximize the utility of the data (e.g., imputation, listwise deletion, etc.).

Identifying individuals across multiple data sources may also prove a challenge, and complete data on individuals may not be available. In particular, data for the Medicare managed care population will be unavailable, as these data are not centrally available through the CMS CCW data warehouse. Similarly, if it is not feasible to accurately identify SeniorCare members in the WIR data, information on immunizations among SeniorCare members, using only the Medicaid/SeniorCare claims data, may be incomplete. In addition, if it is not feasible to identify the Medicaid EBD population in the WIR data, we will not be able to make comparisons of vaccine utilization among SeniorCare members and older adults in Medicaid EBD.

However, common IDs are available to link internal data sources such as SeniorCare and Medicaid data, and these data can also be linked to external sources (i.e., Medicare CCW data and WIR data) using a personal identifier such as Social Security numbers. CMS protocols and best practices in data security and privacy will be used to perform these linkages in a secure, HIPAA-compliant manner. Due to the identifiable nature of these data, a data management plan will be developed and approved by CMS and the UW-Madison Institutional Review Board (IRB) that will outline the administrative, physical and technical safeguards, and incident response preparedness for the data.

The ability to apply the proposed validated quality measures (e.g., PQA measures) will vary depending on data availability and the frequency of such services. For example, our ability to conduct detailed analyses of the quality and impact of SeniorCare CMR/A claims may be limited by the small number of such services provided to SeniorCare members.

When applying the quality measures, our preferred approach will be to follow the technical specifications outlined for each measure, including the appropriate data requirements and associated inclusion and exclusion criteria. However, if sufficient data are not available, the measures may be adapted to allow for their application in a way that is as closely related to the intent of the measure as possible (e.g., pooling multiple years of data or relaxing inclusion/exclusion criteria).

VI. SPECIAL METHODOLOGICAL CONSIDERATIONS

The current SeniorCare waiver is an extension of a longstanding waiver, and has been operating smoothly without administrative changes, appeals, grievances, or corrective action plans. There have been no state issues with CMS-64 reporting or budget neutrality. The evaluation design incorporates quasi-experimental methods in order to test how the program is meeting its objectives under changing circumstances. However, due to SeniorCare's longstanding operation since 2002, the evaluation design no longer incorporates baseline data from the program's implementation.

The ability to incorporate comparison groups requires access to national Medicare data and analysis of the experience of seniors in other states that lack access to the SeniorCare program. The proposed evaluation design includes plans to use such Medicare data to the degree that it becomes available.

This evaluation design assesses the goals of the SeniorCare program as they correspond to Hypotheses 2-4 as articulated in the waiver document. Hypothesis 1 and Hypothesis 5 in the waiver document address matters pertaining to the larger prescription drug market and Medicare program generally. These hypotheses are secondary to the SeniorCare program and have been deemed outside of the scope of this waiver evaluation project.

Finally, the SeniorCare waiver was approved for a ten-year operational period. This evaluation plan addresses the first five years of operation, expecting that the hypotheses may be answered within that period and reassessed. At the five-year point, the state may then identify new questions and hypotheses based on the evaluation findings and changes in the environment or other circumstances. This offers a continuous quality improvement approach and learning cycle for the SeniorCare program, as it moves into a mature ongoing operations period.