

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

NUMBER: 11-W-00286/5

TITLE: Minnesota 2020 System Reform Demonstration

AWARDEE: Minnesota Department of Human Services

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Minnesota for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period of this demonstration extension, be regarded as expenditures under the state's title XIX plan. All requirements of the Medicaid program expressed in law, regulation, and policy statement, not identified as not applicable in this document, shall apply to this demonstration extension beginning with the date of the approval letter through January 31, 2025 (including adherence to income and eligibility system verification requirements under section 1137(d) of the Act).

The following expenditure authorities enable Minnesota to operate its demonstration effective as of the date of the associated CMS approval letter through January 31, 2025:

- 1. Alternative Care Program (AC).** Expenditures to provide a targeted set of home and community-based services (HCBS) as described in the accompanying Special Terms and Conditions (STCs) to people ages 65 and older who are: 1) in need of a nursing facility level of care; 2) not eligible for Medicaid coverage because their income and assets exceed eligibility limits; and 3) their income and/or assets are insufficient to pay for 135 days of nursing facility care. These authorized expenditures are provided under the Alternative Care program component of the demonstration as set forth in the accompanying STCs.

- 2. Children Under 21 with Activities of Daily Living (ADL) Needs.** Expenditures to provide Medicaid State Plan benefits to children under 21 who met the state's March 2010 Medicaid State Plan institutional level of care but do not meet the state's current Medicaid State Plan institutional level of care made effective January 1, 2015 and therefore would otherwise lose Medicaid eligibility and were enrolled on February 1st. These authorized expenditures are provided under the Children with Activities of Daily Living (ADL) Needs program component of the demonstration as set forth in the accompanying STCs. This authority is applicable to eligible expenditures until October 31, 2020.

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

NUMBER: 11-W-00286/5

TITLE: Minnesota 2020 System Reform Demonstration

AWARDEE: Minnesota Department of Human Services

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived in this list, shall apply to the Demonstration from the approval date, through January 31, 2025, unless otherwise specified.

Under the authority of section 1115(a) (1) of the Social Security Act (the Act), the following waivers shall enable Minnesota to implement the Minnesota 2020 System Reform Demonstration.

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

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

2. Cost Sharing Requirements **Section 1902(a)(14) so far as it
it incorporates Section 1916**

To permit the state to impose premiums, deductions, cost sharing, and similar charges that exceed the statutory limitations for individuals in the AC population.

3. Assurance of Transportation **Sections 1902(a)(4) and 1902(a)(19)**

To permit the state not to provide non-emergency transportation benefits to the AC population in this demonstration.

4. Comparability **Section 19029(a)(10)(B) and
1902(a)(17)**

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

5. Retroactive Eligibility **Section 1902(a)(34)**

To the extent necessary to enable the state to not provide Medicaid services to the AC demonstration population prior to the date of application for the demonstration benefits.

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

NUMBER: 11-W-00286/5

TITLE: Minnesota 2020 System Reform Demonstration

AWARDEE: Minnesota Department of Human Services

I. PREFACE

The following are the special terms and conditions (STC) for the “Minnesota 2020 Reform” section 1115(a) Medicaid demonstration (hereinafter “demonstration”), to enable the Minnesota Department of Human Services (hereinafter “state”), to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on those expenditure authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state’s obligations to CMS related to the demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted.

These STCs are effective from February 1, 2020 through January 31, 2025, unless otherwise specified.

The STCs have been arranged into the following subject areas:

- I.** Preface
- II.** Program Description and Objectives
- III.** General Program Requirements
- IV.** Eligibility, Benefits, and Enrollment
- V.** Cost Sharing
- VI.** Delivery Systems
- VII.** General Reporting Requirements
- VIII.** Monitoring Requirements
- IX.** Financial Reporting Requirements
- X.** Monitoring Budget Neutrality
- XI.** Evaluation of the Demonstration
- XII.** Schedule of Deliverables for the Demonstration Extension Period

Additional attachments have been included to provide supplementary information and guidance for specific STCs.

- Attachment A: Developing the Evaluation Design
- Attachment B: Preparing the Interim and Summative Evaluation Reports
- Attachment C: Evaluation Design

II. PROGRAM DESCRIPTION AND OBJECTIVES

Historical Context and Objectives

The demonstration was originally approved on October 18, 2013 for a five year period. As originally approved the demonstration provided federal authority to implement the below three key components of Minnesota's reform initiative to promote independence, increase community integration and reduce reliance on institutional care for older adults and people with disabilities:

1. Medicaid 1115 expenditure authority for the Alternative Care (AC) program, which provides community-supports to elders not financially eligible for Medicaid;
2. Medicaid funding to expand self-directed options under the Community First Services and Supports (CFSS) program for people who would otherwise be ineligible under the 1915(i) and 1915(k) Medicaid State Plan options; and,
3. Medicaid funding for covering children under the age of 21 in the ADL program who met the state's March 23, 2010 institutional level of care but do not meet the state's current required institutional level of care made effective January 1, 2015 and therefore would lose Medicaid eligibility without the demonstration.

The Reform 2020 demonstration goals and objectives were to:

- Achieve better health outcomes;
- Increase and support independence and recovery;
- Increase community integration;
- Reduce reliance on institutional care;
- Simplify the administration of the program and access to the program; and,
- Create a program that is more fiscally sustainable.

On July 21, 2017, the state submitted a request to extend the demonstration with no program changes for a five-year period beyond its scheduled expiration date of June 30, 2018. On February 5, 2018, the state withdrew its 1915 (i) and 1915 (k) Medicaid State plan amendments due to not being able to come into compliance with CMS' section 1915(i) and 1915(k) requirements because of conflicting state legislation. As a result, on March 12, 2018, the state submitted a letter requesting to revise its original extension request to continue the demonstration program without the Community First Services and Supports (CFSS) program component. In accordance, as requested by the state, these STCs remove the authority for the CFSS program as of the effective date of these STCs.

The demonstration extends Medicaid eligibility to: 1) participants in the AC program, and 2) children under the age of 21 within the ADL Needs program who were enrolled as of February 1, 2020. The expenditure authority for the ADL children will remain effective until October 31, 2020.

The initial five-year demonstration period expired on June 30, 2018, and several temporary extensions have been granted since to allot time for CMS and the state to develop an acceptable budget neutrality (BN) model. After careful consideration and analysis, CMS has determined that the state has presented a BN model that is in compliance with our current BN policy.

III. GENERAL PROGRAM REQUIREMENTS

- 1. Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).
- 2. Compliance with Medicaid and Child Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.
- 3. Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.
- 4. Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
 - a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
 - b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of 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 or XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state

plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP state plans govern.

- 6. Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.
- 7. Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

 - a. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;
 - b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
 - c. A data analysis which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable “with waiver” and “without waiver” status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the “with waiver” expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
 - d. An up-to-date CHIP allotment worksheet, if necessary;
 - e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.
- 8. Extension of the Demonstration.** States that intend to request a demonstration extension under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in statute. Otherwise, no later than twelve (12) months prior to the expiration date of the demonstration, the Governor or Chief Executive Officer of the state must submit to CMS either a demonstration extension request that meets

federal requirements at CFR section 431.412(c) or a phase-out plan consistent with the requirements of STC 9.

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

- a. Notification of Suspension or Termination: The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a 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 12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.
- b. Transition and Phase-out Plan Requirements: The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.
- c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.
- d. Transition and Phase-out Procedures: The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210 and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

- e. Exemption from Public Notice Procedures 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
- f. Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.
- g. Federal Financial Participation (FFP). If the project is terminated or any relevant waivers suspended by the state, FFP must be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of dis-enrolling beneficiaries.

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

11. Adequacy of Infrastructure. The state will 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.

12. Public Notice, Tribal Consultation, and Consultation with Interested Parties. The state must comply with the state notice procedures as required in 42 CFR section 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

The state must also comply with tribal and Indian Health Program/Urban Indian 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.

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

IV. ELIGIBILITY, BENEFITS, AND ENROLLMENT

Standards for eligibility remain as set forth under the approved Medicaid State Plan and as described elsewhere in these special terms and conditions.

- 16. Eligibility for the Demonstration.** The following two populations of individuals, who meet the identified criteria, are Medicaid eligible for the services defined in the demonstration.
- a. **Children under 21 with Activities of Daily Living (ADL) Needs** – Children under 21 who met the state’s March 2010 Medicaid State Plan institutional level of care but do not meet the state’s current Medicaid State Plan institutional level of care made effective January 1, 2015 and therefore would otherwise lose Medicaid eligibility.
 - b. **Alternative Care Program (AC)** – Alternative Care provides a targeted set of home and community based services to people ages 65 and older who are: 1) in need of a nursing facility level of care; 2) not eligible for Medicaid coverage because their income and assets exceed eligibility limits; and 3) their income and/or assets are insufficient to pay for 135 days of nursing facility care.

The AC program is a payor of last resort and other insurance is primary. If long-term care (LTC) insurance has paid for all the individual’s assessed needs, the person would not be eligible for the Alternative Care program. If other insurance benefits and/or payments are sufficient to meet all the beneficiary’s assessed needs, the beneficiary would not be eligible for Alternative Care program. If the LTC insurance only paid for a portion of the

beneficiary's assessed needs, the Alternative Care program would pay for other assessed unmet needs.

17. Minimum Essential Coverage (MEC). This demonstration is limited to the provision of services, for the AC population, as described in STC 20 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 in the AC program.

18. Alternative Care Eligibility Process. Applicants must submit applications to lead agencies as identified by the state. Lead agencies must annually re-determine financial and service eligibility. Applicants may be required to provide all information necessary to determine eligibility for Alternative Care and potential eligibility under the Medicaid State Plan. Applicants for Alternative Care who appear to be categorically eligible under the Medicaid State Plan shall receive Alternative Care for up to 60 days while State Plan eligibility is determined.

19. Benefits under the Children under 21 with Activities of Daily Living (ADL) Needs. Benefits provided to these children are the same as provided under the Medicaid State Plan.

20. Benefits under the Alternative Care Program. The Alternative Care program provides an array of home and community-based services similar to the home and community-based services provided under the federally approved 1915(c) Elderly Waiver program (CMS control number 0025.91.R07.00), except that the following services are not covered: transitional support services, assisted living services, adult foster care services, , and benefits that meet primary and acute health care needs. Alternative Care does additionally cover nutrition services and discretionary benefits that address special or unmet needs of a client or family caregiver that are not otherwise defined in the Alternative Care program service menu. The monthly cost of the Alternative Care services must not exceed 75 percent of the monthly budget amount available for an individual with similar assessed needs participating in the Elderly Waiver program. The service definitions and standards for Alternative Care services are the same as the service definitions and standards specified in the federally approved 1915(c) Elderly Waiver. In summary, Alternative Care program benefits include but are not limited to:

- a. Adult day service/adult day service bath;
- b. Family caregiver training and education;
- c. Case management and conversion case management;
- d. Chore services;
- e. Companion services;
- f. Consumer-directed community supports;
- g. Home health services;
- h. Home-delivered meals;
- i. Homemaker services;
- j. Environmental accessibility adaptations;
- k. Nutrition services;

- l. Personal care;
- m. Respite care;
- n. Skilled nursing and home care nursing;
- o. Specialized equipment and supplies including Personal Emergency Response System (PERS);
- p. Non-medical Transportation;
- q. Tele-home care; and,
- r. Individual Community Living Supports (ICLS).

21. Alternative Care Enrollment. Enrollment procedures for the Alternative Care program are very similar to Medicaid home and community-based services waiver enrollment, except that Alternative Care enrollees do not need to select a health plan. Lead agencies (which may be a county or tribal health agency) administer both the Alternative Care program and the 1915(c) Elderly Waiver. Lead agencies determine financial and program eligibility.

- a. Comprehensive Assessment. Each individual will receive a comprehensive assessment under the Long Term Care Consultation process. The certified assessor/case manager also evaluates financial eligibility. Applicants who would be eligible for medical assistance under Medicaid State Plan categorical eligibility standards are referred for medical assistance. The certified assessor/case manager also discusses with applicants the option of qualifying medical assistance under a medically needy basis.
- b. Service Plan. If the AC program is selected, the assessor/case manager develops a person-centered service plan that identifies the amount, frequency and duration of services needed by the beneficiary and, where appropriate, caregiver supports. Approved services are prior authorized in the Medicaid Management Information System (MMIS) system. Reassessments are done at least annually or sooner if individual needs change.

22. Application and Eligibility Determination Process.

The state assures that the eligibility process for the AC program is integrated with other programs that receive federal Medicaid matching funds so that people applying for AC or long term care services are appropriately screened for the most appropriate program and category of eligibility, and that people who apply through the on-line, streamlined application process are directed to the appropriate program for long term care services. The state will integrate eligibility and application processes for the AC program when other long term care programs are integrated into the eligibility system operated by the state for Medicaid State Plan coverage in accordance with section 1943 of the Act.

Within 60 days of CMS approval of this extension, the state will submit for CMS review and approval, its timeline to ensure the state does not make a final determination of ineligibility based on lack of documentation of citizenship/qualified immigration status provided by the applicant until the state first utilizes an alternative process (pre-or post-enrollment) to verify this information through the electronic data sources used for Medicaid state plan eligibility. That timeline will include full implementation within 12 months from the date of submission.

- 23. Person-Centered Planning.** The state assures there is a person-centered service plan for each individual determined to be eligible for services under this demonstration. The person-centered service plan is developed using a person-centered service planning process in accordance with 42 CFR 441.301(c)(1), and the written person-centered service plan meets federal requirements at 42 CFR 441.301(c)(2). The person-centered service plan is reviewed, and revised upon reassessment of functional need as required by 42 CFR 441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.
- 24. Conflict of Interest:** The state agrees that the entity that authorizes the services is external to the agency or agencies that provide the HCBS services. The state also agrees that appropriate separation of assessment, treatment planning and service provision functions are incorporated into the state's conflict of interest policies.
- 25. Community Participation.** The state, must ensure that participants' engagement and community participation is supported to the fullest extent desired by each participant.
- 26. HCBS Settings.** The state assures compliance with the characteristics of HCBS settings as described in 1915(c) and 1915(i) regulations in accordance with implementation/effective dates as published in the Federal Register.

V. COST-SHARING

- 27. Children under 21 with Activities of Daily Living (ADL) Needs Cost-Sharing.** This population is only subject to cost-sharing to the extent allowable under Medicaid State Plan.
- 28. Alternative Care Program Cost-Sharing.** Individuals in the Alternative Care program pay cost-sharing fees up to 30 percent of the average monthly cost of the individual's Alternative Care services.

Determining Fees. Minnesota uses adjusted income and gross assets and the average monthly amount of services authorized for the beneficiary. Adjusted income for a married applicant who has a community spouse is calculated by subtracting the following amounts from gross income: the monthly spousal income allowance to the community spouse (which is calculated using the spousal impoverishment rules applicable under the 1915(c) Elderly Waiver); recurring and predictable medical expenses; and the federally indexed clothing and personal needs allowance. Adjusted income for all other applicants is calculated by subtracting the following amounts from gross income: recurring and predictable medical expenses and the federally indexed clothing and personal needs allowance.

Alternative Care Adjusted Income	Gross Assets	Monthly Fee Charge (percentage of average monthly cost of services)
Less than 100% of the FPL	Less than \$10,000	No monthly fee
Between 100% and 149% of the FPL	Less than \$10,000	5 percent
Between 150% and 199% of the FPL	Less than \$10,000	15 percent
At or greater than 200% of the FPL	At or greater than \$10,000	30 percent

- a. **Billing and Non-payment of Fees.** Enrollee fees are billed the month after services begin. If enrollee fees are not paid within 60 days, the lead agency works with the enrollee to arrange a payment plan. The lead agency can extend the enrollee’s eligibility as necessary while making arrangements to rectify nonpayment of past due amounts and facilitate future payments. If no arrangements can be made, a notice is issued 10 days prior to termination stating that the enrollee will be disenrolled from the program. The enrollee may appeal the disenrollment under the standard State Fair Hearing process. Following disenrollment due to nonpayment of a monthly fee, eligibility may not be reinstated for 30 days.

VI. DELIVERY SYSTEM

29. AC Program Delivery System. These program services are provided on a fee-for-service basis and are administered by counties and tribal human service programs. The service definitions and standards for Alternative Care services are the same as the service definitions and standards specified in the federally approved 1915(c) Elderly Waiver plan. Approved services are prior authorized in the MMIS system. Services are provided by qualified providers who are enrolled Medicaid providers.

30. Children under 21 with Activities of Daily Living (ADL) Needs. These program services are provided on a fee-for-service basis in the same manner as authorized under the Medicaid State Plan.

VII. GENERAL REPORTING REQUIREMENTS

31. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of \$5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter singularly or collectively referred to as “deliverable(s)”) are not submitted timely

to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the demonstration. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

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

- a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submission of required deliverable(s).
- b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.
- c. If CMS agrees to an interim corrective process in accordance with subsection (b), and the state fails to comply with the corrective action steps or still fails to submit the overdue deliverable(s) that meets the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.
- d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.

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

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

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

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

- b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
- c. Submit deliverables to the appropriate system as directed by CMS.

34. HCBS Electronic Visit Verification System. The state will demonstrate compliance with the Electronic Visit Verification System (EVV) requirements for personal care services (PCS) by January 1, 2021 and home health services by January 1, 2023 in accordance with section 12006 of the 21st Century CURES Act.

35. For 1915(c) HCBS services, the state must have an approved Quality Improvement Strategy and is required to work with CMS to develop approvable performance measures within 90 days following approval of the 1115 for the following waiver assurances (a through f below):

- a. **Administrative Authority:** A performance measure should be developed and tracked any authority that the State Medicaid Agency (SMA) delegates to another agency, unless already captured in another performance measure.
- b. **Level of Care:** Performance measures are required for the following two sub-assurances: applicants with reasonable likelihood of needing services receive a level of care determination and the processes for determining level of care are followed as documented. While a performance measure for annual levels of care is not required to be reported, the state is expected to be sure that annual levels of care are determined.
- c. **Qualified Providers:** The state must have performance measures that track that providers meet licensure/certification standards, that non-certified providers are monitored to assure adherence to waiver requirements, and that the state verifies that training is given to providers in accordance with the waiver.
- d. **Service Plan:** The state must demonstrate it has designed and implemented an effective system for reviewing the adequacy of service plans for HCBS participants. Performance measures are required for choice of waiver services and providers, service plans address all assessed needs and personal goals, and services are delivered in accordance with the service plan including the type, scope, amount, duration, and frequency specified in the service plan.
- e. **Health and Welfare:** The state must demonstrate it has designed and implemented an effective system for assuring HCBS participants health and welfare. The state must have performance measures that track that on an ongoing basis it identifies, addresses and seeks to prevent instances of abuse, neglect, exploitation and unexplained death; that an incident management system is in place that effectively resolves incidents and prevents further singular incidents to the extent possible; that state policies and procedures for the use or prohibition of restrictive interventions are followed; and, that the state establishes overall health care standards and monitors those standards based on the responsibility of the service provider as stated in the approved waiver.
- f. **Financial Accountability:** The state must demonstrate that it has designed and implemented an adequate system for insuring financial accountability of the HCBS program. The state must have performance measures that track that it provides evidence that claims are coded and paid for in accordance for services rendered,

and that it provides evidence that rates remain consistent with the approved rate methodology throughout the five year waiver cycle.

36. The state must report annually the deficiencies found during the monitoring and evaluation of the HCBS waiver assurances, an explanation of how these deficiencies have been or are being corrected, as well as the steps that have been taken to ensure that these deficiencies do not reoccur. The state must also report on the number of substantiated instances of abuse, neglect, exploitation and/or death, the actions taken regarding the incidents and how they were resolved. Submission is due no later than 6 months following the end of the demonstration year. NOTE: This information could be included in the annual reports submitted for 1115 waivers detailed in STC 38.
37. The state will submit a report to CMS which includes evidence on the status of the HCBS quality assurances and measures that adheres to the requirements outlined in the March 12, 2014, CMS Informational Bulletin, Modifications to Quality Measures and Reporting in 1915(c) Home and Community-Based Waivers. NOTE: This information could be captured in the Summative Evaluation Report detailed in STC 73.

VIII. MONITORING REQUIREMENTS

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

- a. Operational Updates - Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
- b. Performance Metrics – Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The

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

- c. Budget Neutrality and Financial Reporting Requirements – Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on the CMS-64.
- d. Evaluation Activities and Interim Findings. Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

39. Corrective Action. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10.

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

- a. The draft report must comply with the most current guidance from CMS.
- b. The state will present to and participate in a discussion with CMS on the Close-Out report.
- c. The state must take into consideration CMS' comments for incorporation into the final Close Out Report.
- d. The final Close Out Report is due to CMS no later than thirty (30) calendar days after receipt of CMS' comments.
- e. A delay in submitting the draft or final version of the Close Out Report may subject the state to penalties described in STC 31.

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

- a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to), any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, budget neutrality, and progress on evaluation activities.
- b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.
- c. The state and CMS will jointly develop the agenda for the calls.

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

IX. FINANCIAL REPORTING REQUIREMENTS

- 43. Allowable Expenditures.** This demonstration project is approved for expenditures applicable to services rendered during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.
- 44. Standard Medicaid Funding Process.** The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this Medicaid section 1115 demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state shall submit form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.
- 45. Extent of Federal Financial Participation for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole for the following, subject to the budget neutrality expenditure limits described in section IX:
- a. Administrative costs, including those associated with the administration of the demonstration;
 - b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
 - c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.

46. Sources of Non-Federal Share. The state certifies that its match for the non-federal share of funds for this section 1115 demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

- a. The state acknowledges that CMS has authority to 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 acknowledges that any amendments that impact the financial status of this section 1115 demonstration must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

47. State Certification of Funding Conditions. The state must certify that the following conditions for non-federal share of demonstration expenditures are met:

- a. Units of government, including governmentally operated health care providers, may certify that state or local monies have been expended as the non-federal share of funds under the demonstration.
- b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
- c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR 433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.
- d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments.
- e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that

payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

48. Program Integrity. The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.

49. Medicaid Expenditure Groups (MEG). MEGs are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The following table provides a master list of MEGs defined for this demonstration.

Table 2: Master MEG Chart					
MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description
AC population	Main	N/A	X	X	See Expenditure Authority #1
ADL children	Hypo	N/A	X	X	See Expenditure Authority #2

50. Reporting Expenditures and Member Months. The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00286/5). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

- a. Cost Settlements. The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b, in lieu of lines 9 or 10c. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.
- b. Premiums and Cost Sharing Collected by the State. The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by demonstration year on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.
- c. Pharmacy Rebates. Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.
- d. Administrative Costs. The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the table below, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.
- e. Member Months. As part of the Quarterly and Annual Monitoring Reports described in STC 38, the state must report the actual number of “eligible member months” for all demonstration enrollees for all MEGs identified as WOW Per Capita, and as also indicated in the table below. The term “eligible member months” refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.
- f. Budget Neutrality Specifications Manual. The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state’s Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality

Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

Table 3: MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
AC population	Individuals ages 65 and older who are: 1) in need of a nursing facility level of care; 2) not eligible for Medicaid coverage because their income and assets exceed eligibility limits; and 3) their income and/or assets are insufficient to pay for 135 days of nursing facility care.	<i>N/A</i>	Report on customary lines by category of service	Date of service	MAP	Y	2/01/2020	1/31/2025
ADL children	Expenditures to provide Medicaid State Plan benefits to children under 21 who met the state's March 2010 Medicaid State Plan institutional level of care but do not meet the state's current Medicaid State Plan institutional level of care made effective January 1, 2015.	<i>N/A</i>	Report on customary lines by category of service	Date of service	MAP	Y	2/1/2020	10/31/2020

51. Demonstration Years. Demonstration Years (DY) for this demonstration are defined in the table below.

Table 4: Demonstration Years		
Demonstration Year 7	February 1, 2020 to June 30, 2020	5 months
Demonstration Year 8	July 1, 2020 to June 30, 2021	12 months
Demonstration Year 9	July 1, 2021 to June 30, 2022	12 months

Demonstration Year 10	July 1, 2022 to June 30, 2023	12 months
Demonstration Year 11	July 1, 2023 to June 30, 2024	12 months
Demonstration Year 12	July 1, 2024 to January 31, 2025	7 months

52. Budget Neutrality Monitoring Tool. The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the performance metrics database and analytics (PMDA) system. The tool incorporates the “Schedule C Report” for comparing demonstration’s actual expenditures to the budget neutrality expenditure limits described in section X. CMS will provide technical assistance, upon request.¹

53. Claiming Period. The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.

54. Future Adjustments to Budget Neutrality. CMS reserves the right to adjust the budget neutrality expenditure limit:

- a. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments. CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Social Security Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.
- b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply

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

- with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation. The changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.
- c. If, after review and/or audit, the data supplied by the state to set the budget neutrality expenditure limit are if found to be inaccurate. The state certifies that the data it provided are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief.

X. MONITORING BUDGET NEUTRALITY

- 55. Limit on Title XIX Funding.** The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit may consist of a Main Budget Neutrality Test, and one or more Hypothetical Budget Neutrality Tests, as described below. CMS's assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.
- 56. Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the for all demonstration populations, CMS will not place the state at risk for changing economic conditions; however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.
- 57. Calculation of the Budget Neutrality Limits and How They Are Applied.** To calculate the budget neutrality spending limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which projected fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share of the AC program limit will be calculated by subtracting the EW actual expenditures from the EW expenditure amount as listed on the WOW table below then multiplying it by the Composite Federal Share.

58. Main Budget Neutrality Test. The Main Budget Neutrality Test allows the state to show that demonstration waivers granted have not resulted in increased costs to Medicaid, and that federal Medicaid “savings” have been achieved sufficient to offset the additional projected federal costs resulting from expenditure authority. The Main Budget Neutrality Test will incorporate net savings from the immediately prior demonstration period of July 1, 2015 through June 30, 2019 (but not from any earlier approval period) in the amount of \$16,971,003.70. The table below identifies the MEGs that are used for the Main Budget Neutrality Test. MEGs designated as “WOW Only” or “Both” are components used to calculate the budget neutrality expenditure limit in addition to carry forward savings from the prior demonstration period. MEGs that are indicated as “WW Only” or “Both” are counted as expenditures against the budget neutrality expenditure limit. In addition, any expenditures in excess of limit from Hypothetical Budget Neutrality Tests count as expenditures under the Main Budget Neutrality Test. The Composite Federal Share for this test is calculated based on all MEGs indicated as “Both.”

Table 5: Main Budget Neutrality Test

MEG	PC or Agg*	WOW Only, WW Only, or Both	TREN D	DY 7	DY 8	DY 9	DY 10	DY 11	DY 12
EW	Agg	Both	N/A	\$214,116,141	\$557,878,712	\$605,645,153	\$657,503,575	\$713,800,880	\$452,036,201
AC	WW Only	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

*PC = Per Capita, Agg = Aggregate

59. Hypothetical Budget Neutrality. When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be “hypothetical;” that is, the expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats

these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. If the state’s WW hypothetical spending exceeds the supplemental test’s expenditure limit, the state agrees to offset that excess spending by savings elsewhere in the demonstration or to refund the FFP to CMS.

60. Hypothetical Budget Neutrality Test 1: The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. MEGs that are designated “WOW Only” or “Both” are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as “WW Only” or “Both.” MEGs that are indicated as “WW Only” or “Both” are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

Table 6: Hypothetical Budget Neutrality Test					
MEG	PC or Agg*	WOW Only, WW Only, or Both	Trend rate	DY 7	DY 8
ADL	PC	Both	3.7%	\$10,784.71	\$11,183.74

61. Composite Federal Share. The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration’s approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Main or Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

62. Transitional Phase-Down of Newly Accrued Savings. Beginning with DY 1, the net variance between the without-waiver cost and actual with-waiver cost will be reduced for selected Medical population based MEGs. The reduced variance, calculated as an applicable percentage times the total variance, will be used in place of the total variance to determine

overall budget neutrality for the demonstration. (Equivalently, the difference between the total variance and reduced variance could be subtracted from the without-waiver cost estimate.) The applicable percentages have been determined in accordance with the policy for Transitional Phase-Down of Newly Accrued Savings described in State Medicaid Director Letter # 18-009. This provision only applies to the Main Budget Neutrality Test, and to the MEGs that are designated “Both” without-waiver and with-waiver. The MEGs affected by this provision and the applicable percentages are shown in the table below. If the total variance for an MEG in a DY is negative, the applicable percentage is 100 percent.

Table 7: Savings Phase-Down						
Base	DY 7	DY 8	DY 9	DY 10	DY 11	DY 12
EW Diversion Savings	80%	70%	60%	50%	40%	30%

63. Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from February 1, 2020 to January 31, 2025. If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds received for the AC program or the ADL needs program in excess of the federal share of the limits will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

64. Expenditure Reconciliation and Limitations. At the time of the approval of this demonstration extension, the state does not have full expenditure data available in its CMS 64 report for first 2 quarters of DY 7 to allow CMS to calculate its accrued savings to carry forward into the new demonstration period. The state must complete reporting of expenditures subject to the budget neutrality limit for DY 7 by December 31, 2020, to adjust the savings carry forward amount in STC 62 to be adjusted to consider this partial year. Failure to complete the reconciliation process will result in forfeiture by the state of all budget neutrality savings from the first 2 quarters of DY 7. The inclusion of savings from DY 7 will affect the use of savings for DY 2. As per the SMDL 18-009, only five years of savings can “roll over” into an extension.

65. Mid-Course Correction. If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

Table 9: Main Budget Neutrality Test Mid-Course Correction Calculations		
EW population	Cumulative Target Definition	Percentage
DY 7	Cumulative budget neutrality limit plus:	2.0 percent
DY 7 through DY 8	Cumulative budget neutrality limit plus:	1.5 percent
DY 8 through DY 9	Cumulative budget neutrality limit plus:	1.0 percent
DY 9 through DY 10	Cumulative budget neutrality limit plus:	0.5 percent
DY 10 through DY 11	Cumulative budget neutrality limit plus:	0.0 percent
DY 11 through DY 12	Cumulative budget neutrality limit plus:	0.0 percent

Table 10: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations		
	Cumulative Target Definition	Percentage
DY 7	Cumulative budget neutrality limit plus:	2.0 percent
DY 7 through DY 8	Cumulative budget neutrality limit plus:	1.5 percent
DY 8 through DY 9	Cumulative budget neutrality limit plus:	1.0 percent
DY 9 through DY 10	Cumulative budget neutrality limit plus:	0.5 percent
DY 10 through DY 11	Cumulative budget neutrality limit plus:	0.0 percent
DY 11 through DY 12	Cumulative budget neutrality limit plus:	0.0 percent

XI. EVALUATION OF THE DEMONSTRATION

66. 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 31.

- 67. Independent Evaluator.** Upon approval of the demonstration, the state must begin to arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party to sign an agreement that the independent party will conduct the demonstration evaluation in an independent manner in accord with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.
- 68. Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design, no later than 180 calendar days after approval of the demonstration. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The draft Evaluation Design must be developed in accordance with the following CMS guidance (including but not limited to):
- a. All applicable evaluation design guidance, including guidance about premiums, non-eligibility periods as a consequence of noncompliance with other demonstration policies, and waivers of retroactive eligibility.
 - b. Attachment A (Developing the Evaluation Design) of these STCs, technical assistance for developing CE Evaluation Designs (as applicable, and as provided by CMS), and all applicable technical assistance on how to establish comparison groups to develop a Draft Evaluation Design.
- 69. Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as Attachment C to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the Monitoring Reports. Once CMS approves the Evaluation Design, if the state wishes to make changes, the state must submit a revised Evaluation Design to CMS for approval.
- 70. Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, CMS's measure sets for eligibility and coverage (including community engagement), Consumer Assessment of Health Care Providers and Systems (CAHPS), the

Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults, and/or measures endorsed by National Quality Forum (NQF).

71. 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.

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

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

73. Summative Evaluation Report. The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Evaluation Report) of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

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

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

74. Corrective Action Plan Related to Evaluation. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of a renewal process when associated with the state’s Interim Evaluation Report. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10.

75. 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.

76. 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.

77. Additional Publications and Presentations. For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration over which the state has control. Prior to release of these reports, articles, or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

XII. SCHEDULE OF STATE DELIVERABLES FOR THE DEMONSTRATION APPROVAL PERIOD

Deliverable	Timeline	STC Reference
State acceptance of demonstration extension STCs and expenditure authorities	30 days after demonstration extension approval date	Approval letter
Quarterly Monitoring Report	Within 60 days following the end of each demonstration quarter	STC 38
Annual Monitoring Report	Within 90 days following the end of each demonstration year	STC 38
Draft Evaluation Design Plan	Within 180 days after the approval of the demonstration extension	STC 68
Final Evaluation	Within 60 days following receipt of CMS	STC 69

Plan	comments on Draft Evaluation Design	
Draft Summative Evaluation Report	Within 18 months following the end of this demonstration extension period	STC 73
Final Summative Report	Within 60 days of receipt of CMS comments	STC 73
Draft Final Close Out Demonstration Report	Within 120 days following the expiration of the demonstration (If Applicable)	STC 40
Final Close Out Demonstration Report	Within 30 days of receipt of CMS comments (If Applicable)	STC 40

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 both Congress and CMS about Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Designs

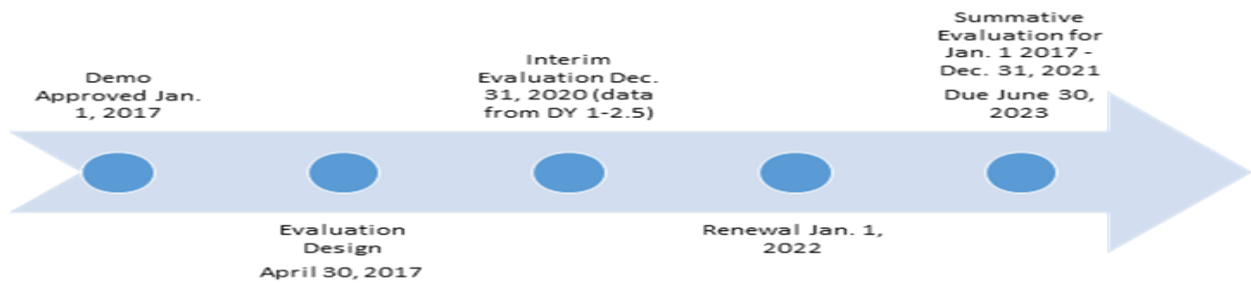
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses,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

The format for the Evaluation Design is as follows:

General Background Information;
Evaluation Questions and Hypotheses;
Methodology;
Methodological Limitations;
Attachments.

Submission Timelines

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



Required Core Components of All Evaluation Designs

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

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

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

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

1. Describe how the state’s demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.
2. Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to

improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams:

<https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf>

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

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

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

- 1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?
- 2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.
- 3) *Evaluation Period* – Describe the time periods for which data will be included.
- 4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by “owning”, defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:
 - a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
 - b. Qualitative analysis methods may be used, and must be described in detail.

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

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

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

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

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

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

E. Attachments

- 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 “No Conflict of Interest” signed by the independent evaluator.

- 2) **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.
- 3) **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

ATTACHMENT B

Preparing the Interim and Summative Evaluation Reports

Introduction

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

Expectations for Evaluation Reports

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

Intent of this Guidance

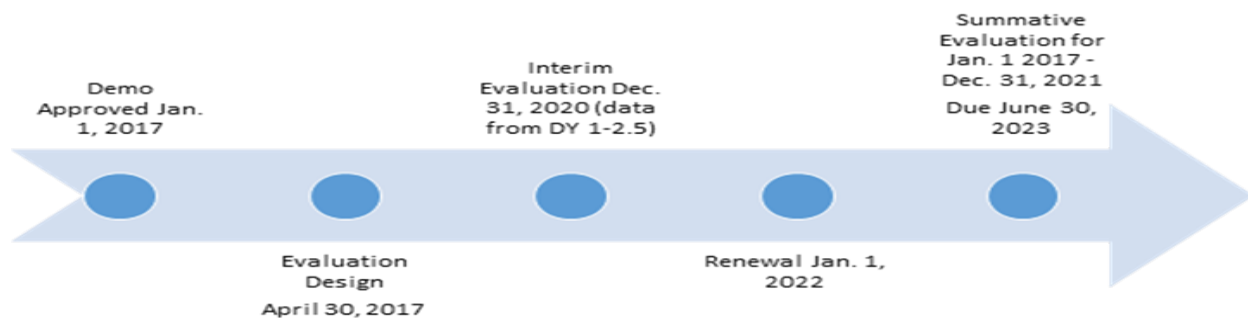
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved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

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

- 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 to the state’s website the evaluation design within thirty (30) days of CMS approval, and publish reports within thirty (30) days of submission to CMS , pursuant to 42 CFR 431.424. CMS will also publish a copy to Medicaid.gov.



Required Core Components of Interim and Summative Evaluation Reports

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

implications on future Medicaid policy. Therefore, the state's submission must include:

- A. Executive Summary** – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.
- B. General Background Information about the Demonstration** – In this section, the state should include basic information about the demonstration, such as:
 - 1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
 - 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
 - 3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
 - 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
 - 5) Describe the population groups impacted by the demonstration.
- C. Evaluation Questions and Hypotheses** – In this section, the state should:
 - 1) Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
 - 2) Identify the state's hypotheses about the outcomes of the demonstration;
 - a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
 - b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
 - c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

D. Methodology – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design.

The evaluation design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

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

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

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.

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

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

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

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

D. 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.

E. 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?

F. Attachment

Evaluation Design: Provide the CMS-approved Evaluation Design

**ATTACHMENT C:
Evaluation Design**

Evaluation Plan for Reform 2020 Section 1115 Demonstration Waiver

This is a proposed evaluation plan for the Alternative Care program under Minnesota’s demonstration waiver entitled Reform 2020: Pathways to Independence. The waiver was originally approved in October 2013 and was extended in February 2020.

Minnesota’s Medicaid program, known as Medical Assistance (MA), offers an array of home and community-based services for low-income seniors and people with disabilities.

Minnesota has been reducing use of institutions through development of home and community-based long-term supports and services for over thirty years. Minnesota has rebalanced its system so that a large majority of the older adults (74% in 2018) and people with disabilities (95% in 2018) who are enrolled in MA and need long term care services are living in the community rather than in institutional settings.

Minnesota has five home and community-based services waivers: Developmental Disability (DD)¹, Community Alternatives for Disabled Individuals (CADI)², Community Alternative Care (CAC)³, Brain Injury (BI)⁴ and Elderly Waiver (EW)⁵. Similar services to support individuals living in the community are offered under each waiver, but since each was developed over time and under different constraints, opportunities, and different populations, HCBS waivers differ from one another in areas such as eligibility criteria and annual spending.

In addition, Minnesota provides the following long-term services and supports through the state plan: home health agency services, private duty nursing services, rehabilitative services (several individualized community mental health services that support recovery) and personal care assistant (PCA) services.

¹ DD: 2019 unduplicated enrollment was 21,120

² CADI: 2019 unduplicated enrollment was 31,715

³ CAC: 2019 unduplicated enrollment was 649

⁴ BI: 2019 unduplicated enrollment was 1,242

⁵ EW: 2019 unduplicated enrollment was 36,680 (managed care and fee-for-service)

There are other Medicaid and state programs that support community living such as day treatment and habilitation, semi-independent living services, the Family Support Grant Program, mental health services, AIDS assistance programs, group residential housing, independent living services, vocational rehabilitation services, extended employment, special education and early intervention.

Minnesota's Reform 2020 demonstration enables the state to continue its history of on-going improvement to enhance its home and community-based service system by enabling the state to provide preventive services to seniors who are likely to become eligible for Medicaid and who need an institutional level of care. The demonstration goals align with those of Medicaid and assist the state in promoting title XIX program objectives in the following ways:

- Achieving better health outcomes;
- Ensuring that the demonstration increases the participants' level of support for independence and recovery;
- Increasing community integration;
- Reducing the reliance on institutional care;
- Simplifying the administration of the program; and
- Ensuring access to the program's offered services.

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Background on the Reform 2020 Section 1115 Waiver for Alternative Care

The Alternative Care or AC program was implemented under Reform 2020 beginning November 1, 2013. Formerly a state-funded program, the Reform 2020 waiver allows Minnesota to receive federal financial participation to provide Alternative Care services to people over age 65 whose functional needs indicate eligibility for nursing facility care but have combined adjusted income and assets exceeding state plan Medicaid standards for aged, blind and disabled categorical eligibility.

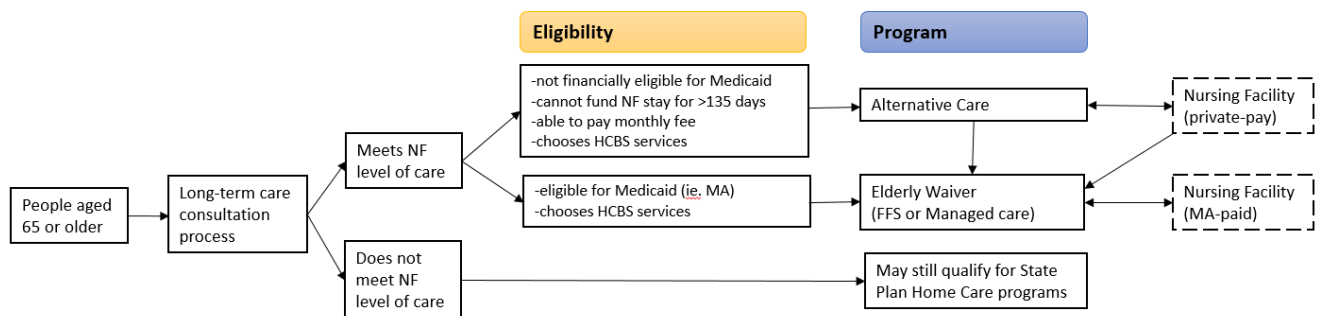
Acute and primary care services are not covered under the program. However, connecting seniors with community services earlier may divert them from nursing facilities and encourage more efficient use of services when full Medicaid eligibility is established. Minnesota has a home and community-based waiver for people over age 65 that need nursing facility care called the Elderly Waiver. Although Alternative Care covers fewer services, service definitions and provider standards for the Alternative Care program are the same as the service definitions and provider standards specified in Minnesota’s federally approved Elderly Waiver. Services are provided by qualified enrolled Medicaid providers.

Alternative Care is available to eligible individuals who meet all of the following *financial requirements*:

- Those with combined income and assets insufficient to pay for 135 days of nursing facility care, based on the statewide average nursing facility rate
- Those not within an uncompensated transfer penalty period
- Those with home equity within the home equity limit applicable under the state plan

Functional eligibility for nursing home care and identification of needed services for Alternative Care is performed using the Long-term Care Consultation process, which is the same assessment tool and process that is used for the Elderly Waiver. Applicants for Alternative Care also discuss the option of qualifying for Medical Assistance under a medically needy basis (see Figure 1).

Figure 1. Minnesota Health Care Program Options for the Elderly



AC, alternative care program; FFS, fee-for-service; HCBS, home and community-based services; MA, Medical Assistance (Minnesota’s Medicaid program); NF, nursing facility; SNF, skilled nursing facility

If an Alternative Care participant is admitted to a nursing facility, their stay is either paid by Medicare (if eligible), other long-term care insurance, or out-of-pocket. Continued facility stays can result in spenddown to MA. A person may also spend-down and become eligible for Medicaid while enrolled in Alternative Care. In

that case, he/she can also transition to the Elderly Waiver. For details on how a person transitions from Alternative Care to Elderly Waiver program, refer to the “AC Operational Protocol”.

The Alternative Care program provides an array of home and community-based services based on assessed need and as authorized in the community support plan or care plan developed for each participant. The monthly cost of the Alternative Care services must not exceed 75 percent of the monthly budget amount available for an individual with similar assessed needs participating in the Elderly Waiver program.

The services available under Alternative Care are the same as the services covered under the federally approved Elderly Waiver, *except*:

- Alternative Care **does not cover** transitional support services, assisted living (customized living) services, adult foster care services, or services that meet primary and acute health care needs
- Alternative Care **additionally covers** nutrition services and discretionary services

The comprehensive list of Alternative Care services is below.

- Adult day service/adult day service bath;
- Family caregiver training and education and family caregiver coaching and counseling/assessment;
- Case management and conversion case management
- Chore services;
- Companion services;
- Consumer-directed community supports;
- Home health agency services;
- Home-delivered meals;
- Homemaker services;
- Environmental accessibility adaptations;
- Nutrition services;
- Personal care;
- Respite care;
- Skilled nursing and private duty nursing;
- Specialized equipment and supplies including Personal Emergency Response System (PERS);
- Non-medical transportation;
- Tele-home care;
- Discretionary services

An overview of the Alternative Care program, services, and outcomes are provided in Figure 2.

Program Goals

The goals of the Alternative Care program are to:

- Provide access to coverage of home and community-based services for individuals with combined adjusted income and assets higher than Medicaid requirements and who require an institutional level of care.

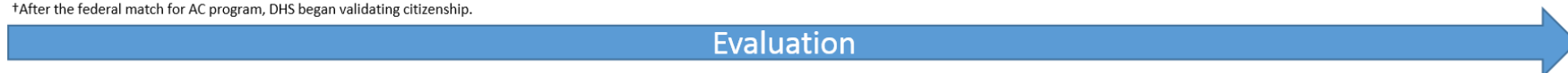
- Provide access to consumer-directed coverage of home and community-based services for individuals with combined adjusted income and assets higher than Medicaid requirements and who require an institutional level of care.
- Provide high-quality and cost-effective home and community-based services that result in improved outcomes for participants measured by less nursing home use over time.

Figure 2: Alternative Care Program Logic Model

Inputs		Outputs		Outcomes	
Resources	Legislative Oversight	Service and Access	Activities	Short-term	Long-term
<ul style="list-style-type: none"> • LTCC/MnChoices assessors • LTC screening assessment to determine whether a person qualifies for nursing facility level of care • Training of staff (e.g. case managers, assessors) • Continuing training (e.g. bulletins, webinars, video conferencing) • Legislative authority • State funding • DHS administrative resources • Local HCBS provider networks • External evaluators and volunteers to survey AC beneficiaries 	<p>Policy Changes</p> <ul style="list-style-type: none"> • Changes in financial eligibility determination • Changes in program fees • Changes in covered services • Changes in provider standards <p>Budget Changes</p> <ul style="list-style-type: none"> • Rate changes 	<p>Accessed in the person's home and community</p> <p>Covered Services</p> <ul style="list-style-type: none"> • Adult Day service • Case management • Chore services • Companion services • Consumer-directed community supports • Home health aides • Home-delivered meals • Homemaker services • Changes to make homes and equipment accessible • Nutrition services • Personal care • Respite care • Skilled nursing • Specialized equipment/supplies • Personal emergency response system • Training and support for family caregivers • Nonmedical transportation • Discretionary services 	<p>State-level</p> <ul style="list-style-type: none"> • Monitoring spending at a county-level* • Monitor AC enrollment and program spending • Issue policies, guidance, and resources • On-site lead agency review of cases every 3 years to assure program compliance • Further develop a HCBS provider network • Add/remove/redesign services per stakeholder feedback • Facilitate participant feedback surveys <p>County-level</p> <ul style="list-style-type: none"> • Assess program eligibility • Determine financial eligibility (includes citizenship validation) † • Develop a support plan to meet assessed needs • Authorize services • Monitor implementation of the support plan • Feedback to DHS on barriers to AC use <p>Provider-level</p> <ul style="list-style-type: none"> • Support the person through provision of services 	<p>Program Beneficiaries</p> <ul style="list-style-type: none"> • Able to live in their homes and communities with necessary supports • Direct their services and supports <p>State-level</p> <ul style="list-style-type: none"> • Collect and internally analyze AC enrollment across time 	<p>Program Beneficiaries</p> <ul style="list-style-type: none"> • Prevent and delay transitions to a nursing facility • Prevent seniors from spending down their assets • Increase the quality-of-life of seniors by spending more time in the community with their family and friends <p>State-level</p> <ul style="list-style-type: none"> • Save Medicaid dollars • Change in expectations about the state's ability to serve older adults in the community rather than in institutions • Rebalancing of public dollars away from institutions and toward HCBS for older adults • Continued AC funding

*Minnesota DHS stopped monitoring county spending on AC program at the 2015 legislative session.

†After the federal match for AC program, DHS began validating citizenship.



Evaluation Questions and Hypotheses

The Reform 2020 demonstration waiver extension is approved for the period February 1, 2020 through January 31, 2025. Since the federal waiver authorization has not resulted in any substantial changes to the Alternative Care program structure, we expect that key evaluation metrics will not change over the extension period (2020–2025) as a result of the continuation of the AC waiver. We will be testing the null hypotheses of no change attributable to the AC waiver extension. We will test these null hypotheses by tracking trends in service use and outcomes and drawing comparisons with a matched sample of EW participants who presumably will be subject to the same external events, such as COVID-19, as AC participants.

We plan to assess the following hypotheses.

As a consequence of the AC Waiver extension from 2020-2025:

- The demographic characteristics and service needs of AC participants will not change.
- AC participants will not experience a change in the types of HCBS services or a decrease in the intensity of services, i.e., number of hours or units of service.
- AC participants will experience equal or better access to consumer-directed service options;
- AC participants will not experience an increase in nursing facility use;
- AC participants will not experience an increase in acute events, as indicated by an increase in acute hospitalizations or emergency department visits; and

The rate of Medicaid conversion for AC participants through transitions between AC and EW and other waiver programs or nursing home use will not increase.

We must consider the possibility of changes occurring in these metrics due to external events outside of the AC waiver itself. These events could influence access to or use of HCBS or other services or change health status over the extension period. For example, the COVID-19 pandemic is an external event that has likely influenced service use patterns and outcomes in 2020-2021 and it may continue to do so in the future. The evaluation design, therefore, should attempt to separate out changes over time due to the AC Waiver from those attributable to COVID-19 or other external events.⁶

To strengthen the evaluation design, we propose to examine trends over a five year period prior to the waiver (2015-2019) as a backdrop to the trends during the extension period. In addition, we will compare the AC participants with a balanced sample of Elderly Waiver participants. By examining past trends, we can estimate the impact of COVID-19 or other identifiable external events, such as HCBS policy changes. We anticipate some disruption of HCBS, acute care, and other service use. In the period 2021-2025, some changes associated with the COVID-19 pandemic may continue. By selecting an EW comparison group that is similar to AC participants in demographics, need, and access to services, we can check for parallel trends and perform difference in difference calculations in an attempt to isolate waiver-related changes from COVID-19

⁶ Available at <https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/1115-covid19-implications.pdf>

or other external events. If AC and EW participants follow the same patterns of HCBS or other service use disruption during or after the COVID-19 pandemic, we have a stronger basis for inferring that it was COVID-19 rather than the AC waiver that contributed to these changes. Given data limitations and the complexity of events during and after COVID-19, we must be cautious in our interpretations of patterns in the data.

Methodology

To test these hypotheses, we will employ multiple strategies: (1) examine trends in repeated 12-month cross-sectional measures of demographics, service use and other patterns for AC participants beginning with the baseline period (2015-2019) and continuing through the extension period (i.e., 2020-2025); (2) conduct a parallel cross-sectional analysis for a comparison groups of EW participants selected through balanced sampling; (3) track patterns in key metrics for longitudinal cohorts of AC participants and EW participants beginning in 2019, 2020, and 2021 and then followed through 2025. In conducting the trend and cohort analyses, we will look for changes in service use and other metrics, particularly any unintended consequences for program participants that could be attributable to the AC waiver compared to external events such as COVID-19.

Comparison of AC Participants and EW Sample

The populations included in the evaluation consist of Alternative Care (AC) program participants and Elderly Waiver (EW) participants. Elderly Waiver participants are similar to Alternative Care program participants. Both groups: 1) are aged 65 and above, 2) must have an assessed need for an institutional level of care, and 3) are using home and community-based services to meet their needs and remain living in the community instead of in a nursing facility.

Some EW participants will use residential services (i.e., customized living, adult foster care). We will identify EW participants in non-residential settings by excluding participants with any claims for residential services. Internal program monitoring and evaluation show that the number of unique participants in AC remained relatively constant from 3,679 in 2015 to 3,652 in 2018; whereas the number of EW participants in non-residential settings increased somewhat from 19,934 in 2015 to 22,042 in 2018.⁷

We will select a comparison group of EW participants according to balance sampling techniques in order to ensure that the EW comparison group is as similar as possible to the AC participants in demographics, health, and functioning.

⁷ Evaluation of Minnesota's Reform 2020 Section 1115 Demonstration Waiver

Alternative Care Program. Minnesota Department of Human Services, June 2021.

Metrics Aligned with Hypotheses

Hypothesis 1. The demographic characteristics and service needs of AC participants will not change.

- Gender, race/ethnicity, age composition, living arrangement, and residential location
- Case mix status (low-need vs. high-need)⁸
- Professional recommendations for service need and supports
- ADL dependencies
- Health status – major diagnoses

Hypothesis 2. AC participants will not experience a change in the types of HCBS services or a decrease in the intensity of services, i.e., number of hours or units of service.

- Prevalence of HCBS waiver services
- Prevalence of state-plan LTSS services, e.g., PCA
- Hours/units of HCBS waiver services
- Hours/units of state-plan services, e.g., PCA

Hypothesis 3. AC participants will experience equal or better access to consumer-directed service options.

- Prevalence of authorized consumer-directed community supports
- Number of units/hours of consumer-directed community supports

Hypothesis 4. AC participants will not experience an increase in nursing facility use.

- Proportion of participant days spent in nursing facilities
- Frequency of nursing facility admission, by length of stay
- Case mix adjusted nursing facility admission
- Number of nursing facility days
- Return or new use of AC or Elderly Waiver programs after discharge from nursing facility

Hypothesis 5. AC participants will not experience an increase in acute events, as indicated by an increase in acute hospitalizations or emergency department visits.

- Rate of acute inpatient admissions
- Rate of ED visits
- Mortality rate

Hypothesis 6. The rate of Medicaid conversion for AC participants through transitions between AC and EW and other waiver programs or nursing home use will not increase.

- AC participants converting to Medicaid

⁸ See section 2.42 for details on case mix is determined and level of need is defined.

- Transition from AC to EW or other HCBS waiver program
- AC participant transition to Essential Community Supports⁹
- Days alive in the community and not on Medicaid

Data Sources and Variable Construction

Data Sources

MMIS

Medicaid Management Information Systems (MMIS) is the largest health care payment system in Minnesota. Health care providers, county staff, and DHS administration uses the MMIS to pay the medical bills and managed care payments for over 525,000 Minnesotans enrolled in Minnesota Health Care Programs. The MMIS contains both fee-for-service claims and data on use of services by individuals enrolled in managed care plans. The following types of data will be used for the current evaluation:

- Program begin and end date
- Claims for HCBS and other services
- Death date
- Demographics
- In residential or non-residential setting

LTC Screening Document

This form is used to document pre-admission screening and long-term care consultation (LTC)

activities. It is used to record public programs eligibility determination as well as to collect information about people screened, assessed, or receiving services under home and community-based services programs. These assessments contain the following variables that will be used for the current evaluation:

- Program type (i.e., indicates waived program, change to another waived program)
- Entry and exit from waived programs (including death) and exit reasons
- Continued use of waived program at reassessment
- Case mix
- Health functions (e.g. activities of daily living (ADLs))
- Level of care
- Housing type (e.g. nursing facility, assisted living, foster care)

⁹ The Essential Community Supports Program (ECS) program was established by the Minnesota Legislature and became effective January 1, 2015. Initially designed to provide support for individuals who might lose their HCBS program eligibility as a result of changes to the nursing facility level of care criteria that also became effective January 1, 2015, it was also adopted as an ongoing program for individuals aged 65 and older with emerging needs for HCBS but who do not yet meet level of care criteria and who are not MA eligible but meet the AC financial eligibility criteria. This program has a relatively small basket of services and monthly budget.

- Authorization of CDCS services

Minimum Data Set (MDS)

This is a federally mandated assessment. Nursing facilities conduct the MDS assessment on each resident and transmit that data to the Minnesota Department of Health (MDH). Case mix related functions are conducted by the MDH on behalf of the Medicaid program under contract to the DHS (the Medicaid Agency). The MDH determines the resident's case mix classification based on the MDS data and also conducts regular audits of the MDS data submitted by NFs to ensure the data is accurate. These assessments contain the following variables that will be used for the current evaluation:

- Admission and discharge date
- Admission source (e.g., acute and primary care or community) and discharge destination (e.g. acute and primary care transfer, community, or mortality)
- Post-acute Medicare stay, either alone or in combination with a subsequent long stay.
- Health and functional status at admission and the latest assessment before discharge back to the community, if applicable.

Medicare Data

Medicare claims will provide utilization for non-Medicaid-covered services (particularly for AC participants or for periods when a participant is not covered by Medicaid), but otherwise will largely duplicate what we can learn from MMIS. Medicare files will be requested for persons age 65+ who were enrolled in Medicaid or AC (from existing MMIS) and anyone using skilled nursing facilities (from MDS). The MBSF and MedPAR files will provide sufficient information for the outcome variables.

- Dates of acute hospital stays and emergency department visits
- Utilization outside of periods of Medicaid eligibility or for services not covered by Medicaid
- Associated diagnoses and procedure codes
- Date of death
- Special Variable Construction
- Case mix

Case mix is a classification tool that is used in both AC and EW programs to establish monthly budget limits for HCBS services. A copy of the Case Mix Classification Worksheet describing the factors used to determine a case mix classification for all AC and EW participants is at <https://edocs.dhs.state.mn.us/lfsrserver/Public/DHS-3428B-ENG>. The classification is based on assessed need in:

- Eight activities of daily living (ADLs): bathing, dressing, grooming, walking, toileting, positioning, transferring, and eating
- The need for clinical monitoring in combination with a physician-ordered treatment, and
- The need for staff intervention due to behavioral or cognitive needs.

After assessment, the individual is assigned a case mix classification of A-L based on their combination of ADLs, clinical monitoring and behavioral/cognitive needs.¹⁰

Level of Need

For purposes of this evaluation, the case mix classifications have been grouped as follows:

- Low Need (A, L): This group includes individuals with 0-3 ADL dependencies
- Moderate Need (B, D, E): This group includes individuals with 4-6 ADL dependencies and/or behavioral/cognitive needs.
- High Need (G, H, I, J): This group includes individuals with dependencies in 7 or 8 ADLs (G), and those with specific other needs in combination with 7-8 ADL dependencies.
- High Need Clinical (C, F, K, V): This group includes individuals with varying number of dependencies but who have an assessed need for clinical monitoring at least once every 8 hours.

Analytic Methods

We propose the following methods to address the hypotheses for the evaluation. The sections below provide information about each approach, including the comparison group(s), metrics, and statistical methods.

Data Set Development

The cross-sectional data sets will be developed by assembling data each calendar year from 2015-2025 for AC and EW participants, constructing all relevant variables, and sample balancing matching to select the EW participant sample.

For each calendar year, we will identify AC and Elderly Waiver participants using LTC screening assessment data (also available in MMIS). We will further identify Elderly Waiver participants in non-residential settings by excluding participants with any claims for procedure codes denoting residential services (i.e., customized living, adult foster care, and residential care services). While living in the community, if an AC participant uses CDCS, this information will be recorded in the MMIS claims data, as well as the total dollars paid for CDCS in a fiscal year. We will categorize acuity into two categories: low-need and high-need and calculate differences in case mix for each year between AC and Elderly Waiver participants by acuity type.

The cohort data sets will consist of participants selected from the cross-sectional data sets in 2019-2021. Longitudinal data will be assembled for three participant cohorts from the beginning cohort year (2019, 2020, or 2021) through 2025. Although the cross-sectional and cohort samples will be separated analytically, the data sets will have overlapping participants who were receiving waived services in more than one year.

¹⁰ EW also has a case mix V for people who are vent dependent

Comparison Sample Selection

We will employ a sample balancing methodology to select samples of EW participants that match as close as possible on key characteristics of the AC participants.¹¹ Predictor variables include gender, race/ethnicity, age composition, living arrangement, and residential location, case mix status (low-need vs. high-need), professional recommendations for service need and supports, ADL dependencies, and health status and major diagnoses.

The matching sample with the minimum total difference (Mahalanobis distance) will be used for the analysis.¹² Individual characteristics will be compared between the pseudo control and assisted groups and tested for significant differences ($P < 0.05$) with t-tests and Fisher's exact test.

Repeated Cross-Sectional Analysis

In the first step in the analysis, we will compare annual cross-sections of AC participants to the matched samples of EW participants. We will calculate the proportions and intensity (hours or units) of HCBS other Medicaid services. We will also count the number of acute care episodes and nursing home admissions. We will calculate the proportion of individuals that remain enrolled in AC, those that switched to Elderly Waiver, and the days alive in the community and not on Medicaid (i.e., not using residential services). We will also account for death and loss of AC eligibility.

For all measures, we will report the denominator, number and percent of participants, and person months in each service category, program category, and care setting. We will test the difference in proportions and means between AC and EW participants in each year, as well as differences between years. We will apply t-tests or Z-tests to test for differences in means and proportions. We will also test for differences in trends in service use over time with generalized estimating equations (GEE).¹³

Cohort Analysis

Patterns in outcomes (e.g., transitions between program statuses or care settings) for AC and EW participants in the three cohorts (2019, 2020, 2021) will be visualized with time plots. Separate Cox-proportional hazard models were used to test for differences in the time to event. Variables causing a violation of the proportional hazards assumption will be removed. Multilevel or mixed effect growth models will be used to evaluate HCBS and other service utilization. The models will be calendar quarter time periods from 2019 – 2021. Service use will be the outcome. Calendar quarter, AC participation, and interaction between quarter and AC participation will be fixed effects.

¹¹ Deville, J. C., & Tillé, Y. (2004). Efficient balanced sampling: the cube method. *Biometrika*, 91(4), 893-912.

¹² Rosenbaum, P. R. (1989). Optimal Matching for Observational Studies. *Journal of the American Statistical Association*, 84(408), 1024-1032.

¹³ Hardin JW, Hilbe JM (2003) Generalized estimating equations. Boca Raton: CRC Press.

Table 1. Design Table for the Evaluation of the Demonstration

Research Question	Outcome measure used to address the research question	Data Sources	Sample or population	Analytic Methods
Hypothesis 1. The demographic characteristics and service needs of AC participants will not change				
1a. What are demographic characteristics of people who use the AC waiver?	<ul style="list-style-type: none"> - Gender, race/ethnicity, age composition, living arrangement, and residential location 	<ul style="list-style-type: none"> - MMIS - LTC assessment 	Recipients who are eligible for either Alternative Care (AC) or Elderly Waiver (EW)	<ul style="list-style-type: none"> - Multiple cross-section comparisons - Descriptive statistics - Chi-square test/Fishers exact test
1b. What are the service needs of people who use the AC waiver?	<ul style="list-style-type: none"> - Case mix status (low-need vs. high-need)¹⁴ - Professional recommendations for service need and supports - ADL dependencies - Health status – major diagnoses 	<ul style="list-style-type: none"> - LTC Screening Document - MMIS 	<p>Recipients who are eligible for either Alternative Care (AC) or Elderly Waiver (EW)</p> <p>AC compared to all EW participants and to EW sample matched to AC on demographics</p>	<ul style="list-style-type: none"> - Multiple cross-section comparisons for successive years - Descriptive statistics - Chi-square test/Fishers exact test - Regression models with service need as an outcome, controlling for demographics

¹⁴ See section 2.42 for details on case mix is determined and level of need is defined.

Research Question	Outcome measure used to address the research question	Data Sources	Sample or population	Analytic Methods
<p>Hypothesis 2. AC participants will not experience a change in the types of HCBS services or a decrease in the intensity of services, i.e., number of hours or units of service.</p>				
<p>2a. What are the types of services used by AC participants?</p>	<ul style="list-style-type: none"> - Prevalence of HCBS waiver services - Prevalence of state-plan LTSS services, e.g., PCA 	<ul style="list-style-type: none"> - MMIS 	<p>Recipients who are eligible for either Alternative Care (AC) or Elderly Waiver (EW)</p> <p>AC compared to all EW participants and to EW sample matched to AC on demographics and service need</p>	<ul style="list-style-type: none"> - Multiple cross-section comparisons for successive years - Descriptive statistics - Chi-square test/Fishers exact test - Regression models with service use as an outcome, controlling for demographics and service need
<p>2b. What is the intensity of services used by AC participants?</p>	<ul style="list-style-type: none"> - Hours/units of HCBS waiver services - Hours/units of state-plan services, e.g., PCA 	<ul style="list-style-type: none"> - MMIS 	<p>Recipients who are eligible for either Alternative Care (AC) or Elderly Waiver (EW)</p> <p>AC compared to all EW participants and to EW sample matched to AC on demographics and service need</p>	<ul style="list-style-type: none"> - Multiple cross-section comparisons for successive years - Descriptive statistics - t-tests - Regression models with service intensity as an outcome controlling for demographics and service need

Research Question	Outcome measure used to address the research question	Data Sources	Sample or population	Analytic Methods
Hypothesis 3. AC participants will experience equal or better access to consumer-directed service options.				
3a. What is the utilization of consumer-directed support (CDCS) options for AC waiver participants?	<ul style="list-style-type: none"> Prevalence of authorized consumer-directed community supports Number of units/hours of consumer-directed community supports 	- MMIS	<p>Recipients who are eligible for either Alternative Care (AC) or Elderly Waiver (EW)</p> <p>AC compared to all EW participants and to EW sample matched to AC on demographics and service need</p>	<ul style="list-style-type: none"> - Multiple cross-section comparisons for successive years - Descriptive statistics - t-tests - Regression models with CDCS use as an outcome controlling for demographics and service need
Hypothesis 4. AC participants will not experience an increase in nursing facility use.				
4a. What are the utilization trends in nursing facility use?	<ul style="list-style-type: none"> - Time to nursing home use - Proportion of participant days spent in nursing facilities - Frequency of nursing facility admission, by length of stay - Case mix adjusted nursing facility admission - Number of nursing facility days - Return or new use of AC or Elderly Waiver programs after discharge from nursing facility 	MDS, MMIS	<p>Recipients who are eligible for either Alternative Care (AC) or Elderly Waiver (EW)</p> <p>AC compared to all EW participants and to EW sample matched to AC on demographics and service need</p> <p>AC and EW longitudinal cohorts consisting of current and new participants in 2019, 2020, and 2021 through 2025.</p>	<ul style="list-style-type: none"> - Multiple cross-section comparisons for successive years - Descriptive statistics - Chi-square/Fishers exact test, t-tests - Regression models with NH use as an outcome controlling for demographics and service need - Time-to-event models (e.g., Cox proportional hazard)

Research Question	Outcome measure used to address the research question	Data Sources	Sample or population	Analytic Methods
<p>Hypothesis 5. AC participants will not experience an increase in acute events, as indicated by an increase in acute hospitalizations or emergency department visits.</p>				
<p>5a. What is the rate of acute events of people participating in AC waiver?</p>	<ul style="list-style-type: none"> - Rate of acute inpatient admissions - Rate of ED visits - Mortality rate 	<ul style="list-style-type: none"> - MMIS - Medicare data 	<p>Multiple cross-sections of people who are eligible for either Alternative Care (AC) or Elderly Waiver (EW)</p> <p>AC compared to all EW participants and to EW sample matched to AC on demographics and service need</p> <p>AC and EW longitudinal cohorts consisting of current and new participants in 2019, 2020, and 2021 through 2025.</p>	<ul style="list-style-type: none"> - Multiple cross-section comparisons for successive years - Descriptive statistics - Chi-square/Fishers exact test, t-tests - Cross-sectional regression and growth models controlling for demographics and service need - Time-to-event models (e.g., Cox proportional hazard)
<p>Hypothesis 6. The rate of Medicaid conversion for AC participants through transitions between AC and EW and other waiver programs or nursing home use will not increase.</p>				
<p>6a. What are the trends of Medicaid conversion for AC participants through transitions to EW, other waiver use, or nursing home use?</p>	<ul style="list-style-type: none"> - Time to conversion - AC participants converting to Medicaid - Transition from AC to EW or other HCBS waiver program - AC participant transition to Essential Community Supports - Days alive in the community and not on Medicaid 	<ul style="list-style-type: none"> - MMIS - Medicare data 	<p>Multiple cross-sections of people who are eligible for Alternative Care (AC)</p> <p>AC longitudinal cohorts consisting of current and new AC participants in 2019, 2020, and 2021 - 2025.</p>	<ul style="list-style-type: none"> - Multiple cross-section comparisons for successive years - Descriptive statistics - Cross-sectional regression models - Time-to-event models (e.g., Cox proportional hazard)

Methodological Limitations

Establishing a Baseline

Prior Alternative Care Evaluation reports have chosen the period prior to the introduction of the waiver (2010-2013) as the pre-waiver baseline, while 2014-2017 served as the implementation period after the waiver. The AC program underwent significant changes, as did the Elderly Waiver program over these years. However, we found no evidence that these changes occurred because of the waiver. There were other external events, such as policy, programmatic, and demographic changes) that affected the program. The evaluation of the waiver extension will involve a baseline period of 2015-2019 and an evaluation period from 2020-2025. We selected this baseline for the extension period in order to estimate trends prior to the extension period, while avoiding a baseline that is too lengthy and where major policy changes had occurred, such as the change in the nursing facility level of care criteria at the end of 2014.

Selecting a Comparison Population

The Elderly Waiver population serves as a comparator for Alternative Care in most of the analysis. EW participants differ significantly from AC participants in some respects. Controlling statistically for these differences would strengthen the evaluation design. A sample balancing methodology will be used in order that the EW comparison group is as similar as possible to the AC participants in demographics, health, and functioning. Consideration will be given to characteristics and matching techniques for this population throughout the baseline and extension periods.

External Events – COVID-19

The COVID-19 public health emergency is likely to have had an impact on service needs and use of care for the AC population at the beginning of the extension period and perhaps continuing throughout the period. We will address this and other potential confounders by conducting a trend analysis for a period prior to COVID-19 and extending beyond the pandemic, assuming hopefully that it is nearing an end in mid-2021. Additionally, the EW participant comparison group will be employed as an indicator of the COVID-19 effect.=

Cautious Generalization

We must exercise caution in the interpretation of our findings because of the strong possibility of unmeasured events or policy changes and the difficulty of inferring causality from our observational, quasi-experimental design.

Attachments

Please see the following attachments for additional information:

1. Independent Evaluator
2. Evaluation Budget
3. Timeline and Major Milestones

Attachment 1. Independent Evaluator

Since May 2016, the Minnesota Department of Human Services has had a Professional/Technical Contract with the University of Minnesota to conduct the evaluation of the Alternative Care demonstration waiver. According to Minn. Stat. 16C.06 Subd. 3b(b), the combined length of a contract and amendments cannot exceed five years, unless approved by the Commissioners of the Department of Administration and Minnesota Management and Budget. DHS has approval to continue this contract with the University of Minnesota beginning July 1, 2021.

The contract between DHS and the University details the services to be performed during the contract period, a description of deliverables, such as reports, their due date, and amount to be paid for each deliverable. It also specifies the total payment obligation for all compensation and reimbursements to the University under this contract.

In addition, this contract details information privacy and security obligations in a Data Sharing Agreement and Business Associate Agreement Terms and Conditions. This covers all Protected Health Information and non-public information under the Minnesota Government Data Practices Act that is shared between the state and University. This outlines the protected data to be shared and responsibilities in the case of a breach.

Independent Capacity: This contract is between the State of Minnesota and the Regents of the University of Minnesota, an independent contractor, not an employee of the State of Minnesota. The contract certification form specifies that a contract shall not establish an employment relationship between the state or the agency performing work under the contract. The contractor and agency must not be employees of the state. Minnesota Professional Technical contracts also certify that the contractors' employees and agents will not be considered employees of the state. Any claims that may arise under the Minnesota Workers' Compensation Act on behalf of these employees or agents are in no way the state's obligation or responsibility. By the terms of the contract the University certifies that it has liability insurance. Each party shall be responsible for claims, losses, damages and expenses which are proximately caused by wrongful or negligent acts or omissions of that party or its agents, employees or representatives acting within the scope of their duties. The liability of each party is as set out in chapter 3.736 of the Minnesota Statutes and subject to the limitations therein.

Attachment 2. Evaluation Budget

Below are the proposed tasks, staffing, and costs for the evaluation budget. The budget is based on estimated costs incurred by the State of Minnesota in the form of staff time and a contract with an external evaluator who will conduct the analysis.

Evaluation Budget Tasks

Project Management and Consultation: The external evaluator and State of Minnesota will participate in bi-monthly meetings, and additional consultation via email, phone calls, and other methods as needed to support the research and evaluation activities. This includes support to administer the contract and provide subject matter expertise on policies, processes, and data needed to develop, implement, and interpret analytic models. In addition, presentations and summaries are expected to be used for ongoing monitoring of the evaluation. The State of Minnesota expects to dedicate 0.2 FTE of a program evaluation specialist, 0.1 FTE of a research and analysis supervisor, and 0.05 FTE of a research and analysis manager to this work each year.

Contract Deliverables: The external evaluation contract is expected to include annual deliverables, such as implementing an updated evaluation plan, annual analyses, and the interim and summative evaluation reports due Feb. 2024 and July 2026. It also includes the cost of Medicare data as made available to the University by CMS. Projections are estimated based on deliverable costs for the previous five year waiver reporting period.

Annual Costs

The table below reflects annual costs during the waiver reporting period. These include a 3% annual adjustment to account for inflationary cost increases.

	2020	2021	2022	2023	2024	2025	2026
Project Management & Consultation	\$44,079	\$ 45,401	\$ 46,763	\$48,166	\$49,611	\$51,100	\$52,633
Contract Deliverables		\$ 45,085	\$ 54,546	\$61,800	\$57,819	\$59,553	\$67,474
Total	\$44,079	\$ 90,486	\$ 101,309	\$ 109,967	\$ 107,430	\$ 110,653	\$120,106

Attachment 3. Timeline and Major Milestones

This demonstration approved period is from February 1, 2020 through January 31, 2025. The table below displays the timeline for the deliverables for the demonstration period including who is responsible.

Deliverable	Responsible Party (from to)	Date
Draft Evaluation Design Plan	State to CMS	Within 120 days after the approval of the demonstration extension (July 30, 2020)
Final Evaluation Plan	State to CMS	Within 60 days following receipt of CMS comments on Draft Evaluation Design Plan
Annual internal report to DHS from independent evaluator	Independent Evaluator to DHS	June of each year during demonstration
Interim Evaluation Report	Independent Evaluator to DHS	June 2023
Final evaluation report	Independent Evaluator to DHS	Within 12 months following the end of the demonstration extension period
Draft Summative Evaluation Report	State to CMS	Within 18 months following the end of the demonstration extension period
Final Summative Report	State to CMS	Within 60 days of receipt of CMS comments