

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850



State Demonstrations Group

June 25, 2025

Michelle Probert
Director, Office of MaineCare Services
Maine Department of Health and Human Services
109 Capitol Street
Augusta, Maine 04333-0011

Dear Director Probert:

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

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

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

Updates to Demonstration Monitoring

Below are the updated aspects of demonstration monitoring for the Maine Medicaid Section 1115 Health Care Reform Demonstration for Individuals with HIV/AIDS (Project Number 11-W-00128/1) demonstration.

Reporting Cadence and Due Date

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

with the Maine Medicaid Section 1115 Health Care Reform Demonstration for Individuals with HIV/AIDS STCs, CMS is retaining the cadence of annual monitoring reporting for this demonstration (see also section 1115(d)(2)(D)-(E) of the Act). However, CMS is extending the due date of the annual monitoring report from 90 days to 180 days after the end of each demonstration year to balance Medicaid claims completeness with the state's work to draft, review, and submit the report timely.

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

The next annual monitoring report for the Maine Medicaid Section 1115 Health Care Reform Demonstration for Individuals with HIV/AIDS will be due on June 29, 2026, which reflects the first business day following 180 calendar days after the end of the current demonstration year. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect the new reporting cadence and due date.

Structured Monitoring Report Template

As noted in STC 27, "Monitoring Reports," monitoring reports "must follow the framework provided by CMS, which is subject to change as monitoring systems are developed and/or evolve, and will be provided in a structured manner that supports federal tracking and analysis." Pursuant to that STC, CMS is introducing a structured monitoring report template to minimize variation in content of reports across states, which will facilitate drawing conclusions over time and across demonstrations with broadly similar section 1115 waivers or expenditure authorities. The structured reporting framework will also provide CMS and the state opportunities for more comprehensive and instructive engagement on the report's content to identify potential risks and vulnerabilities and associated mitigation efforts as well as best practices, thus strengthening the overall integrity of demonstration monitoring.

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

Demonstration Monitoring Calls

As STC 30 "Monitoring Calls" describes, CMS may "convene periodic conference calls with the state," and the calls are intended "to discuss ongoing demonstration operation, to include (but not limited to) any significant actual or anticipated developments affecting the demonstration." Going forward, CMS envisions implementing a structured format for monitoring calls to provide consistency in content and frequency of demonstration monitoring calls across demonstrations.

CMS also envisions convening quarterly monitoring calls with the state and will follow the structure and topics in the monitoring report template. We anticipate that standardizing the expectations for and content of the calls will result in more meaningful discussion and timely assessment of demonstration risks, vulnerabilities, and opportunities for intervention. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect that monitoring calls will be held no less frequently than quarterly.

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

In the coming weeks, CMS will reach out to schedule a transition meeting to review templates and timelines outlined above. As noted above, the pertinent Maine Medicaid Section 1115 Health Care Reform Demonstration for Individuals with HIV/AIDS STCs will be updated in the next demonstration amendment or extension approval to reflect these updates.

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

Sincerely,



Karen LLanos
Action Director

Enclosure

cc: Gilson DaSilva, State Monitoring Lead, Medicaid and CHIP Operations Group

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

NUMBER: 11-W-00128/1

TITLE: Maine Medicaid Section 1115 Health Care Reform Demonstration for Individuals with HIV/AIDS

AWARDEE: Office of MaineCare Services (OMS)

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Maine 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.

The following expenditure authority shall enable Maine to implement the Maine section 1115 demonstration for individuals with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS). Except as identified below as not applicable to the demonstration expenditures, all Medicaid requirements will apply.

- 1. Demonstration Population 2 (“Enrollees”)** Expenditures for medical assistance for individuals who do not meet the eligibility requirements of MaineCare, but who are HIV-positive and are at or below 250 percent of the federal poverty level.
- 2. Disease Management Services:** Expenditures for case management services that coordinate care and services related to HIV/AIDS that are not otherwise available under the state plan.

Requirements Not Applicable to the Demonstration Expenditures:

1. Section 1902(a)(10) of the Act -- Benefit Package Requirements:

To the extent necessary to enable the state to provide only a targeted benefit to demonstration population 2, which may not include all required benefits available to state plan populations.

2. Section 1902(a)(14) of the Act -- Premiums and Cost Sharing:

To the extent necessary to permit the state to impose premiums or cost sharing upon demonstration population 2.

3. Section 1902(a)(43) of the Act -- Early and Periodic Screening Diagnosis and Treatment (EPSDT) Services

To the extent necessary to permit the state to limit the provision of EPSDT services for demonstration population 2 to examinations and other services included in the targeted benefit package.

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

NUMBER: **11-W-00128/1**

TITLE: **Maine Medicaid Section 1115 Health Care Reform Demonstration for
Individuals with HIV/AIDS**

AWARDEE: **Office of MaineCare Services (OMS)**

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived in this list, shall apply to MaineCare members, as described for the demonstration project, beginning April 19, 2019, through December 31, 2028.

The following waivers shall enable Maine to implement the section 1115 demonstration for MaineCare members with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS).

1. Amount, Duration, and Scope of Services Section 1902(a)(10)(B)

To enable Maine to offer additional benefits to MaineCare members than are being otherwise offered under the Medicaid state plan.

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

NUMBER: 11-W-00128/1

TITLE: Maine Medicaid Section 1115 Health Care Reform Demonstration for Individuals with HIV/AIDS

AWARDEE: Office of MaineCare Services (OMS)

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the “Maine Medicaid Section 1115 Health Care Reform Demonstration for Individuals with HIV/AIDS” section 1115(a) Medicaid demonstration (hereinafter “demonstration”) to enable the Maine Department of Health and Human Services (“DHHS”) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted the state waiver and expenditure authorities authorizing federal matching of demonstration costs that are not otherwise matchable, and which are separately enumerated. These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state’s obligations to CMS related to this demonstration. The “Maine Medicaid Section 1115 Health Care Reform Demonstration for Individuals with HIV/AIDS” demonstration will be statewide and is approved for a 10-year period, from April 19, 2019 through December 31, 2028.

The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description And Objectives
- III. General Program Requirements
- IV. Eligibility, Benefits, and Enrollment
- V. Cost Sharing
- VI. Delivery Systems
- VII. General Reporting Requirements
- VIII. Evaluation of the Demonstration
- IX. General Financial Requirements Under Title XIX
- X. Monitoring Budget Neutrality for the Demonstration

Attachment A: Developing the Evaluation Design

Attachment B: Preparing the Evaluation Report

Attachment C: Evaluation Design (reserved)

II. PROGRAM DESCRIPTION AND OBJECTIVES

This section 1115(a) demonstration expands access to individuals with HIV/AIDS and provides a targeted benefits package through the demonstration without having to spend down income or resources. The demonstration is designed to provide more effective, early treatment of HIV disease by making available a limited but comprehensive package of services, including anti-retroviral therapies.

The state believes that early treatment and case management services provided to individuals with HIV/AIDS create efficiencies that allow Medicaid to help individuals maintain access to critical treatments, keeping them from disease progression. The demonstration includes two groups: “Members” who are MaineCare eligibles identified as HIV-positive individuals who are at or below 133 percent of the federal poverty level (FPL); and, “Enrollees” who do not meet the eligibility requirements of MaineCare, but who are HIV-positive and are at or below 250 percent of the FPL.

The state’s goal in implementing the demonstration is to improve the health status of individuals living with HIV/AIDS in Maine by:

- Improving access to continuous health care services;
- Arresting progression of HIV/AIDS status by providing early and optimal care coupled with high quality and cost efficiency; and
- Expanding coverage to additional low-income individuals living with HIV with the savings generated from Disease Prevention and the delayed onset of full-blown AIDS

III. GENERAL PROGRAM REQUIREMENTS

- 1. Compliance with Federal Non-Discrimination Laws.** The state must comply with applicable federal civil rights laws relating to non-discrimination in services and benefits in its programs and activities. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and Section 1557 of the Affordable Care Act (Section 1557). Such compliance includes providing reasonable modifications to individuals with disabilities under the ADA, Section 504, and Section 1557 in eligibility and documentation requirements, to ensure they understand program rules and notices, as well as meeting other program requirements necessary to obtain and maintain benefits.
- 2. Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program, expressed in federal law, regulation, and written policy, not expressly identified as not applicable in the expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

- 3. Changes in Medicaid Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid programs that occur during this demonstration approval period, unless the provision being changed is expressly waived. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes of an operational nature without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 calendar days in advance of the expected approval date of the amended STCs to allow the state to provide comment.
- 4. Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
- a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration to comply with such change. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
 - b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under federal law, whichever is sooner.
- 5. State Plan Amendments.** The state will not be required to submit title XIX state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan may be required, except as otherwise noted in these STCs. In all such instances, the Medicaid state plan governs.
- 6. Changes Subject to the Amendment Process.** If not otherwise specified in these STCs, changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, 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, 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 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 reports required in the approved STCs and other deliverables in a timely fashion according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:
- a. A detailed description of the amendment including impact on beneficiaries, with sufficient supporting documentation;
 - b. A data analysis worksheet which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include 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 detail projections of the change in the “with waiver” expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
 - c. An explanation of the public process used by the state consistent with the requirements of STC 13; and,
 - d. If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.
- 8. Extension of the Demonstration.** States that intend to request 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 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 42 CFR 431.412(c) or a transition and 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 13, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

- b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its transition and phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.
- c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must 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, 431.211, 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 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 C.F.R. 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). FFP will be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

10. Expiring Demonstration Authority. For demonstration authority that expires prior to the demonstration's expiration date, the state must submit a demonstration authority expiration plan to CMS no later than six months prior to the applicable demonstration authority's expiration date, consistent with the following requirements:

- a. Expiration Requirements. The state must include, at a minimum, in its demonstration authority expiration plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility prior to the termination of the demonstration authority for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities.
- b. Expiration Procedures. The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, 431.211, and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to 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 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).
- c. Federal Public Notice. CMS will conduct a 30-day federal public comment period consistent with the process outlined in 42 CFR 431.416 in order to solicit public input on the state's demonstration authority expiration plan. CMS will consider comments received during the 30-day period during its review of the state's demonstration authority expiration plan. The state must obtain CMS approval of the demonstration authority expiration plan prior to the implementation of the expiration activities. Implementation

of expiration activities must be no sooner than fourteen (14) calendar days after CMS approval of the demonstration authority expiration plan.

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

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

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

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

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

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

14. Federal Financial Participation (FFP). No federal matching for state expenditures under this demonstration, including for administrative and medical assistance expenditures, will be

available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.

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

IV. ELIGIBILITY, BENEFITS, AND ENROLLMENT

The Maine HIV/AIDS demonstration provides a comprehensive set of services to those who are both HIV positive and are at or below 250 percent of the FPL. The demonstration expands access to individuals with HIV/AIDS who are otherwise ineligible for MaineCare; however beneficiaries with other insurance may still receive this benefit. MaineCare may pay premiums/cost-sharing for this insurance according to current MaineCare rules.

16. Eligibility. Mandatory state plan groups described below (“members”) are subject to all applicable Medicaid laws and regulations, except to the extent expressly waived, or listed as not applicable to demonstration expenditures, in the list of waivers and expenditure authorities issued with the award letter for this demonstration.

Those non-Medicaid eligible groups described below (“enrollees”) who are made eligible for the demonstration by virtue of the expenditure authorities expressly granted in this demonstration are subject to Medicaid laws or regulations only as specified in the expenditure authorities for this demonstration.

The eligibility criteria for the HIV/AIDS demonstration for both members and enrollees are as follows:

- Positive HIV status;
- Financially eligible;
- Completed information form related to other insurance, i.e., third party liability (TPL);
- Payment of premiums (if applicable); and
- Willingness to sign informed consent that includes;
 - Understanding of requirements of the benefit; and
 - Willingness to comply with treatment recommendations

| Demonstration Eligibility Groups | Federal Poverty Level (FPL) and qualifying | Eligible Benefit |
|----------------------------------|--|------------------|
|----------------------------------|--|------------------|

| | criteria | |
|---|---|---|
| <u>“Members”</u> State Plan Groups* | HIV-positive individuals below 133 percent of FPL | Full Medicaid benefits offered under the state plan and case management services. |
| <u>“Enrollees”</u> Expansion Populations** | HIV-positive individuals at or below 250 percent of FPL | Targeted benefit |

* These state plan eligible beneficiaries (“Members”) are enrolled in the demonstration for the benefit of enhanced coordination.

** These “Enrollee” eligible beneficiaries are expansion populations who would not otherwise be eligible for medical assistance.

17. Eligibility Exclusions. The following persons are excluded from the HIV/AIDS demonstration.

| |
|---|
| Negative HIV Status |
| Individuals with HIV and income over 250 percent of the FPL |

18. Maine HIV/AIDS Demonstration Benefits. Benefits are based on a disease model with the goal to delay, prevent, and reverse the progression of HIV/AIDS. The HIV/AIDS demonstration benefit is not an entitlement program. It is a disease management program with defined treatment protocols. A candidate for the benefit must agree to be monitored and participate in medical treatment. Participants must meet certain eligibility requirements and must follow treatment recommendations after being determined eligible for the program.

The 1115 HIV/AIDS Participant “Members” receive all of the medically necessary covered MaineCare services, while “Enrollees” receive a targeted essential set of MaineCare services as listed in the chart below. Services may also be provided by a qualified provider employed by a Federally Qualified Health Center, Rural Health Center or Indian Health Center.

The following MaineCare categories of services and respective policies of the MaineCare Benefits Manual (MCBM) are included in the limited benefit for “Enrollees”:

| General Category of Service | Services* |
|-----------------------------|--|
| Inpatient | MCBM Section 45, Hospital Services |
| Psychiatric Facility | MCBM Section 46, Psychiatric Facilities Services |
| Outpatient | MCBM Section 45, Hospital Services |

| General Category of Service | Services* |
|--|--|
| EPSDT Examinations | MCBM Section 94, Early and Periodic Screening, Diagnosis and Treatment Services (EPSDT); Section 90, Physician Services; Examinations: Physician Services |
| Medications | MCBM Section 80, Pharmacy Services |
| Community Support Services | MCBM Section 17, Community Support Services; Section 92, Behavioral Health Home Services |
| Lab & X-ray | MCBM Section 55, Laboratory Services; Section 101, Medical Imaging Services |
| Transportation | MCBM Section 113, Non-Emergency Transportation Services; benefit will only pay for transportation to and from MaineCare covered services; MCBM, Section 5, Ambulance Services |
| Ambulatory Care | MCBM Section 3, Ambulatory Care Clinic Services; Section 4, Ambulatory Surgical Center Services |
| Case Management | MCBM Section 13.03, Targeted Case Management Services |
| Family Planning | MCBM Section 30, Family Planning Agency Services |
| Behavioral Health | MCBM Section 65, Behavioral Health Services (including Psychological Services); Section 92, Behavioral Health Home Services |
| Medicare Crossover-A | MCBM Section 45, Hospital Services |
| STI/STD Testing and Treatment | MCBM Section 30, Family Planning Services; MCBM, Section 90, Physician Services |
| Medicare Crossover-B | MCBM Section 90, Physician Services; Section 31, Federally Qualified Health Center Services; Section 103, Rural Health Clinic Services |
| Physician, Physician Assistant, Advanced Practice Registered Nurse, Certified Nurse Practitioner | MCBM Section 90, Physician Services; MCBM Section 14, Advanced Practice Registered Nurse; Section 91, Health Home Services; Section 31, Federally Qualified Health Center Services; Section 103, Rural Health Clinic Services, and Section 9, Indian Health Services |

| General Category of Service | Services* |
|--|---|
| Services for Children with Intellectual Disability or Autism | MCBM Section 28, Rehabilitative and Community Support Services for Children with Cognitive Impairments and Functional Limitations |
| Development and Behavioral Clinical Services | MCBM Section 23, Developmental and Behavioral Clinic Services |
| Substance Abuse Treatment | MCBM Section 65, Behavioral Health Services |

*All services in the table are found in Chapter II of MCBM unless otherwise specified.

The following MaineCare categories of services and respective policies of the MCBM are **not included** in the “Enrollee” participant benefit package, which are included for the “Member” groups.

| General Category of Service | Services* |
|---|---|
| Adult Family Care | MCBM Section 2, Adult Family Care Services |
| Consumer Directed Attendant | MCBM Section 12, Consumer Directed Attendant Services |
| Home and Community-Based Waiver Services for the Elderly and Adults with Disabilities | MCBM Section 19, Home and Community-Based Waiver Services for the Elderly and for Adults with Disabilities |
| Home and Community Benefits | MCBM Chapter II, Section 21, Home and Community Benefits for Persons with Intellectual Disabilities or Autistic Disorder; Section 29, Support Services for Adults with Intellectual Disabilities or Autistic Disorder; Section 20, Home and Community-Based Services for Adults with Other Related Conditions; Section 18, Home and Community-Based Services for Adults with Brain Injury |
| Private Non-Medical Institution | MCBM Section 97, Private Non-Medical Institution Services |

| General Category of Service | Services* |
|--|--|
| Day Health | MCBM Section 26, Day Health Services |
| Home Health | MCBM Section 40, Home Health Services |
| Hospice | MCBM Section 43, Hospice Services |
| Medical Supplies and Durable Medical Equipment | MCBM Section 60, Medical Supplies and Durable Medical Equipment |
| Nursing Facility | MCBM Section 67, Nursing Facility Services |
| Optician, Optometrist | MCBM Section 75, Vision Services (Ophthalmologist services are covered if the services are provided by a qualified practitioner billing under MCBM Section 90, Physician Services) |
| Physical Therapy | MCBM Section 85, Physical Therapy Services; except when provided by a qualified provider billing under MBM, Section 90, Physician Services, Section 31, Federally Qualified Health Center Services, Section 9, Indian Health Services, or Section 45, Hospital Services |
| Private Duty Nursing and Personal Care | MCBM Section 96, Private Duty Nursing and Personal Care Services |
| Primary Care Case Management | MCBM Chapter VI, Section 1, Primary Care Case Management |
| Speech-Language Pathology | MCBM Section 109, Speech and Hearing Services, except when provided by a qualified provider billing under MCBM, Section 90, Physician Services, Section 31 Federally Qualified Health Center Services, Section 103 Rural Health Clinic Services or Section 45, Hospital Services |
| Speech and Hearing Services and Audiology | MCBM Section 109, Speech and Hearing Services |
| Chiropractic | MCBM Section 15, Chiropractic Services |
| Dental | MCBM Section 25, Dental Services |

| General Category of Service | Services* |
|---|--|
| Intermediate Care Facility for Persons with Intellectual Disability | MCBM Section 50, ICF-ID Services |
| Occupational Therapy | MCBM Section 68, Occupational Therapy Services; except when provided by a qualified provider billing under MCBM, Section 90, Physician Services, Section 31, Federally Qualified Health Center Services, Section 9, Indian Health Services, or Section 45, Hospital Services |
| Dialysis Services | MCBM Section 7, Free-standing Dialysis Services |
| Podiatric | MCBM Section 95, Podiatric Services |
| Rehabilitative Services | MCBM Section 102, Rehabilitative Services |

*All services in the table are found in Chapter II of MCBM unless otherwise specified.

19. Minimum Essential Coverage (MEC). The Maine demonstration is limited to the provision of services as described in STC 18. Consequently, this demonstration is not recognized as Minimum Essential Coverage (MEC) with respect to enrollees, consistent with the guidance set forth in the State Health Official Letter #14-002, issued by CMS on November 7, 2014.

V. COST SHARING

20. Co-payments. Demonstration “Enrollees” pay a co-payment for physician services and pharmaceuticals that is higher than MaineCare “Member” participants. For all other services, “Enrollees” pay the same co-payments as MaineCare “Members” (see table below).

Demonstration Co-Payments

| Services | Demonstration “ <u>Enrollees</u> ” | Demonstration “ <u>Members</u> ” |
|---|---------------------------------------|---|
| Prescription Drugs ^b | \$10.00 | \$3.00, capped at \$30 per month per member |
| Physician Visits | \$10.00 | None |
| Outpatient Hospital Services | \$3.00 | \$3.00 |
| Home Health Services | N/A | \$3.00 |
| Durable Medical Equipment | N/A | \$3.00 |
| Private Duty Nursing and Personal Care Services | N/A | \$3.00 |
| Ambulance Services | \$3.00 | \$3.00 |
| Physical Therapy Services | \$2.00 | \$2.00 |
| Occupational Therapy Services | \$2.00 | \$2.00 |
| Speech Therapy Services | N/A | \$2.00 |
| Podiatry Services | N/A | \$2.00 |
| Psychologist Services | \$2.00 | \$2.00 |
| Chiropractic Services | N/A | \$2.00 |
| Laboratory Services | \$1.00 | \$1.00 |
| Optical Services | N/A | \$2.00 |
| Optometric Services | N/A | \$3.00 |
| Mental Health Clinic Services | \$2.00 | \$2.00 |
| Substance Abuse Services | \$2.00 | \$2.00 |
| Hospital Inpatient Services | \$3.00 per patient day | \$3.00 per patient day |
| Federally Qualified Health Center Services | \$3.00 per patient day | \$3.00 per patient day |
| Rural Health Center Services | \$3.00 per patient day | \$3.00 per patient day |

- a. No co-payment may be imposed on either “Members” or “Enrollees” with respect to the following services and populations:
 - i) Family planning;
 - ii) Individuals under 21 years of age;
 - iii) An individual who is an inpatient in a hospital, nursing facility, or other institution, and is required to spend all their income for costs of care, with the exception of a minimal amount of for personal needs;
 - iv) Pregnant women, and services furnished during the post-partum phase of maternity

- care to the extent permitted by federal law;
- v) Emergency services, as defined by OMS;
- vi) Any other service or services required to be exempt under the provisions of the Social Security Act, Title XIX and successors to it.
- b. The AIDS Drug Assistance Program (ADAP), funded by Title II, provides coverage for the co-payment of HIV related drugs for “Members” and “Enrollees” as well as provides premium assistance for certain “Enrollees” required to pay a premium under the demonstration. ADAP is considered a “wrap” around benefit for all demonstration participants. “Members” and “Enrollees” participate in both benefit programs and receive both a MaineCare card and an ADAP card.
- 21. Monthly Premiums.** “Enrollees” are responsible for payment of a monthly premium dependent on their income level. These premiums when added to other payments made by the “enrollee’s” family to CHIP or Medicaid will not exceed five percent of an “enrollee’s” gross annual income.

Premiums have been inflated by five percent annually, and for the extension period the premiums will be:

| Demonstration Year (DY) | Actual Premium, Income level <150% FPL | Actual Premium, Income level 150-200% of FPL | Actual Premium, Income level 200-250% of FPL |
|-------------------------|--|--|--|
| DY17 1/2019 – 12/2019 | \$0 | \$35.93 | \$71.85 |
| DY18 1/2020 – 12/2020 | \$0 | \$37.73 | \$75.44 |
| DY19 1/2021 – 12/2021 | \$0 | \$39.61 | \$79.22 |
| DY20 1/2022 – 12/2022 | \$0 | \$41.59 | \$83.18 |
| DY21 1/2023 – 12/2023 | \$0 | \$43.67 | \$87.34 |
| DY22 1/2024 – 12/2024 | \$0 | \$45.85 | \$91.71 |
| DY23 1/2025 – 12/2025 | \$0 | \$48.14 | \$96.30 |
| DY24 1/2026 – 12/2026 | \$0 | \$50.55 | \$101.12 |
| DY25 1/2027 – 12/2027 | \$0 | \$53.08 | \$106.18 |
| DY26 1/2028 – 12/2028 | \$0 | \$55.73 | \$111.49 |

- 22. Cost Sharing Protections.** In the event demonstration “enrollees” fail to pay premiums by the date on which they are due, the state will provide a reasonable grace period of no less than 60 days during which the “enrollee” may make the payment without termination from the program. During the grace period, the state will notify the “enrollee” of failure to make the required payment and may face termination from the program if the payment is not made. The state will give the individual the right to appeal any adverse actions for failure to pay premiums. In addition, before final disenrollment can occur, the state will perform a

Medicaid eligibility determination to ensure that the participant is not eligible for the state plan. If the Medicaid eligibility determination finds that the demonstration “enrollee” is ineligible for Medicaid, the state will disenroll the participant. The individual may reenroll in the demonstration as soon as the individual is able to pay the required premium, subject to enrollment limitations.

VI. DELIVERY SYSTEMS

23. Service Delivery. Services for the demonstration are provided using the same mechanism as other MaineCare members, including services that require prior authorization and are ordered and prescribed by a physician. Participants will be permitted to choose among participating providers (agencies).

Individuals with other insurance may be members of this benefit. MaineCare Services may pay premiums/cost-sharing for this insurance according to current Medicaid state plan rules.

VII. GENERAL REPORTING REQUIREMENTS

24. 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 \$1,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly 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 current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

The follow 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 submissions of required deliverable(s). For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state’s anticipated date of submission. Should CMS agree to the state’s request, a corresponding extension of the deferral process can be provided. 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.

- b) 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.
- c) 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.
- d) 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.

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

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

- a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
- b. Ensure all 1115, 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.

27. Monitoring Reports. No later than 90 days following the end of each demonstration year, the state must submit an annual progress report that represents the status of the demonstration's various operational areas and any state analysis of program data collected for the demonstration year. The Annual Monitoring Report will include all elements required by 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 Annual Monitoring Report must follow the framework provided by CMS, which is subject to change as monitoring systems are developed and/or evolve, and will be provided in a structured manner that supports federal tracking and analysis. Each Annual Monitoring Report must minimally include the following:

- 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.

28. 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 11.

29. 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 24.

30. 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.

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

VIII.EVALUATION OF THE DEMONSTRATION

32. Cooperation with Federal Evaluators. As required under 42 CFR 431.420(f), the state shall cooperate fully and timely with CMS and its contractors' in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to: commenting on design and other federal evaluation documents; 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, 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 24.

- 33. 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.
- 34. Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with attachment B (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred twenty (120) calendar days after the effective date of these STCs. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state may choose to use the expertise of the independent party in the development of the draft Evaluation Design.
- 35. 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 an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the 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.
- 36. Evaluation Questions and Hypotheses.** Consistent with attachments B and C (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, 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).

37. 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.

38. 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 C (Preparing the Evaluation Report) of these STCs.

39. Summative Evaluation Report. The draft Summative Evaluation Report must be developed in accordance with attachment C (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.

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

40. 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 expenditure authorities, as outlined in STC 11.

41. 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, and/or the summative evaluation.

42. 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.

43. 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.

IX. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

44. 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.

45. 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.

46. 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.

47. 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.

48. 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.

49. 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.

50. 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 1: Master MEG Chart | | | | | |
|---------------------------|-----------------------------------|----------------|---------------|----|--|
| MEG | To Which BN Test Does This Apply? | WOW Per Capita | WOW Aggregate | WW | Brief Description |
| Enrollees | Hypo 1 | X | | X | Expenditures for medical assistance and case management services that coordinate care related to HIV/AIDS, not otherwise available under the state plan. |

51. 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-00128/1). 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 Annual Monitoring Reports described in section VII, 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 2: MEG Detail for Expenditure and Member Month Reporting | | | | | | | | |
|--|----------------------|------------|--|----------------------------|------------|----------------------------|----------------|-------------------|
| MEG (Waiver Name) | Detailed Description | Exclusions | CMS-64.9 Line(s) To Use | How Expend. Assigned to DY | MAP or ADM | Report Member Months (Y/N) | MEG Start Date | MEG End Date |
| Enrollees | Refer to STC 16 | N/A | Follow CMS-64.9 Base Category of Service Definitions | Date of service | MAP | Y | April 19, 2019 | December 31, 2028 |

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

| Table 3: Demonstration Years | | |
|------------------------------|--------------------------------------|-----------|
| Demonstration Year 17 | January 1, 2019 to December 31, 2019 | 12 months |
| Demonstration Year 18 | January 1, 2020 to December 31, 2020 | 12 months |
| Demonstration Year 19 | January 1, 2021 to December 31, 2021 | 12 months |
| Demonstration Year 20 | January 1, 2022 to December 31, 2022 | 12 months |
| Demonstration Year 21 | January 1, 2023 to December 31, 2023 | 12 months |
| Demonstration Year 22 | January 1, 2024 to December 31, 2024 | 12 months |
| Demonstration Year 23 | January 1, 2025 to December 31, 2025 | 12 months |
| Demonstration Year 24 | January 1, 2026 to December 31, 2026 | 12 months |
| Demonstration Year 25 | January 1, 2027 to December 31, 2027 | 12 months |
| Demonstration Year 26 | January 1, 2028 to December 31, 2028 | 12 months |

53. 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 IX. CMS will provide technical assistance, upon request.¹

54. 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.

55. 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 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

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.

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 FOR THE DEMONSTRATION

- 56. 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.
- 57. 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.
- 58. Calculation of the Budget Neutrality Limits and How They Are Applied.** To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which 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 will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.
- 59. Main Budget Neutrality Test.** This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests. Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS.

60. 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. This approach reflects CMS’s current view that states should not have to “pay for,” with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, during negotiations. If the state’s WW hypothetical spending exceeds the supplemental test’s expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending by savings elsewhere in the demonstration or to refund the FFP to CMS.

61. Hypothetical Budget Neutrality Test: Enrollees. The demonstration makes a limited benefits package, including medical assistance and case management services, available to individuals with HIV/AIDS. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test. MEGs that are designated “WOW Only” or “Both” are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the 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 4: Hypothetical Budget Neutrality Test | | | | | | | | | |
|--|------------|------------------|------------|------------|------------|------------|------------|------------|------------|
| MEG | PC or Agg* | WOW, WW, or Both | Base Year | Trend Rate | DY 17 | DY 18 | DY 19 | DY 20 | DY 21 |
| Enrollees | PC | Both | \$1,110.28 | 5% | \$1,165.80 | \$1,224.09 | \$1,285.29 | \$1,349.55 | \$1,417.03 |
| | | | | | DY 22 | DY 23 | DY 24 | DY 25 | DY 26 |
| | | | | | \$1,487.88 | \$1,562.27 | \$1,640.38 | \$1,722.40 | \$1,808.52 |

- 62. 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.
- 63. Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from April 19, 2019 to December 31, 2028. If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds 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. 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.

Hypothetical Budget Neutrality Test

| Table 5: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations | | |
|--|--|-------------------|
| Demonstration Year | Cumulative Target Definition | Percentage |
| DY 17 | Cumulative budget neutrality limit plus: | 2.0 percent |
| DY 17 through DY 18 | Cumulative budget neutrality limit plus: | 1.5 percent |
| DY 17 through DY 19 | Cumulative budget neutrality limit plus: | 1.0 percent |
| DY 17 through DY 20 | Cumulative budget neutrality limit plus: | 0.5 percent |
| DY 17 through DY 21 | Cumulative budget neutrality limit plus: | 0.0 percent |
| DY 17 through DY 22 | Cumulative budget neutrality limit plus: | 0.0 percent |

| | | |
|---------------------|---|-------------|
| DY 17 through DY 23 | Cumulative budget neutrality limit plus: | 0.0 percent |
| DY 17 through DY 24 | Cumulative budget neutrality limit plus: | 0.0 percent |
| DY 17 through DY 25 | Cumulative budget neutrality limit plus: | 0.0 percent |
| DY 17 through DY 26 | Cumulative budget neutrality limit plus: | 0.0 percent |

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

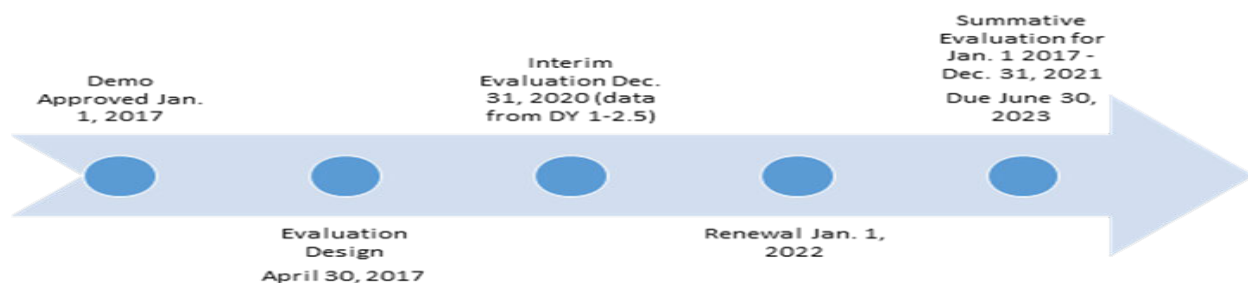
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, 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).
 - f. 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).
 - g. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

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

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

- 6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:
- a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example

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

- b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
 - c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
 - d. The application of sensitivity analyses, as appropriate, should be considered.
- 7) *Other Additions* – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

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

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

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

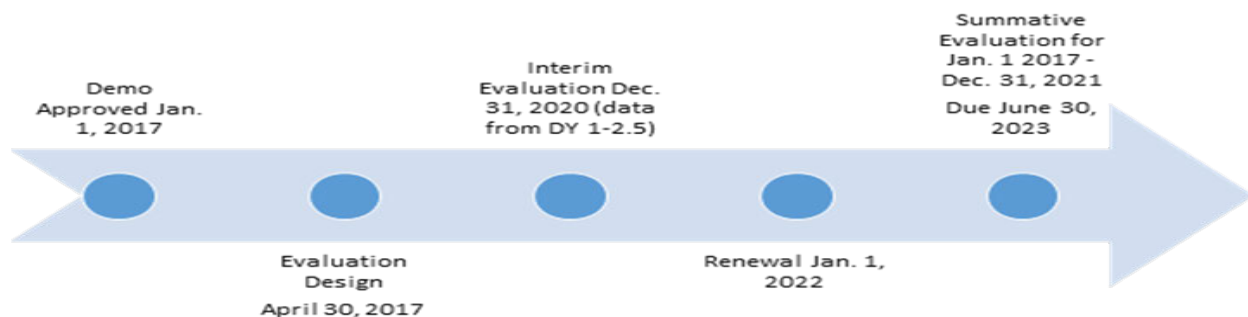
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved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

Approved Evaluation Design

General Background Information

Early treatment with anti-retroviral therapies for individuals with Human Immunodeficiency Virus (HIV) has been shown to delay disease progression, while comprehensive case management is an important tool in helping individuals maintain access to these critical treatments.^{2,3} In 2002, Maine's Medicaid program, MaineCare, was granted a 1115 demonstration waiver from Centers for Medicare and Medicaid Services (CMS) entitled *Maine Medicaid Section 1115 Health Care Reform Demonstration for Individuals with HIV/AIDS* to provide a broad range of healthcare services to Maine residents living with HIV infection that are designed to provide more effective, early treatment of HIV disease by making available a limited but comprehensive package of services, including antiretroviral therapies and comprehensive case management. Additional healthcare services include physician services, outpatient laboratory and radiology, prescription medications, inpatient and outpatient hospital services, behavioral health and substance abuse services, and transportation. The demonstration expanded Medicaid access to individuals with HIV/AIDS through a targeted benefits package, allowing them to avoid spending down income or resources.⁴ Over the course of the seventeen years of this demonstration, the Office of MaineCare Services has continued to work to improve access to medical services for Maine residents with HIV/AIDS, providing medical services to 542 demonstration enrollees. In addition, 389 Medicaid members with HIV/AIDS received the benefit of enhanced care coordination.

. Under this extension of the original demonstration which was approved on April 19, 2019 and will continue until December 31, 2028, the state will continue to provide a comprehensive set of services to those who have HIV/AIDS and are at or below 250 percent of the federal poverty level (FPL). This demonstration works to expand access to individuals with HIV/AIDS who are otherwise ineligible for MaineCare. In this demonstration, there are two populations: Medicaid enrollees with HIV/AIDS who have incomes at or below 133 percent of the FPL, known as "members," and demonstration enrollees with HIV/AIDS who have incomes above 133 percent and at or below 250 percent of the FPL, known as "enrollees" (Exhibit 1). "Members" receive all of the medically necessary Medicaid state plan-covered services as well as case management services, while "enrollees" receive a targeted essential set of services. The demonstration requires co-payments of \$10 for physician office visits and prescription drugs for the "enrollees" group with income above 150 percent up to and including 250 percent of the FPL. For the purposes of this evaluation, "members" and "enrollees" will be grouped together and

¹ INSIGHT START Study Group, Lundgren JD, Babiker AG, Gordin F, Emery S, Grund B, Sharma S, Avihingsanon A, Cooper DA, Fätkenheuer G, Llibre JM, Molina JM, Munderi P, Schechter M, Wood R, Klingman KL, Collins S, Lane HC, Phillips AN, Neaton JD. Initiation of Antiretroviral Therapy in Early Asymptomatic HIV Infection. *N Engl J Med*. 2015 Aug 27;373(9):795-807.

² Brennan-Ing M, Seidel L, Rodgers L, Ernst J, Wirth D, Tietz D, et al. (2016) The Impact of Comprehensive Case Management on HIV Client Outcomes. *PLoS ONE* 11(2).

³ Office of MaineCare services. *Maine Medicaid Section 1115 Health Care Reform Demonstration for Individuals with HIV/AIDS*.

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referred to collectively as participants since they are receiving many of the same benefits.

Exhibit 1. Demonstration eligibility criteria and benefits.

| Demonstration Eligibility Groups | Federal Poverty Level (FPL) and qualifying criteria | Eligible Benefit |
|--|---|---|
| "Members" State Plan Groups* | HIV-positive individuals at or below 133 percent of FPL | Full Medicaid benefits offered under the state plan and case management services. |
| "Enrollees" Expansion Populations** | HIV-positive individuals at or below 250 percent of FPL | Targeted benefit |

*These state plan eligible beneficiaries ("Members") are enrolled in the demonstration for the benefit of enhanced coordination.

** These eligible beneficiaries ("Enrollees") are expansion populations who would not otherwise be eligible for medical assistance.

Outreach under this demonstration will continue to include trainings and site visits with providers, including newly hired case managers. Posters and brochures continue to be distributed throughout the state to Office for Family Independence regional offices, pharmacies, physician offices, hospitals, municipalities, soup kitchens, schools, homeless shelters, and family planning agencies, in hopes to broaden awareness within communities and allow for timely access to coverage and care. The waiver has resulted in the provision of substantial health benefits for both members and enrollees, while associated costs have been well below the budget neutrality permitted under the waiver.

TARGET POPULATION

As shown in Exhibit 2, the majority of people living with HIV (PLWH) in Maine in 2015 were between the ages of 40 and 59 years (62%). New cases were more likely to occur among adults 20 to 39 years old (48%) compared with other age groups.

Exhibit 2. New and Existing HIV cases (PLWH) in Maine, by age, 2015

| Age group | New HIV diagnoses | | Existing HIV cases (PLWH) | |
|--------------|-------------------|-------------|---------------------------|-------------|
| | N | % | N | % |
| Under 13 | 2 | 4% | 13 | 1% |
| 13-19 | 2 | 4% | 8 | <1% |
| 20-29 | 10 | 21% | 67 | 4% |
| 30-39 | 13 | 27% | 225 | 13% |
| 40-49 | 9 | 19% | 433 | 25% |
| 50-59 | 7 | 15% | 657 | 37% |
| 60 and older | 5 | 10% | 363 | 21% |
| Total | 48 | 100% | 1,766 | 100% |

Source: Maine Electronic HIV and AIDS Reporting System (eHARS)

While more than two-thirds of PLWH were non-Hispanic white (77%), the rate of infection among blacks or African-Americans was more than 10 times higher than for whites and nearly 5 times higher among Hispanics or Latinos compared with whites (Exhibit 3). These findings highlight the importance of reaching minority communities through demonstration activities.

Exhibit 3. Existing HIV cases (PLWH) in Maine, by race/ethnicity, 2015

| Race/ethnicity | N | % | Rate per 100,000 |
|-----------------------------------|------|-----|------------------|
| White* | 1356 | 77% | 109.0 |
| Black/African-American* | 237 | 13% | 1,296.1 |
| Hispanic/Latino(a) | 108 | 6% | 516.2 |
| Other or multi-race* | 44 | 2 | N/A |
| Asian* | 10 | 1 | N/A |
| American Indian/Alaska Native* | 10 | 1 | N/A |
| Native Hawaiian/Pacific Islander* | 1 | <1% | N/A |

*Non-Hispanic, N/A- data not available

Source: Maine Electronic HIV and AIDS Reporting System (eHARS)

Evaluation Questions and Hypotheses

The goal of care management services provided by the waiver program is to delay the progression of HIV to AIDS. Its success is reflected in the percentage of patients who do not develop AIDS defining illness (i.e., remain asymptomatic HIV positive). Achieving this goal also means that medical costs are lower than they would have been in the absence of the program. The overall aim of the demonstration is to delay or prevent the progression of HIV for low-income PLWH in Maine and to meet the objectives of the Medicaid program. The primary drivers to achieve this aim are:

- ▲ Improving access to continuous healthcare services;
- ▲ Arresting progression of HIV status by providing early and optimal care coupled with high quality and cost efficiency; and
- ▲ Expanding coverage to additional low-income individuals living with HIV with the savings generated from disease prevention and the prevention of or delayed onset of AIDS.

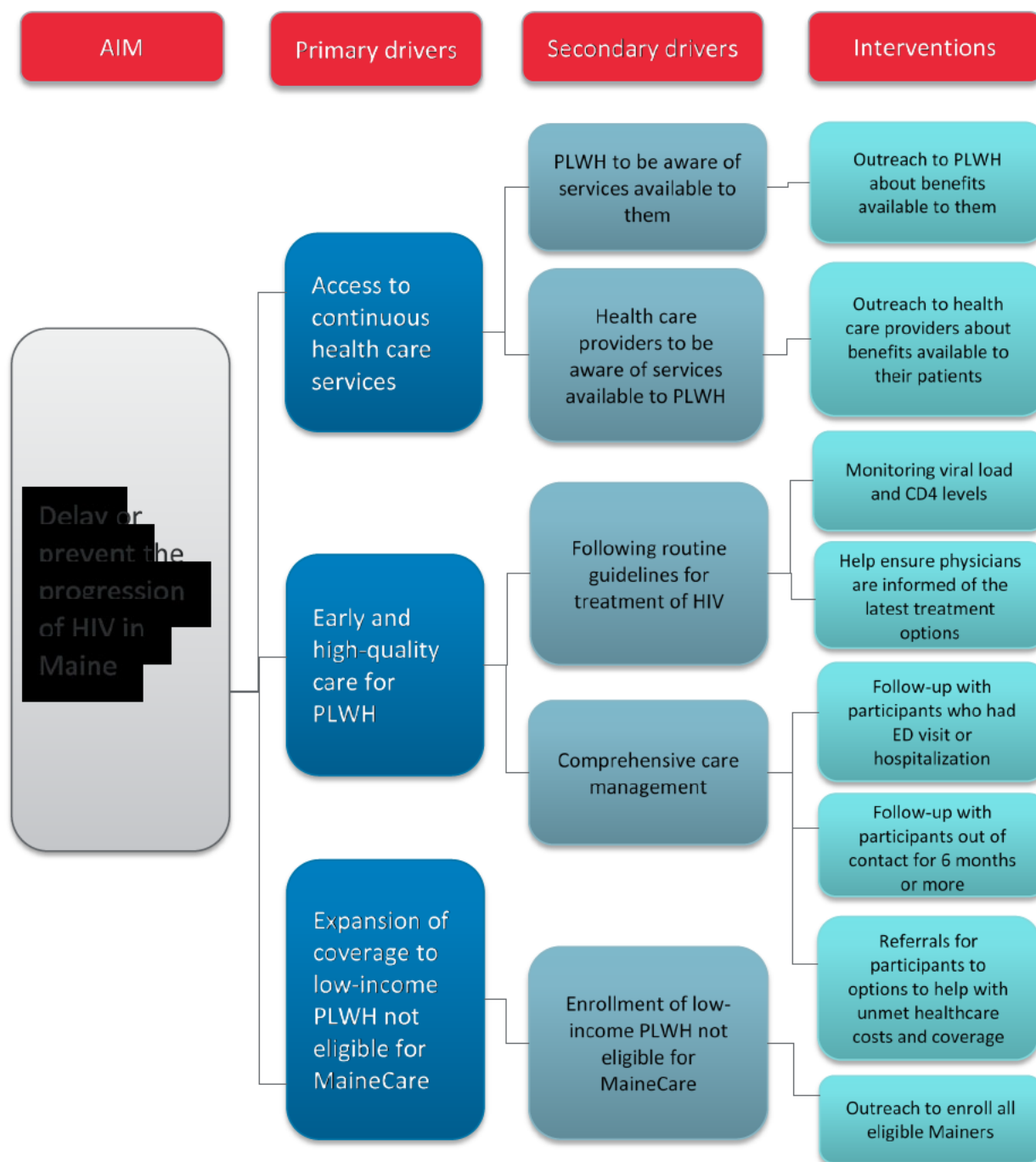
The State hypothesizes that:

- ▲ Improved access to continuous health care will lead more demonstration participants to seek routine care.
- ▲ Greater access to early, high quality care will slow disease progression in demonstration participants and improve overall health status.
- ▲ The prevention or delay of disease progression will allow more low-income individuals living with HIV access to high-quality care.

The driver diagram in Exhibit 4 displays the primary and secondary drivers, as well as the interventions that demonstrate the cause and effect of the variants behind the demonstration features and intended outcomes. Through administrative data, member and provider surveys, and comparison to national benchmarks, this evaluation will be able to assess overall trends and progress toward the goals of the demonstration in the following research questions:

- ▲ What is the relationship between patients' perception of access to care and routine medical visits?
- ▲ What percentage of demonstration participants are meeting the routine treatment guidelines?
 - What percentage of demonstration participants are meeting CDC recommendations for viral load monitoring?
 - What percentage of patients are meeting the recommendations for HIV RNA control?
 - What percentage of demonstration participants are meeting the threshold for medication adherence (Proportion of days covered)?
 - What is the relationship between medication adherence and self-efficacy for medication management?
- ▲ How have rates of emergency department (ED) visits and hospitalizations changed over time for demonstration participants?
 - What is the relationship between self-rated health status and acute health incidents, such as ED visits and hospitalizations?
 - Do those who meet treatment guidelines (routine visits, PDC threshold and HIV RNA control) have fewer acute health incidents (ED visits, hospitalizations)?
- ▲ How has enrollment of Mainers eligible for HIV services changed over time?
 - What is the relationship between self-rated health status and health-related quality of life and length of participation in the demonstration?

Exhibit 4. Driver Diagram for the Section 1115 Demonstration Waiver.



Methodology

EVALUATION DESIGN

The design of the Maine section 1115 demonstration evaluation will be a repeated cross-sectional design (also referred to as time-series design). Measures will be repeated each of the 10 years of the demonstration providing an opportunity to see long-term trends in outcomes for PLWH in Maine. Additionally, a longitudinal cohort analysis will be conducted with a subgroup of individuals tracked over the entire demonstration period. Since the demonstration has been in place since 2002, a pre-post design is not possible. Additionally, there are very few PLWH in Maine not receiving benefits, so obtaining a demographically similar comparison group is not feasible, precluding a quasi-experimental design.

TARGET AND COMPARISON POPULATIONS

The inclusion criteria for the HIV/AIDS demonstration, the target population, are as follows:

- Positive HIV status
- Financially eligible (at or below 250 percent of federal poverty level)
- Completed information form related to other insurance, i.e., third party liability (TPL)
- Payment of premiums (if applicable)
- Willingness to sign informed consent that indicates:
 - Understanding of requirements of the benefit
 - Willingness to comply with treatment recommendations

Those with a negative HIV status or those with HIV and income over 250 percent of the FPL are not eligible for benefits under the demonstration.

For evaluation purposes, the unit of analysis will be the individual and data will be aggregated yearly to provide population estimates. Due to the length of time the demonstration has been in place and a lack of a similar group not receiving benefits in Maine, obtaining a comparable comparison group will be a challenge.

Maine population rates will be compared to national CDC data on HIV/AIDS from the Medical Monitoring Project⁴; however, this will only be for reference purposes since the national cohort is not demographically similar to the Maine population in terms of income level and race/ethnicity. The Transformed Medicaid Statistical Information System (T-MSIS) may also be a source of comparison data for Maine demonstration enrollees.⁶ The T-MSIS data set is evolving and currently contains enhanced

⁴ Centers for Disease Control and Prevention. Behavioral and Clinical Characteristics of Persons with Diagnosed HIV Infection—Medical Monitoring Project, United States 2016 Cycle (June 2016–May 2017). Surveillance Special Report 21. Accessed on July 23, 2019 from <https://www.cdc.gov/hiv/statistics/systems/mmp/resources.html>.

⁵ Transformed Medicaid Statistical Information System (T-MSIS). <https://www.medicaid.gov/medicaid/data-and-systems/macbis/tmsis/index.html>. Accessed December 9, 2019.

information about beneficiary eligibility, beneficiary and provider enrollment, service utilization, claims and managed care data, and expenditure data for Medicaid and CHIP. It is unclear what demographic characteristics and HIV status variables will be available for comparison with the Maine sample as the demonstration progresses. Given the 10-year period of performance for the demonstration, the state will explore data quality, completeness, and usability as T-MSIS matures further in the next 3-4 years. At that time, the state can provide CMS with an assessment of whether exploring T-MSIS still would seem to be a viable option for the state to pursue, and based on the state's assessment, CMS and the state can revisit the approach. When the demonstration is in the final years (Years 7 or 8), T-MSIS data will be requested and assessed for use as a comparison.

Within the Maine population, subgroup comparisons will be made where sufficient sample size is available to see if the rates of change over time differ by demographic characteristics such as age, gender, and mode of transmission. Given the length of time of the demonstration, it will allow for time series analysis to examine trends over time among PLWH in Maine. Newly diagnosed cases will be included each year and can be assessed separately to compare baseline to post-enrollment outcomes, however the sample size, approximately 40 newly diagnosed each year, will likely not allow for sufficient power to detect statistical differences. Finally, the state will identify a cohort of participants enrolled in the demonstration over an extended period of time to conduct a longitudinal analysis of within group changes in outcomes.

From the target population, a convenience sample of PLWH in Maine will be identified comprising those who have available data and respond to the member surveys each year. At the end of 2018, there were 774 demonstration participants and survey data were available for about half of these individuals (387 participants).⁷ With sample sizes of 774 for administrative data outcomes and 387 for survey outcomes, sample proportions can be calculated with 4% and 5% margins of error and a 95% level of confidence (this assumes a population proportion of a given outcome is 50%, a conservative estimate). Based on the past five years of data, a growth rate for enrollees is estimated at 2.8% per year. Exhibit 5 displays the expected number of enrollees from which administrative data and survey data will be available, given 2.8% growth each year, which accounts for both newly enrolled as well as attrition.

Exhibit 5. Expected number of total expected demonstration participants each year.

| Year | Number of total participants with administrative data (100% of enrollees) | Number of total participants with survey data (50% of enrollees) |
|-------------|--|---|
| 2018 | 774 | 387 |
| 2019 | 796 | 398 |
| 2020 | 818 | 409 |
| 2021 | 841 | 421 |
| 2022 | 864 | 432 |
| 2023 | 888 | 444 |

⁶ Office of Maine Care Services. Annual Report, HIV/AIDS 1115 Demonstration Project, (01/01/18 - 12/31/18).
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| | | |
|------|------|-----|
| 2024 | 913 | 457 |
| 2025 | 938 | 469 |
| 2026 | 964 | 482 |
| 2027 | 991 | 496 |
| 2028 | 1019 | 510 |

EVALUATION PERIOD

The demonstration approval period is from April 19, 2019, through December 31, 2028. The demonstration evaluation will comprise data for each of the years from 2020 through 2028. An interim evaluation report comprising data through year 8 (April 2027) will be submitted in December 20, 2027 and the final report will be submitted 18 months after the end of the demonstration, June 30, 2029. See Appendix 3 for more details on the timeline of the demonstration and major milestones.

EVALUATION MEASURES

HIV is a mandatory reporting condition; therefore, the incidence and prevalence of positive test results are required to be reported to the CDC. The state accesses information from MaineCare claims and Maine CDC about primary care provider visits, emergency department (ED) visits, hospitalizations, prescription refills, HIV viral load and CD4 testing, opportunistic infections (OIs), and other items for demonstration participants. MaineCare also tracks contact with demonstration participants from nurse care managers and other staff and administers a member survey annually to demonstration participants via mail. This evaluation will include the examination of health outcomes as well as process measures to assess patients' access to routine care. Exhibit 6 describes the measures that will be used in the evaluation of the Maine HIV demonstration waiver including the type of measure, source, measure steward or reference, numerator and denominator.

Exhibit 6. Outcome and process measures for the evaluation of the Maine Section 1115 Demonstration Waiver

| Measure Title | Description | Data Source | Numerator/ Denominator | Steward Ref# or code |
|---|---|---------------------|---|-------------------------|
| Outcome measures | | | | |
| All-cause emergency department (ED) visits ⁷ | Rate of emergency department (ED) visits per 1,000 enrollee months among enrollees. Each ED visit is counted once and visits that resulted in an inpatient stay are not included. | Administrative data | Number of all cause ambulatory ED Visits/ Eligible member months | NCQA AMB-HH |
| All-cause hospital admissions ⁷ | Rate of acute inpatient care and services (total, maternity, mental and behavioral disorders, surgery, and medicine) per 1,000 enrollee months. | Administrative data | Number of all cause hospital admissions/ Eligible member months | CMS IU-HH |

| Measure Title | Description | Data Source | Numerator/ Denominator | Steward Ref# or code |
|---|--|---------------------|---|--|
| HIV viral load suppression ⁸ | Percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/ml at last viral load test during the measurement year. Viral load is a marker of response to ART. The key goal of ART is to achieve and maintain durable viral suppression. | Administrative data | Number of enrollees with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year/ Number of enrollees with at least one medical visit in the measurement year | HRSA NQF #2082 |
| General health status ⁹ | Self-assessed health status is a measure of how an individual perceives his or her health—rating it as excellent, very good, good, fair, or poor. Self-assessed health status has been validated as a useful indicator of health for a variety of populations and allows for broad comparisons across different conditions and populations. | Member survey | Number of enrollees in excellent or very good health/ All enrollees completing a survey in the measurement period | Healthy People 2020 |
| Health-related Quality of Life ^{10,11} | The Healthy Days Measures are a brief set of survey-based questions designed to assess self-reported Health-related Quality of Life defined as "perceived physical and mental health over time." They include a core set of four questions that are scored to determine number of healthy and unhealthy days in a 30-day measurement period. | Member survey | Number of enrollees with more healthy days than unhealthy days in a given measurement period/ All enrollees completing a survey in the measurement period | Behavioral Risk Factor Surveillance System |
| Process measures | | | | |

⁷ Core Set of Health Care Quality Measures for Medicaid Health Home Programs. <https://www.medicaid.gov/state-resource-center/medicaid-state-technical-assistance/health-home-information-resource-center/downloads/FFY-19-HH-Core-Set-Manual.pdf>. Accessed December 9, 2019.

⁸ HIV/AIDS Bureau Performance Measures. 2019. <https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/coremeasures.pdf>. Accessed December 9, 2019.

⁹ Idler E, Benyamini Y. Self-rated health and mortality: A review of 28 studies. *J Health Soc Behav.* 1997;38(1):21–37.

¹⁰ Moriarty D.G., Zack M.M., Kobau R. The Centers for Disease Control and Prevention's Healthy Days Measures—population tracking of perceived physical and mental health over time. *Health Qual. Life Outcomes.* 2003;1:37.

¹¹ Newschaffer CJ. *Validation of Behavioral Risk Factor Surveillance System (BRFSS) HRQOL measures in a statewide sample.* Atlanta: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion; 1998
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| Measure Title | Description | Data Source | Numerator/ Denominator | Steward Ref# or code |
|--|--|---------------------|---|--|
| HIV medical visit frequency ⁸ | Percentage of patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between medical visits. A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care. Measurement period is 24 months. | Administrative data | Number of enrollees who had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between first medical visit in the prior 6-month period and the last medical visit in the subsequent 6-month period/ Number of enrollees with at least one medical visit in the first 6 months of the 24-month measurement period | HRSA NQF#2079 |
| Proportion of Days Covered (PDC) ¹² | PDC is the percent of days in the measurement period “covered” by prescription claims for the same medication or medications in its therapeutic category. The antiretroviral medications measure requires a 90% threshold for ≥3 antiretroviral medications. | Administrative data | Percentage of enrollees who met the 90% threshold for medication adherence/ Enrollees dispensed at least 3 prescriptions for ART on 2 unique dates during the measurement year | Pharmacy Quality Alliance PDC-ARV2019 |
| RNA Control for Patients with HIV (eCQM) | Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS, with at least two visits during the measurement year, with at least 90 days between each visit, whose most recent HIV RNA level is <200 copies/mL | Administrative data | Enrollees whose most recent HIV RNA level is <200 copies/mL during the measurement period/ All enrollees aged 13 years and older with at least two visits during the measurement year, with at least 90 days between each visit | CMS N/A |

¹² PQA Measure Overview. 2019.

https://pqa.memberclicks.net/assets/Measures/2019_PQA_Measure_Overview.pdf. Accessed July 25, 2019.

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| Measure Title | Description | Data Source | Numerator/ Denominator | Steward Ref# or code |
|---|--|---------------|--|---|
| Patient perception of accessibility of care ¹³ | Self-report of ability to obtain medical care, tests, or treatments they or a doctor believed were necessary, number of times they were unable to receive care, main barriers to care. | Member survey | Number of enrollees unable to receive necessary care/ All enrollees completing a survey in the measurement period | Medical Expenditure Panel Survey |
| Medication management ¹⁴ | The PROMIS measures assess self-efficacy for managing chronic conditions through 4 questions about the ability to obtain and comply with medication prescriptions. | Member survey | Number of enrollees unable to manage medications/ All enrollees completing a survey in the measurement period | Patient-Reported Outcomes Measurement Information System (PROMIS) |

Provider Survey Data

To enhance the evaluation results, information gathered from health care providers will be assessed. A provider survey is administered annually via mail to infectious disease specialists and primary care providers who, at the time of the mailing, were treating demonstration participants. Questions ask about medical practice specialty, number of HIV/AIDS patients managed, provider awareness of current treatment guidelines and new recommendations for HIV/AIDS patients, barriers affecting adherence/compliance with medication, provider awareness of funding and training opportunities through the Maine AIDS Education and Training Center (MEAETC), provider awareness of the MaineCare HIV/AIDS waiver, provider awareness of the AIDS Drug Assistance Program (ADAP), and providers' preferences on receiving letters and updates via an HIV-specific listserv. These measures were developed by Maine and have been used for several years to assess programmatic data about the HIV demonstration waiver. These measures have not been validated and will therefore only be used for descriptive purposes.

Demographic and Other Characteristics

Demographic characteristics, including gender, primary mode of HIV transmission, race/ethnicity, housing stability and food security will be obtained either from administrative records or from member survey data for use in modeling to assess differences over time by demographic group. Differences will also be assessed based on other characteristics such as length of time since HIV diagnosis, length of time participating in the demonstration and whether or not the participant is a MaineCare member or waiver

¹³ Zuvekas S et al, Validating Household Reports of Health Care Use in the Medical Expenditure Panel Survey Health Services Research 2009 oct 44(5 Pt1): 1679 – 1700.

¹⁴ Gruber-Baldini AL et al Validation of the PROMIS measures of self-efficacy for managing chronic conditions, Quality of Life Research, 2017 Jul; 26(7) 1915 -1924.

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DATA SOURCES

All state-level administrative data will be obtained from the Maine Electronic HIV and AIDS Reporting System (eHARS) and MaineCare claims. The Ryan White Part B Program has been using CAREWare since 2004, including support of a statewide network that includes all Ryan White HIV/AIDS Program recipients in Maine since 2007. Additionally, member surveys are conducted each year. The member survey is sent to all demonstration participants who are enrolled at the time of the mailing and who have not previously opted out. The response rate for this survey is typically around 48%. If a 40% response rate is not achieved, a second survey is sent to members who did not respond to the first survey. Provider surveys are mailed to infectious disease specialists and primary care providers who, at the time of the mailing, are treating MaineCare and waiver members with HIV/AIDS. The response rate for this survey is typically around 37%.

All data will be inspected for consistency, missing values, and values outside of the expected ranges. Errors will be corrected, and clean datasets will be created for analysis using SAS Software for Windows Version 9.4.

National benchmarks will be determined based on the National Institute of Health's guidelines for treatment¹⁵ and the CDC's Medical Monitoring Project¹⁶ containing national surveillance data for HIV. Data will also be requested from the Transformed Medicaid Statistical Information System (T-MSIS) to potentially provide comparison data.

ANALYTIC METHODS

To compare outcomes from year to year in groups that may or may not contain the same population (repeated cross-sectional or time series design), regression modeling will be performed with year as a covariate. This type of modeling will allow for tracking changes over time cross-sectionally with different groups each year. The type of regression model (logistic, linear, Poisson) will depend on the format of the outcome variable. Demographic and other characteristics, such as length of time with HIV diagnosis and length of time in the demonstration will be included in the regression models and interactions with year will be examined to determine if the change over time varies based on certain characteristics. Relationships between measures, such as self-reported health status and routine medical visits will be analyzed with bi-variate methods appropriate for the data type (Chi-square tests, t-tests, Wilcoxon

¹⁵ Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at <http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf>. Section accessed July 25, 2019.

¹⁶ Centers for Disease Control and Prevention. Behavioral and Clinical Characteristics of Persons with Diagnosed HIV Infection—Medical Monitoring Project, United States, 2016 Cycle (June 2016–May 2017). HIV Surveillance Special Report 21. <https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published February 2019. Accessed July 1, 2019.

signed rank tests) and using regression modeling to control for demographic or other factors. To track changes over time within a cohort of individuals enrolled in the demonstration for an extended period, longitudinal modeling techniques, such as mixed models or generalized estimating equations will be used depending on the format of the outcome variable (discrete, continuous, non-normal). Complete case analysis will be used, therefore, any individuals missing data for one or more of the model variables will be excluded from analysis. This will provide the most conservative estimates; however, it cannot be assumed that data are missing completely at random (MCAR) and those with missing data may be different in other ways from those with complete data. Analyses will be performed using SPSS and SAS Software. For this evaluation, alpha levels of 0.05 or less will be considered significant. Exhibit 7 displays the overall evaluation design, including the research questions for each hypothesis, the outcome measures, sample population, data sources and analytic methods that will be used to evaluate each question.

Evaluation Design Table

| Research Question | Outcome measures used to address the research question | Sample or population subgroups to be compared | Data Sources | Analytic Methods |
|---|--|--|--|--|
| Hypothesis 1 Improved access to continuous health care will lead more HIV waiver enrollees to seek routine care. | | | | |
| 1.1 What is the relationship between patients' perception of access to care and routine medical visits? | <ul style="list-style-type: none"> • Patient perception of accessibility of care • HIV medical visit frequency | Demonstration participants: Comparisons made between years and demographic characteristics | <ul style="list-style-type: none"> • Member survey • Administrative data | <ul style="list-style-type: none"> • Descriptive statistics • Time series modeling • Repeated measures modeling |
| 1.2a. What percentage of demonstration participants are meeting CDC recommendations for viral load monitoring? | HIV viral load suppression | Demonstration participants: Comparisons made between years and demographic characteristics as well as to National Benchmarks | <ul style="list-style-type: none"> • Administrative data • CDC Medical Monitoring Project report | <ul style="list-style-type: none"> • Descriptive statistics • Time series modeling • Repeated measures modeling |
| 1.2b. What percentage of patients are meeting the recommendations for HIV RNA control? | RNA Control for Patients with HIV (eCQM) | Demonstration participants: Comparisons made between years and demographic characteristics as well as to National Benchmarks | <ul style="list-style-type: none"> • Administrative data • CDC Medical Monitoring Project report | <ul style="list-style-type: none"> • Descriptive statistics • Time series modeling • Repeated measures modeling |
| 1.2c. What percentage of demonstration participants are | Proportion of Days Covered (PDC) | Demonstration participants: Comparisons made between years and | <ul style="list-style-type: none"> • Administrative data | <ul style="list-style-type: none"> • Descriptive statistics • Time series modeling |

| Research Question | Outcome measures used to address the research question | Sample or population subgroups to be compared | Data Sources | Analytic Methods |
|---|--|--|--|--|
| meeting the threshold for medication adherence (Proportion of days covered)? | | demographic characteristics as well as to National Benchmarks | <ul style="list-style-type: none"> • CDC Medical Monitoring Project report | <ul style="list-style-type: none"> • Repeated measures modeling |
| 1.2d. What is the relationship between medication adherence and self-efficacy for medication management? | <ul style="list-style-type: none"> • Proportion of Days Covered (PDC) • Medication management | Demonstration participants: Comparisons made between years and demographic characteristics | <ul style="list-style-type: none"> • Administrative data • Member survey | <ul style="list-style-type: none"> • Descriptive statistics • Time series modeling • Repeated measures modeling |
| Hypothesis 2 Greater access to early, high quality care will slow disease progression in HIV waiver enrollees and improve overall health status. | | | | |
| 2.1 How have rates of emergency department (ED) visits and hospitalizations changed over time for demonstration participants? | <ul style="list-style-type: none"> • All-cause emergency department (ED) visits • All-cause hospital admissions | Demonstration participants: Comparisons made between years and demographic characteristics | Administrative data | <ul style="list-style-type: none"> • Descriptive statistics • Time series modeling • Repeated measures modeling |
| 2.1a. What is the relationship between self-rated health status and acute health incidents, such as ED visits and hospitalizations? | <ul style="list-style-type: none"> • All-cause emergency department (ED) visits • All-cause hospital admissions • General health status | Demonstration participants: Comparisons made between years and demographic characteristics | <ul style="list-style-type: none"> • Administrative data • Member survey | <ul style="list-style-type: none"> • Descriptive statistics • Time series modeling • Repeated measures modeling |

| Research Question | Outcome measures used to address the research question | Sample or population subgroups to be compared | Data Sources | Analytic Methods |
|---|---|--|--|--|
| 2.1b. Do those who meet treatment guidelines (routine visits, PDC threshold and HIV RNA control) have fewer acute health incidents (ED visits, hospitalizations)? | <ul style="list-style-type: none"> • All-cause emergency department (ED) visits • All-cause hospital admissions • HIV viral load suppression • RNA Control for Patients with HIV (eCQM) • Proportion of Days Covered (PDC) | Demonstration participants: Comparisons made between years and demographic characteristics | Administrative data | <ul style="list-style-type: none"> • Descriptive statistics • Time series modeling • Repeated measures modeling |
| Hypothesis 3 Decreased costs associated with disease prevention will allow more low-income individuals living with HIV access to high-quality care. | | | | |
| 3.1. How has enrollment of Mainers eligible for HIV services changed over time? | Enrollment numbers | Demonstration participants | Administrative data | <ul style="list-style-type: none"> • Descriptive statistics • Time series modeling • Repeated measures modeling |
| 3.1a. What is the relationship between self-rated health status and health-related quality of life and length of participation in the demonstration? | <ul style="list-style-type: none"> • Length of time of participation • Health-related Quality of Life • General health status | Demonstration participants | <ul style="list-style-type: none"> • Member survey • Administrative data | <ul style="list-style-type: none"> • Descriptive statistics • Time series modeling |

Methodological Limitations

Since the demonstration has been ongoing in Maine since 2002, a pre-post evaluation will not be possible among those already enrolled, however, newly diagnosed enrollees will be assessed to compare their baseline to post-enrollment outcomes, although the sample size may not allow sufficient power to detect differences. Additionally, almost all of the PLWH in Maine that are eligible to receive services under the demonstration are receiving services, therefore a reliable comparison group is not available in the state of Maine. Any PLWH who are eligible and not receiving benefits are likely the hardest to reach; therefore, they will not be available to provide reliable data. Furthermore, the

demographic characteristics of Maine (rural, predominately white) make it difficult to compare to national estimates, although options for data comparisons, including to T-MSIS data will be explored toward the end of the demonstration. Without a comparison group, it will not be possible to isolate the effect of the demonstration waiver from other programs present in Maine over the demonstration period. However, since Maine will have over 25 years of data by the end of the demonstration, it will be an excellent opportunity to longitudinally assess changes in disease progression among PLWH in Maine.

Attachments

1. Independent Evaluator
2. Evaluation Budget
3. Timeline
4. Member and provider surveys and sampling method

ATTACHMENT 1. INDEPENDENT EVALUATOR

Independent Evaluator Qualifications

Though there are no specific staffing requirements or qualifications, the following applies:

- Potential evaluation entities will be assessed on their relevant work experience, staff expertise, data management and analytic capacity, experience working with state agency program and research staff, proposed resource levels and availability of key staff, and the overall quality of their proposal.

Process for Obtaining an Independent Evaluator

DHHS has written procedures for purchasing services, which includes consulting and evaluation. As with other programmatic needs, the Department may contract for these services when there is a lack of expertise with existing resources or when there is sufficient urgency such that the existing staff cannot fit within their workload. Written procedures for purchasing provide guidance for all stages of the purchasing processing, including:

- Competitive procurement requirements;
- Waiver to competitive bids;
- General policies and guidance; and
- Detailed procedures for putting contracts into place and for making payments.

The procedures consider business need, availability of Department resources, value (fair and reasonable costs), competition, and sourcing nature.

Consultants are required to sign contracts, detailing services to be performed, dates of service, any deliverables including reports, and a payment schedule. Consultants may be required to sign no conflict of interest statements, if required. Consultants are also required to sign special agreements, called Business Associate Agreements, when they are viewing confidential department data, such as Protected Health Information (PHI). This additional document outlines the consultant's responsibilities should the

data be compromised.

Independent Capacity: In the performance of this Agreement, the parties hereto agree that the Provider, and any agents and employees of the Provider, shall act in the capacity of an independent contractor and not as officers or employees or agents of the State.

Employment and Personnel: The Provider shall not engage any person in the employ of any State Department or Agency in a position that would constitute a violation of 5 M.R.S.A. § 18 or 17 M.R.S.A. § 3104. The Provider shall not engage on a full-time, part-time or other basis during the period of this Agreement, any other personnel who are or have been at any time during the period of this Agreement in the employ of any State Department or Agency, except regularly retired employees, without the written consent of the State Purchases Review Committee. Further, the Provider shall not engage on this project on a full-time, part-time or other basis during the period of this Agreement any retired employee of the Department who has not been retired for at least one year, without the written consent of the State Purchases Review Committee. The Provider shall cause the foregoing provisions to be inserted in any subcontract for any work covered by this Agreement so that such provisions shall be binding upon each subcontractor, provided that the foregoing provisions shall not apply to contracts or subcontracts for standard commercial supplies or raw materials.

State Employees not to Benefit: No individual employed by the State at the time this Agreement is executed, or any time thereafter shall be admitted to any share or part of this Agreement or to any benefit that might arise there from directly or indirectly that would constitute a violation of 5 M.R.S.A. § 18 or 17 M.R.S.A. § 3104. No other individual employed by the State at the time this Agreement is executed, or any time thereafter shall be admitted to any share or part of this Agreement or to any benefit that might arise there from directly or indirectly due to his employment by or financial interest in the Provider or any affiliate of the Provider, without the written consent of the State Purchases Review Committee. The Provider shall cause the foregoing provisions to be inserted in any subcontract for any work covered by this Agreement so that such provisions shall be binding upon each subcontractor, provided that the foregoing provisions shall not apply to contracts or subcontracts for standard commercial supplies or raw materials.

Conflict of Interest: The Provider covenants that it presently has no interest and shall not acquire any interest, direct or indirect, which would conflict in any manner or degree with the performance of its services hereunder. The Provider further covenants that in the performance of this Agreement, no person having any such known interests shall be employed.

ATTACHMENT 2. EVALUATION BUDGET

Listed below are the proposed tasks, staffing and costs for the evaluation budget. The budget is based on estimated costs to be incurred by the State of Maine and an external evaluator selected to assist with evaluation efforts.

Evaluation Budget Tasks

Project Management: External evaluator activities for this task include at least quarterly meetings with the State of Maine, operational support for administering the evaluation contract, emails and phone conferences, and additional duties as needed. A total of 100 hours annually for this task are estimated in years 2020 through 2026 while 200 hours annually are planned in years 2027 through 2030.

Instrument Design and Data Collection: In years 2020 through 2028, the State of Maine will spend an estimated 150 hours annually on instrument design and data collection. This estimate includes the design and data collection related to the annual member and provider surveys.

IRB Approval: The research-based approach of this evaluation requires review and approval by an Institutional Review Board (IRB). Approval is typically granted at the start of the project and renewed annually until data collection is completed. The cost for the annual IRB review is estimated at \$2,000 in the first year and external evaluator time to assemble IRB packages is estimated at 80 hours in 2020 and 40 hours in years 2021 through 2028.

Data Cleaning / Analysis: In years 2020 through 2026, the external evaluator will spend an estimated 60 hours annually to compile clean and analyze data collected during that year for an annual monitoring report for the State of Maine. In years 2027 through 2029, the external evaluator will be cleaning and analyzing data for the interim and final reports to be submitted to CMS; 200 hours per year are estimated for the external evaluator to complete these activities.

Reporting: In years 2020 through 2026, the external evaluator will spend an estimated 50 hours annually to complete an annual monitoring report for the State of Maine. In years 2027 through 2030, the external evaluator will be writing and revising interim and final reports to be submitted to CMS; 150 hours per year are estimated for the external evaluator to complete these activities.

Staffing

The external evaluator would utilize the following general staff classifications during the course of the project:

- Project Manager
- Subject Matter Expert Consultant
- Senior Analyst
- Junior Analyst
- Operations Manager

Evaluation Budget Costs

Grand total for entire demonstration over 10 years: \$660,993

There is a 3% increase from year-to-year to accommodate cost-of-living / inflation costs over time.

| Task | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 |
|---------------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|------------------|-----------------|-----------------|
| Project Management | \$13,000 | \$13,390 | \$13,792 | \$14,206 | \$14,632 | \$15,071 | \$15,523 | \$31,978 | \$32,938 | \$33,926 | \$34,944 |
| Instrument Design and Data Collection | \$5,631 | \$5,799 | \$5,973 | \$6,153 | \$6,337 | \$6,527 | \$6,723 | \$6,925 | \$7,133 | | |
| IRB Approval | \$12,400 | \$7,416 | \$7,639 | \$7,868 | \$8,105 | \$8,348 | \$8,599 | \$8,858 | \$9,124 | | |
| Data Cleaning and Analysis | \$7,800 | \$8,034 | \$8,275 | \$8,524 | \$8,779 | \$9,043 | \$9,314 | \$31,978 | \$32,938 | \$33,926 | |
| Reporting | \$6,500 | \$6,695 | \$6,896 | \$7,103 | \$7,316 | \$7,536 | \$7,762 | \$19,986 | \$20,586 | \$21,204 | \$21,840 |
| Total | \$45,331 | \$41,334 | \$42,575 | \$43,854 | \$45,169 | \$46,525 | \$47,921 | \$99,725 | \$102,719 | \$89,056 | \$56,784 |

ATTACHMENT 3. TIMELINE AND MAJOR MILESTONES

The demonstration approval period is from April 19, 2019, through December 31, 2028. The demonstration evaluation will comprise data for each of the years from 2020 through 2028. Exhibit 8 displays the timeline for the demonstration period including data collection, evaluation, reporting and demonstration milestones.

Timeline and Major Milestones.

| | 2019 | 2020-2026 | 2027 | 2028 | 2029 | 2030 |
|---------------------------------|--|--|---|---|--|---|
| Data collection | <ul style="list-style-type: none"> • Provider survey • Member survey • Administrative data | <ul style="list-style-type: none"> • Annual Provider survey • Annual Member survey • Administrative data | <ul style="list-style-type: none"> • Provider survey • Member survey • Administrative data | <ul style="list-style-type: none"> • Provider survey • Member survey • Administrative data | | |
| Evaluation activities | <ul style="list-style-type: none"> • Creation of the evaluation design • State to begin process for procurement of an outside contractor | <ul style="list-style-type: none"> • Cross-sectional analysis of Annual data • State to execute and award contract with outside contractor | Longitudinal analysis of years 2019-2026 | | Longitudinal analysis of years 2019-2028 | |
| Reporting | Submission of evaluation design to CMS | Annual Monitoring report | Dec 20: Interim evaluation report | | | Jun 30: Final evaluation report submitted to CMS |
| Demonstration milestones | Apr: Section 1115 HIV waiver Demonstration extension begins | | | Dec: Section 1115 HIV waiver Demonstration ends | | |

ATTACHMENT 4. MEMBER AND PROVIDER SURVEYS AND SAMPLING METHOD

Member Survey

Annually, MaineCare sends a survey to all members and enrollees who are part of the demonstration. The purpose of this survey is to gain feedback on members' ability to obtain services, their experiences and satisfaction with MaineCare and other providers (specifically their targeted case manager), their health status, living situation, food, and access to care and medications. These surveys are coded so MaineCare can identify members who may need follow up to address concerns, remove barriers, and linked to needed services.

Provider Survey

Annually, MaineCare sends a survey to all infectious disease specialists and primary care providers who, at the time of the mailing, are treating demonstration members and enrollees. This survey is used as a tool to determine areas of weakness within the delivery of healthcare services. Survey questions address topics such as awareness of current treatment guidelines and new recommendations, barriers affecting medication adherence and compliance, awareness of the Maine AIDS Education and Training Center, the MaineCare waiver, and the AIDS Drug Assistance Program.