

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



State Demonstrations Group

JAN 21 2020

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

Dear Ms. Probert:

The Centers for Medicare & Medicaid Services (CMS) has approved Maine's evaluation design, which responded to CMS comments provided to the state, for the section 1115 demonstration entitled "Maine Medicaid Section 1115 Health Care Reform Demonstration for Individuals with HIV/AIDS" (Project Number 11-W-00128/1), effective through December 31, 2028. We sincerely appreciate the state's commitment to a rigorous evaluation approach of your initiative.

CMS has added the approved evaluation design to the demonstration Special Terms and Conditions (STC) as part of Attachment C. A copy of the STCs, that includes the new attachment, is enclosed with this letter per 42 CFR 431.424(c). The approved evaluation design may now be posted to the state's Medicaid website within thirty days of CMS approval. CMS will also post the approved evaluation design as a standalone document, separate from the STCs, on Medicaid.gov.

Please note that an interim evaluation report, consistent with this approved evaluation design, is due to CMS one year prior to the expiration of the demonstration, or at the time of the renewal application if the state chooses to extend the demonstration. Likewise, a summative evaluation report, consistent with this approved design, is due to CMS within 18 months of the end of the demonstration period.

We look forward to our continued partnership with you and your staff on the Maine Medicaid Section 1115 Health Care Reform Demonstration for Individuals with HIV/AIDS. If you have any questions, please contact your CMS project officer, Ms. Wanda Boone-Massey. Ms. Boone-Massey can be reached by email at Wanda.[Boone-Massey@cms.hhs.gov](mailto:Boone-Massey@cms.hhs.gov).

Sincerely,

/s/

Danielle Daly  
Director  
Division of Demonstration  
Monitoring and Evaluation

/s/

Andrea J. Casart  
Director  
Division of Eligibility and Coverage  
Demonstrations

Enclosure

cc: Francis T. McCullough, Acting Deputy Director, Division of Medicaid Field Operations East



# MAINE HIV DEMONSTRATION WAIVER EVALUATION DESIGN

August 22, 2019

Submitted to: Emily Bean, Program Manager  
DHHS/MaineCare Services

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SOLUTIONS TO ADVANCE HEALTH

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# General Background Information

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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.<sup>1,2</sup> 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.<sup>3</sup> 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 referred to collectively as participants since they are receiving many of the same benefits.

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<sup>1</sup> 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.

<sup>2</sup> 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).

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



### Exhibit 1. Demonstration eligibility criteria and benefits.

| Demonstration Eligibility Groups       | Federal Poverty Level (FPL) and qualifying criteria     | Eligible Benefit  |
|--|---|---|
| “Members”<br>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”<br>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%         |
| <b>Total</b> | <b>48</b>         | <b>100%</b> | <b>1,766</b>              | <b>100%</b> |

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:

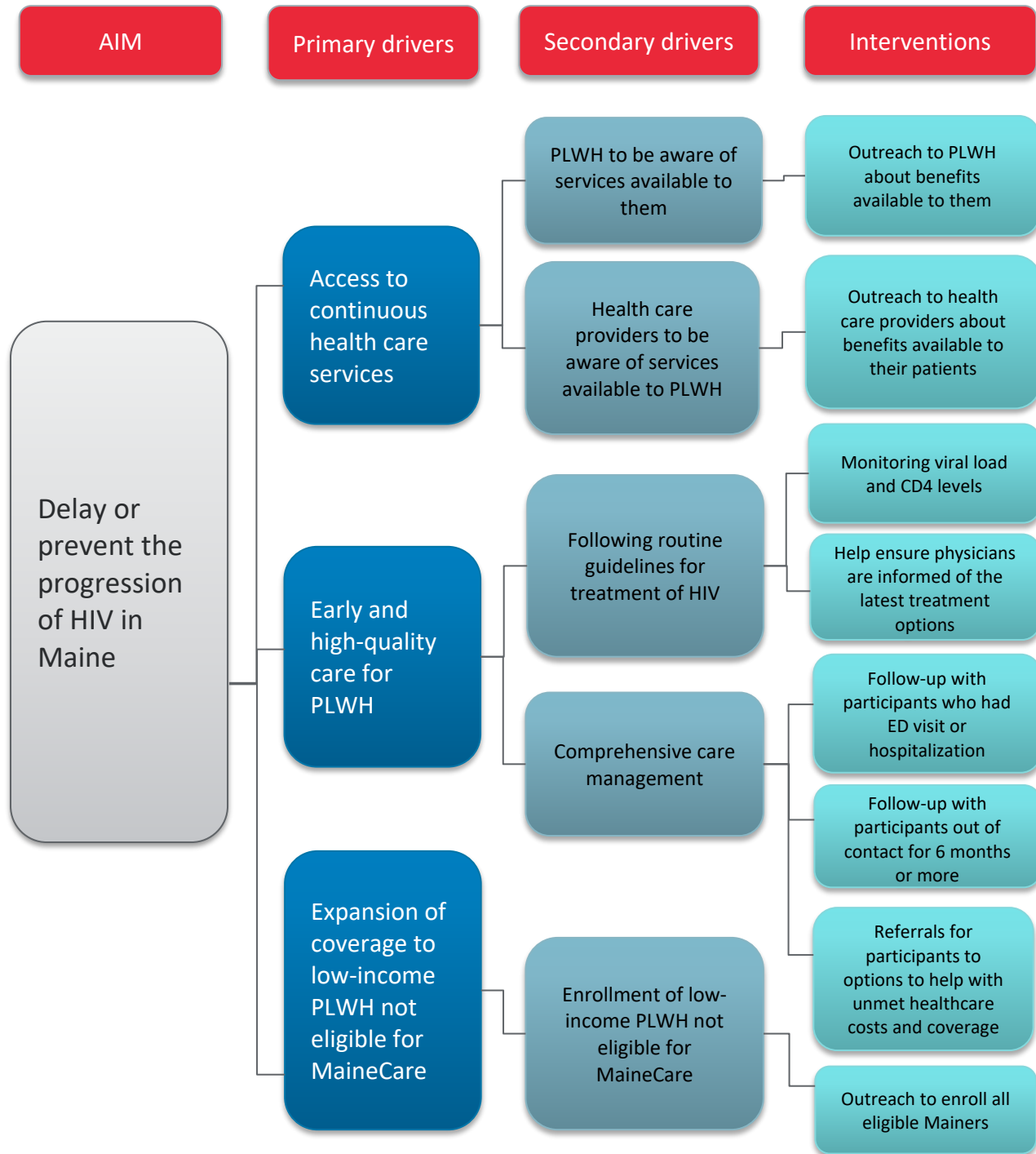
- ▲ What is the relationship between patients' perception of access to care and routine medical visits?
- ▲ What percentage of demonstration participants are meeting the routine treatment guidelines?
  - What percentage of demonstration participants are meeting CDC recommendations for viral load monitoring?



- 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

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## 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 Project<sup>4</sup>; 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.<sup>5</sup> The T-MSIS data set is evolving and currently contains enhanced 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

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<sup>4</sup> 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>.

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



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).<sup>6</sup> 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  |
| 2024 | 913   | 457  |
| 2025 | 938   | 469  |
| 2026 | 964   | 482  |
| 2027 | 991   | 496  |
| 2028 | 1019  | 510  |

<sup>6</sup> Office of Maine Care Services. Annual Report, HIV/AIDS 1115 Demonstration Project, (01/01/18 - 12/31/18).



## 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/<br>Denominator   | Steward<br>Ref# or code |
|---|---|---------------------|---|-------------------------|
| <b><i>Outcome measures</i></b>                          |   |                     |   |                         |
| All-cause emergency department (ED) visits <sup>7</sup> | 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/<br>Eligible member months | NCQA<br>AMB-HH          |
| All-cause hospital admissions <sup>7</sup>              | 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/<br>Eligible member months  | CMS<br>IU-HH            |

<sup>7</sup> 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.



| Measure Title                                   | Description  | Data Source         | Numerator/<br>Denominator   | Steward<br>Ref# or code                    |
|---|--|---------------------|---|--|
| HIV viral load suppression <sup>8</sup>         | 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.<br><br>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/<br><br>Number of enrollees with at least one medical visit in the measurement year | HRSA<br>NQF #2082                          |
| General health status <sup>9</sup>              | 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/<br>All enrollees completing a survey in the measurement period  | Healthy People 2020                        |
| Health-related Quality of Life <sup>10,11</sup> | 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/<br>All enrollees completing a survey in the measurement period  | Behavioral Risk Factor Surveillance System |
| <b>Process measures</b>                         |  |                     |   |  |
| HIV medical visit frequency <sup>8</sup>        | Percentage of patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in each 6-   | Administrative data | Number of enrollees who had at least one medical visit in each 6-month period of the  | HRSA<br>NQF#2079                           |

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

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

<sup>10</sup> 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.

<sup>11</sup> 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



| Measure Title   | Description  | Data Source         | Numerator/<br>Denominator  | Steward<br>Ref# or code                  |
|---|--|---------------------|--|--|
|   | 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. |                     | 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/<br>Number of enrollees with at least one medical visit in the first 6 months of the 24-month measurement period |  |
| Proportion of Days Covered (PDC) <sup>12</sup>            | 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<br>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/<br>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<br>N/A                               |
| Patient perception of accessibility of care <sup>13</sup> | 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/<br>All enrollees completing a survey in the measurement period   | Medical Expenditure Panel Survey         |

<sup>12</sup> PQA Measure Overview. 2019.

[https://pqa.memberclicks.net/assets/Measures/2019\\_PQA\\_Measure\\_Overview.pdf](https://pqa.memberclicks.net/assets/Measures/2019_PQA_Measure_Overview.pdf). Accessed July 25, 2019.

<sup>13</sup> 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.



| Measure Title                       | Description  | Data Source   | Numerator/<br>Denominator  | Steward<br>Ref# or code   |
|-------------------------------------|--|---------------|--|---|
| Medication management <sup>14</sup> | 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/<br>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 enrollee.

## 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

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<sup>14</sup> 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.



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 treatment<sup>15</sup> and the CDC's Medical Monitoring Project<sup>16</sup> 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

In each year of the evaluation, descriptive statistics (means and frequencies) will be developed for the outcome and process measures and compared to national benchmarks using 95% confidence intervals. 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 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

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<sup>15</sup> 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.

<sup>16</sup> 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.



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.

**Exhibit 7. Evaluation Design Table**

| Research Question  | Outcome measures used to address the research question   | Sample or population subgroups to be compared  | Data Sources   | Analytic Methods   |
|--|--|--|--|--|
| <b>Hypothesis 1</b> 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"> <li>• Patient perception of accessibility of care</li> <li>• HIV medical visit frequency</li> </ul> | Demonstration participants: Comparisons made between years and demographic characteristics                                   | <ul style="list-style-type: none"> <li>• Member survey</li> <li>• Administrative data</li> </ul>                         | <ul style="list-style-type: none"> <li>• Descriptive statistics</li> <li>• Time series modeling</li> <li>• Repeated measures modeling</li> </ul> |
| 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"> <li>• Administrative data</li> <li>• CDC Medical Monitoring Project report</li> </ul> | <ul style="list-style-type: none"> <li>• Descriptive statistics</li> <li>• Time series modeling</li> <li>• Repeated measures modeling</li> </ul> |
| 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"> <li>• Administrative data</li> <li>• CDC Medical Monitoring Project report</li> </ul> | <ul style="list-style-type: none"> <li>• Descriptive statistics</li> <li>• Time series modeling</li> <li>• Repeated measures modeling</li> </ul> |
| 1.2c. What percentage of demonstration participants are meeting the threshold for medication adherence (Proportion of days covered)? | Proportion of Days Covered (PDC)   | Demonstration participants: Comparisons made between years and demographic characteristics as well as to National Benchmarks | <ul style="list-style-type: none"> <li>• Administrative data</li> <li>• CDC Medical Monitoring Project report</li> </ul> | <ul style="list-style-type: none"> <li>• Descriptive statistics</li> <li>• Time series modeling</li> <li>• Repeated measures modeling</li> </ul> |
| 1.2d. What is the relationship between medication adherence and self-efficacy for  | <ul style="list-style-type: none"> <li>• Proportion of Days Covered (PDC)</li> <li>• Medication management</li> </ul>                  | Demonstration participants: Comparisons made between years and demographic characteristics                                   | <ul style="list-style-type: none"> <li>• Administrative data</li> <li>• Member survey</li> </ul>                         | <ul style="list-style-type: none"> <li>• Descriptive statistics</li> <li>• Time series modeling</li> <li>• Repeated measures modeling</li> </ul> |





| Research Question   | Outcome measures used to address the research question  | Sample or population subgroups to be compared  | Data Sources   | Analytic Methods   |
|---|---|--|--|--|
| medication management?  |   |  |  |  |
| <b>Hypothesis 2</b> 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"> <li>All-cause emergency department (ED) visits</li> <li>All-cause hospital admissions</li> </ul>   | Demonstration participants: Comparisons made between years and demographic characteristics | Administrative data  | <ul style="list-style-type: none"> <li>Descriptive statistics</li> <li>Time series modeling</li> <li>Repeated measures modeling</li> </ul> |
| 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"> <li>All-cause emergency department (ED) visits</li> <li>All-cause hospital admissions</li> <li>General health status</li> </ul>  | Demonstration participants: Comparisons made between years and demographic characteristics | <ul style="list-style-type: none"> <li>Administrative data</li> <li>Member survey</li> </ul> | <ul style="list-style-type: none"> <li>Descriptive statistics</li> <li>Time series modeling</li> <li>Repeated measures modeling</li> </ul> |
| 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"> <li>All-cause emergency department (ED) visits</li> <li>All-cause hospital admissions</li> <li>HIV viral load suppression</li> <li>RNA Control for Patients with HIV (eCQM)</li> <li>Proportion of Days Covered (PDC)</li> </ul> | Demonstration participants: Comparisons made between years and demographic characteristics | Administrative data  | <ul style="list-style-type: none"> <li>Descriptive statistics</li> <li>Time series modeling</li> <li>Repeated measures modeling</li> </ul> |
| <b>Hypothesis 3</b> 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"> <li>Descriptive statistics</li> <li>Time series modeling</li> <li>Repeated measures modeling</li> </ul> |
| 3.1a. What is the relationship between self-rated health status and health-related quality of life  | <ul style="list-style-type: none"> <li>Length of time of participation</li> <li>Health-related Quality of Life</li> </ul>   | Demonstration participants   | <ul style="list-style-type: none"> <li>Member survey</li> <li>Administrative data</li> </ul> | <ul style="list-style-type: none"> <li>Descriptive statistics</li> <li>Time series modeling</li> </ul>                                     |



| Research Question                                 | Outcome measures used to address the research question                  | Sample or population subgroups to be compared | Data Sources | Analytic Methods |
|---|---|---|--------------|------------------|
| and length of participation in the demonstration? | <ul style="list-style-type: none"><li>• General health status</li></ul> |   |              |                  |

## Methodological Limitations

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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

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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 process, 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        |
| <b>Total</b>                          | <b>\$45,331</b> | <b>\$41,334</b> | <b>\$42,575</b> | <b>\$43,854</b> | <b>\$45,169</b> | <b>\$46,525</b> | <b>\$47,921</b> | <b>\$99,725</b> | <b>\$102,719</b> | <b>\$89,056</b> | <b>\$56,784</b> |



### 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.

**Exhibit 8. Timeline and Major Milestones.**

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



## 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.