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

August 26, 2024

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

Dear Director Probert:

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Maine SUD Pilot Project Evaluation Design Addendum, which is required by the Special Terms and Conditions (STCs), specifically, STC #45 "Draft Evaluation Design" of Maine's section 1115 demonstration, "Substance Use Disorder Care Initiative" (Project No: 11-W-003381), effective through December 31, 2025. CMS has determined that the Evaluation Design, which was amended on January 17, 2023 to reflect the pilot demonstration component(s) and revised on March 29, 2024, meets the requirements set forth in the STCs and our evaluation design guidance, and therefore approves the state's Pilot Project Evaluation Design Addendum.

CMS has added the approved Pilot Project Evaluation Design Addendum to the demonstration's STCs as Attachment E. A copy of the STCs, which includes the new attachment, is enclosed with this letter. In accordance with 42 CFR 431.424, the approved Evaluation Design may now be posted to the state's Medicaid website within 30 days. 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 the approved Evaluation Design, is due to CMS one year prior to the expiration of the demonstration, or at the time of the extension 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. In accordance with 42 CFR 431.428 and the STCs, we look forward to receiving updates on evaluation activities in the demonstration monitoring reports.

Page 2 – Michelle Probert

We appreciate our continued partnership with Maine on the Substance Use Disorder Care Initiative section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle Daly Digitally signed by Danielle Daly -S
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Date: 2024.08.26
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Danielle Daly Director

Division of Demonstration Monitoring and Evaluation

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

State of Maine Department of Health and Human Services



Substance Use Disorder Care Initiative Section 1115(a) Demonstration 11-W-003381

Pilot Project Evaluation Design Addendum

July 21, 2022 - December 31, 2025

Draft Submitted to CMS January 17, 2023; Revised September 19, 2023; Revised Final March 29, 2024

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I. General Background Information

The Maine Substance Use Disorder Care Initiative Section 1115(a) Demonstration was approved on December 22, 2020, effective January 1, 2021 through December 31, 2025. The Demonstration provides the State with authority to provide high-quality, clinically appropriate treatment for beneficiaries with a substance use disorder (SUD) while they are short-term residents in residential and inpatient treatment settings that qualify as Institutions for Mental Diseases (IMDs).

As part of Maine's request to CMS, the State sought approval for several Pilot Projects aimed at providing specialized services and supports to parents with an SUD whose children were involved with Maine's Office of Child and Family Services. This included parents of children at risk of removal from the home and those whose children had already been removed.

On July 21, 2022, CMS authorized three Pilot Projects for the remainder of the Demonstration period (ending December 31, 2025) for parents with SUD who are involved with or at-risk of involvement with Child Protective Services (CPS). These include:

- <u>Pilot 1 Maintenance of Medicaid Coverage</u>. Maine will expand eligibility to continue covering parent(s) who would otherwise lose Medicaid eligibility due to the change in household size when their child is removed from the home pursuant to State law.
- <u>Pilot 2 Parenting Support Services</u>. Parenting support services will focus on two services to support children and families: (A) Attachment Biobehavioral Catch-up (ABC) and (B) Visit Coaching. Eligible parents will receive services that focus on increasing caregiver knowledge of child development, increasing caregiver nurturance, improving parenting practices, strengthening parent-child attachment, meeting the child's health-related and safety needs, and increasing child behavioral and biological regulation, while decreasing caregiver behaviors that could be frightening or overwhelming for their child.
- <u>Pilot 3 Home-Based Skill Development Services</u>. This pilot will focus on the development of
 daily living skills, community integration, and housing supports services to eligible parents with
 an SUD. Parents with an SUD may have challenges surrounding self-care, daily living skills,
 personal adjustment, socialization, relationship development, and adaptive skills necessary to
 reside in community settings.

This Evaluation Design addendum will assess whether the pilot initiatives are effective in assisting members struggling with SUD in strengthening their parenting skills and improving outcomes for families and youth. As applicable and feasible, the evaluation will accommodate data collection and analyses stratified by race/ethnicity and geographic region to identify disparities in access, treatment, or health outcomes.

The remainder of this section will provide an overview of each Pilot Project, goals of the pilot, covered benefits and populations impacted by the Demonstration.

Description of Pilot Projects

The Maine Department of Health and Human Services (DHHS) is the umbrella agency responsible for oversight of Maine's public health, behavioral health, Medicaid, and other human service programs. The Office of MaineCare Services (OMS) within the DHHS is the Single State Agency that administers Maine's Medicaid program, known as MaineCare. Medicaid programs supporting treatment and recovery services for persons with an SUD are developed in collaboration with the Office of Behavioral Health (OBH), Office of Child and Family Services (OCFS) and OMS. The Office of Family Independence (OFI) is responsible for Medicaid eligibility determinations. All entities are within DHHS.

In developing and administering the Demonstration's Pilot Project Implementation Protocol OMS is collaborating with OCFS and OBH to expand evidence-based interventions for Medicaid eligible families involved with Child Protection Services (CPS). Pilots are targeted to Medicaid members with an SUD and are involved with or are at risk of involvement with Child Protective Services (CPS). Each of the Pilot Projects is described in brief below

<u>Pilot 1 - Maintenance of Medicaid Coverage</u>. Maine will provide continuing covering for parent(s) who would otherwise lose Medicaid eligibility due to the change in household size when their child is removed from the home pursuant to State law. Medicaid coverage provides access to state plan services as well as access to therapeutic services and rehabilitation under the other Pilot Projects. Medicaid coverage through the waiver will be discontinued if the parent is no longer participating in rehabilitation, no longer participating in the family reunification plan, or has their parental rights terminated.

The parent's eligibility will be periodically renewed consistent with 42 CFR 435.916. If the parent is no longer eligible for reasons other than the change in household composition (e.g., an income increase that would lead to loss of Medicaid eligibility if the household had remained intact), Medicaid coverage will end. The State will redetermine eligibility on other bases prior to termination consistent with 42 CFR 435.916(f), and if ineligible on all bases, will send advance notice and terminate coverage consistent with 42 C.F.R. §431.206 through §431.214 and 42 C.F.R. §435.917.

<u>Pilot 2 - Parenting Support Services</u>. Parenting support services will focus on two programs to support children and families: Attachment Biobehavioral Catch-up (ABC) and Visit Coaching. The ABC program is focused on preventing the removal of young children from the home by helping caregivers improve their knowledge of child development, improving parenting practices, child health and safety. Visit Coaching seeks to assist parents in gaining the skills necessary to support reunification after a child has been removed from the home. An overview of each program is provided below.

- A. Attachment Biobehavioral Catch-up: ABC is an evidence-based intervention designed for caregivers of infants and toddlers who have experienced early adversity. The ABC program consists of ten to twelve 1-hour sessions in the member's home, facilitated by a coach certified in ABC. The Pilot Project will offer support for women beginning in the sixth month of pregnancy and parents of young children up to 24 months of age. ABC services include:
 - 1) Family support including a skill-based intervention to help caregivers interpret their child's behavioral signs and respond sensitively, address the child's behavior, and help develop secure attachments between child and caregiver;

- Psychosocial education to improve the parent's understanding of their child's behavioral cues, understanding mental health and how it impacts attachment, understanding intrusive and frightening behaviors, and considering how history affects parenting and attachment; and
- 3) Therapeutic intervention through in-the-moment prompts and feedback to address target behaviors and foster caregiver nurturance, positive engagement, and attachment between parent and child.
- B. Visit Coaching: Visit Coaching is a program designed for child welfare-involved families whose children of any age are placed in foster care and are working toward reunification. Visit Coaching is a strengths-based therapeutic intervention between the coach and the family. Service intensity and duration may vary based on need. Services offered through the Medicaid Visit Coaching program include:
 - 1) Counseling to prepare for visits, giving feedback on visits, and improve communication with the foster parent;
 - 2) Treatment planning with the parent and the coach based on the child's specific needs;
 - Psychoeducation including modeling and coaching parents on how to engage with their children through play and other age-appropriate activities and the unique needs of the child; and
 - 4) Family coaching with the parents and child(ren) while in the home, engaging with the entire family throughout the visit.

<u>Pilot 3 - Home-Based Skill Development Services</u>. Home-Based Skill Development services are currently offered as part of the Medicaid State Plan and 1915c waiver authority for members with serious mental illness and members with intellectual disabilities who meet institutional level of care. This pilot will examine the effectiveness of offering similar services and supports to Medicaid members who are parents with SUD. Daily living skills development services include:

- 1) Psychosocial Rehabilitation to restore and maintain functioning
- 2) Social skills training in appropriate community services; and
- 3) Development of positive personal support networks.

This service will assist members to develop the skills necessary for living in the community and aid in their recovery process through daily living skills development, community integration, and housing supports. Members will receive recovery supports aimed at preventing use of more intensive interventions, developing social opportunities and natural support systems, and increasing self-advocacy. The service will be delivered at an intensity and duration determined to be clinically appropriate to address the individual's needs.

Pilot Project Goals

Maine's SUD delivery system includes therapeutic and support services aimed at strengthening family stability and helping youth in custody achieve permanency in their living situations. MaineCare's State Plan Authority and treatment services available under Early, Periodic, Screening, Diagnosis and Treatment (EPSDT) authorities assure children have access to medically necessary services designed to ameliorate defects and address physical and mental illness and conditions. Recognizing the importance of early childhood development, the Pilot Projects under the Demonstration are expected to promote caregiver skills in supporting healthy child development expected under the EPSDT program and enhance family stability.

In total, these efforts support the following goals:

- 1. Maintain or improve access to SUD and mental health treatment for Medicaid members whose children are removed from the home
- 2. Improve family stability and parenting skills when young children are at risk of removal from the home
- 3. Improve child health outcomes by avoiding adverse childhood experiences (ACEs)
- 4. Support family reunification when a child(ren) has been removed from the home
- 5. Maintain community living and avoid more intensive residential, ED or hospital services for parents who have an SUD and their child(ren).

Exhibit 1-1 provides an overview of each project by target group and goal areas.

Exhibit 1-1 Pilot Project, Target Group and Goal Area Alignment

| Pilot Project | Target Group | | | | | |
|------------------------------------|---|-------------|----------|----------|----------|----------|
| Pilot Project | Target Group | 1 | 2 | 3 | 4 | 5 |
| Continued Coverage | Medicaid members who would otherwise lose Medicaid eligibility when a child is removed from the home, pursuant to State law | ✓ | | \ | √ | ✓ |
| Parenting Support | | | \ | \ | | ✓ |
| Services | B. Visit Coaching Medicaid members with SUD whose child(ren) have been removed from the home by CPS | > | | > | \ | |
| Home-Based Skill Development | Medicaid members with SUD who are parenting and who are involved with or at risk for involvement with CPS | ✓ | ✓ | ✓ | ✓ | √ |

The Pilot Projects support the original SUD Demonstration goals to increase the rates of identification, initiation, and engagement in treatment for SUD, as well as to increase adherence to and retention in treatment for SUD. In the long term, these services have a potential to reduce overdose deaths when parents engage and are retained in SUD treatment and recovery services.

MaineCare SUD Benefits and Delivery System

Maine offers a comprehensive SUD benefits package through the Medicaid State Plan and the SUD IMD Demonstration. MaineCare utilizes ASAM criteria and other mental health/SUD screening and assessment tools to support treatment and level of care decisions. MaineCare covers all ASAM levels of care, including Medication Assisted Treatment (MAT) and recovery supports. Medicaid members involved in the Pilot Projects will continue to have access to all SUD treatment and recovery support services in the State Plan and under the SUD Demonstration.

The Pilot projects are focused on improving parenting skills and supporting healthy child development. Projects are aimed at family reunification when a child has been removed from the home and family stability for those Medicaid families whose children are at risk of removal. Medicaid members may receive services simultaneous or sequentially from several the projects, based on family need and whether the child(ren) has been removed from the home. Exhibit 1-2 provides an overview of when pilots project enrollment may be simultaneous (\checkmark) or sequential (*).

Exhibit 1-2 Pilots with potential for simultaneous enrollments

| | Continued Coverage | ABC | Visit Coaching | HCBS |
|------------------------------|-----------------------|-----|----------------|------|
| Continued Coverage | | * | ✓ | ✓ |
| ABC | * | | * | ✓ |
| Visit Coaching | ✓ | * | | ✓ |
| Home-based Skill Development | ✓ | ✓ | ✓ | |

^{*}Families may receive services from these programs sequentially if the child is removed or reunified, as applicable for program eligibility. In rare cases a parent may receive ABC and Visit Coaching simultaneously, however it is not expected under the Demonstration.

Programs offered under the parenting support pilot (ABC and Visit Coaching) are currently offered in two locations. Medicaid funding will allow for the expansion statewide and support the integration of comprehensive treatment planning of Medicaid services for at-risk families.

Pilot 2 (ABC and Visit Coaching programs) will be expanded statewide over the course of the Demonstration. Pilot Project 3 (Home-Based Skill Development for parents with an SUD) does not currently exist. OMS will work with partner agencies to develop Pilot Project 3 program rules and standards. The Pilot Projects will be incorporated into the existing delivery system using sole source (Pilot Project 2) and competitive procurements (Pilot Project 3).

Alignment with Title XIX Medicaid Program Objectives

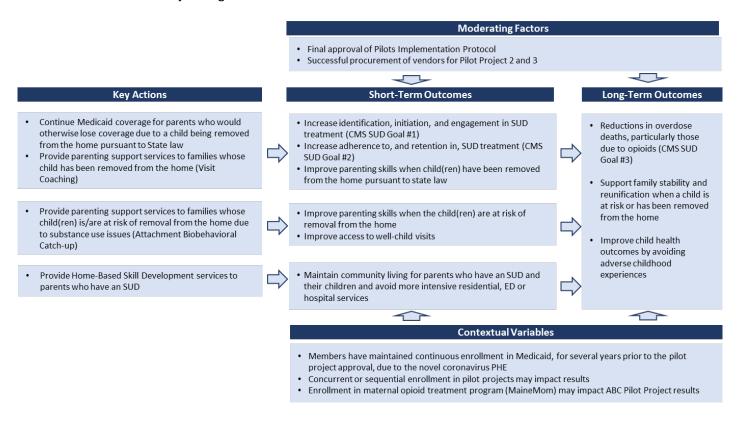
The Maine SUD Demonstration and its Pilot Projects supports the federal Medicaid program in its core mission: to meet the health and wellness needs of our nation's vulnerable and low-income individuals and families and to improve access to high-quality, person-centered services that produce positive health outcomes for individuals.

Logic Model and Quantifiable Outcomes

The Pilot Projects are currently under development and are expected to be operational in Demonstration Year 3. Pilot Project 1 is expected in October of 2023 and Pilots 2 and 3 are expected to begin in July of 2023.

Allowing parents to retain Medicaid eligibility (Pilot Project 1) is expected to increase access to SUD and MH treatment services and support retention in treatment for parents/caregivers who are involved with CPS. Pilot Project 2 and 3 will support parents/caregivers in understanding child development and health needs, improving family stability, and promoting reunification as applicable. Pilot Project 3 will provide parents/caregivers with support in improving and enhancing the skills needed to address their substance use, maintain safe and stable community living, and provide a nurturing environment for their children. In the long term, all Pilots are expected to contribute to a reduction in overdose deaths, support family stability and improve child health by avoiding adverse childhood events. Moderating and contextual variables are discussed in Sections II – VII. Exhibit 1-3 provides a visual depiction (Logic Model) of the goals of the Pilot Projects.

Exhibit 1-3. Pilot Project Logic Model



II. Pilot Project 1 Maintaining Medicaid Coverage

Pilot Project 1 will allow for continued Medicaid coverage for parent(s) who would otherwise lose Medicaid eligibility due to the change in household size when their child is removed. The pilot is projected to serve approximately 850 members during each calendar year (CY). The effective date of the pilot is expected to be October 1, 2023. An overview of the evaluation questions, hypotheses, measures, and methods, including methodological limitation is presented in the following sections.

Evaluation Questions and Hypotheses

The Pilot provides continued Medicaid coverage as well as access to therapeutic services and rehabilitation offered through the other Pilot Projects with the goal of family reunification. The OMS anticipates that the continuation of coverage will allow Medicaid members to seek treatment for SUD and/or mental health challenges and that that members will be retained in treatment services.

The evaluation activities for Pilot Project 1 will consider three primary evaluation questions and four hypotheses. An overview of the evaluation questions and hypotheses associated with the Pilot Project 1 is presented in Exhibit 2-1 below.

Exhibit 2-1. Pilot Project 1 Evaluation Questions and Hypotheses

| | Evaluation Question | | Hypothesis |
|----|--|----|--|
| 1. | Does Pilot Project 1 maintain or improve access to SUD and mental health treatment for Medicaid members whose children were removed from the home? | 1. | Members who participate in Pilot Project 1 will maintain or increase utilization of community-based SUD and/or MH treatment services. |
| 2. | Does Pilot Project 1 maintain or improve retention in treatment services? | 1. | Members who participate in Pilot Project 1 will maintain or improve retention in treatment. |
| 3. | Does Pilot Project 1 support family reunification? | | The number of children who are reunified with their parents will increase for parents who participate in Pilot Project 1. Children who were returned to the home will be maintained in the home setting for at least nine (9) months after reunification. |

Methodology

This section describes the evaluation design for Pilot project 1. It also includes a description of the population, evaluation period, measures. Data sources, cleaning and validation and the expected analytical method for each Pilot is presented in Section V.

Evaluation Design

Pilot Project 1 will be examined using a quasi-experimental pre/post enrollment design. Utilization of services will be assessed before and after children are removed from the home to determine if maintaining Medicaid coverage resulted in parents accessing more mental health and SUD treatment services while participating in Pilot Project 1.

Target and Comparison Populations

All Medicaid members participating Pilot Project 1 will be included in the study group. Members who are non-compliant or who lose parental rights will be removed from the sample. A comparison strategy identifying Members not participating the Pilot was ruled out due to following factors:

- Once a member is terminated from the Medicaid program, information on their utilization of health care services or health status is not available.
- Voluntary participation in Demonstration evaluation activities is unlikely given that Medicaid members who are terminated are either non-compliant with treatment or have lost parental rights.

Evaluation Period

Implementation of Pilot Project 1 is expected on October 1, 2023. The evaluation for Pilot Project 1 will encompass the pre-enrollment period from October 1, 2022 to October 1, 2023 and continue through the end of the Demonstration on December 31, 2025. Should the Pilot begin before or after October 1, 2023, the baseline period will be adjusted to be one year prior to enrollment.

Evaluation Measures

Evaluation measures, data sources and analytic approach for each question and hypothesis are presented in Exhibit 2-2 on the following page.

The evaluation will rely on administrative data collected by OMS, OFI and OCFS. The primary sources of data will be the Maine Integrated Health Management Solution (MIHMS); the Automated Client Eligibility System (ACES) maintained by the OFI; and the Maine Child Welfare Information System (KATAHDIN). These data sources are described in detail in Section V.

Exhibit 2-2. Pilot Project 1 Evaluation Questions, Hypotheses, Measures and Analytic Approach

| Measure/Steward* | Numerator | Denominator | Data Source | Analytics/Frequency | | |
|--|---|---|-----------------|-------------------------------------|--|--|
| Evaluation Question 1. Does Pilot Project 1 | maintain or improve access to community- | based SUD and mental health treatm | ent for Medicai | d members whose | | |
| children were removed from the home? | | | | | | |
| Hypothesis 1. Members who participate in I | Pilot Project 1 will maintain or increase utili | zation of community-based SUD and, | or MH treatme | ent services. | | |
| Percent of members receiving outpatient treatment for MH or SUD | The number of members with an outpatient mental health or SUD treatment service | The number of members participating in the Pilot Project | MIHMS | Pre/ post with t- test; annually | | |
| Evaluation Question 2. Does Pilot Project 1 | maintain or improve retention in treatmen | t services? | | | | |
| Hypotheses 1. Members who participate in | Pilot Project 1 will maintain or improve ret | ention in treatment. | | | | |
| Percent of members who engage with MH or SUD services over six-month period with no more than a 45-day gap between visits | The number of members with a mental health or SUD treatment service during a 180-day period with no more than a 45-day gap between visits | The number of members participating in the Pilot Project | MIHMS | Pre/ post with t- test; annually | | |
| Evaluation Question 3. Does Pilot Project 1 | support family reunification? | | | | | |
| Hypothesis 1. The number of children who | are reunified with their parents will increas | ed for members participating in the P | Pilot Project. | | | |
| Percent of children involved in the Pilot program who are returned to the home during the measurement period | The number of families with one or more children returned to the home during the measurement period | The number of families participating in the Pilot during the measurement period | KATAHDIN | Pre/ post with t- test; annually | | |
| The percent of children statewide in out- of-home placement pursuant to State law who are returned to the home during the measurement period | The number of families with one or more children returned to the home during the measurement period | The number of families involved with CPS statewide whose child(ren) are removed from the home during the measurement period | KATAHDIN | Pre/ post with t- test; annually | | |
| Hypothesis 2. Children who were returned to the home will be maintained in the home setting for at least nine (9) months after reunification | | | | | | |
| The percent of children returned home during the demonstration period who were maintained in the home setting for at least nine months after reunification | The number of families whose children were maintained in the home for at least nine months after reunification | The number of families with one or more children returned to the home during the measurement period | KATAHDIN | Pre/ post with t- test; annually | | |

^{*} Unless otherwise noted, all measures are state-specific and developed by the evaluation team

III. Pilot Project 2 Parenting Support Services

The Parenting Support Services Pilot Project is comprised of two programs: Attachment Biobehavioral Catch-up (ABC) and Visit Coaching. The ABC program is focused on preventing the removal of young children from the home by helping caregivers improve their knowledge of child development, improving parenting practices, child health and safety. Visit Coaching seeks to assist parents in gaining the skills necessary to support reunification after a child has been removed from the home. It is anticipated that approximately 200 Medicaid members per year will be served in the ABC program and 100 per year in the Visit Coaching program. Both programs are expected to begin July 1, 2023.

The OCFS case worker will complete an UNCOPE assessment to determine if substance use risk factors are present in the home. For all UNCOPE screens that are positive the caseworker will provide information to the caregivers regarding their eligibility in Pilot Project 2, as applicable. Members will be referred by OCFS to the vendor for final determination of eligibility and enrollment in the Pilot. The vendor is required to track all enrollments, level of engagement and retention in program services.

Evaluation Questions and Hypotheses

The Parenting Support Services Pilot is expected to support parents in gaining the skills they need to promote healthy child development and address their own substance use risk factors as applicable. The evaluation activities for Pilot Project 2 will consider four primary evaluation questions and five hypotheses. An overview of the evaluation questions and hypotheses associated with Pilot Project 2 is presented in Exhibit 3-1 below.

Exhibit 3-1. Pilot Project 2 Evaluation Questions and Hypotheses

| Ma | ineCare Pilot Project Evaluation Question | | Hypothesis |
|----|--|----|---|
| 1. | Does the ABC pilot result in improved family stability (e.g., children remaining in the family home)? | 1. | Children whose caregivers participate in ABC services will be maintained in the home for at least nine months following program completion. |
| 2. | Does the ABC pilot improve access to primary or preventive care for children whose parents complete the program? | 1. | Children whose caregivers participate in ABC services will increase the number of well child visits during the measurement period |
| | | 1. | The number of children who are reunified with |
| 3. | Does the visit coaching pilot result in family reunification when a child(ren) has been | | their caregivers will increase for parents who complete Visit Coaching services |
| | removed from the home pursuant to State law | 2. | Children who were returned to the home will not re-enter the program in the nine (9) months after the completion of Pilot Project services |
| 4. | Are members satisfied with the services they received from the visit coaching program? | 1. | Members who participate in Visit Coaching will report improved satisfaction with the vendor and service model |

Methodology

This section describes the evaluation design for Pilot Project 2. It also includes a description of the population, evaluation period, measures. Data sources, cleaning and validation and the expected analytical method for each Pilot is presented in Section V.

Evaluation Design

The evaluation for Pilot Project 2 will rely on quasi-experimental methods. The evaluator will work with OMS and OCFS to determine if a comparison strategy is feasible. If feasible, the design will employ Propensity Score or Coarsened Exact Matching to create a treatment and comparison group. If the comparison strategy is not feasible or matching does not yield balanced groups, the design will employ pre/post methods to measure change before and after parent/caregiver enrollment in Pilot Project 2.

Target and Comparison Populations

The evaluation study group will include all Medicaid members who are enrolled in Pilot Project 2 services through the State's vendor(s). To the extent possible, the evaluation team will work with OMS and OCFS to identify a comparison sample of Medicaid enrolled families working with child protective services who are not receiving pilot program services. Variables considered for matching include:

- UNCOPE score at time of CPS involvement or removal from the home
- Age of child at time of CPS involvement (for ABC program and children who are not removed from the home)
- Age of child at time of out-of-home placement pursuant to State law (for visit coaching)
- Age of parent/caregiver at time of CPS involvement or removal of child(ren) from the home
- County of residence for the caregiver participating in Pilot Project 2

Members will be excluded from the comparison sample if they received treatment services under Pilot Projects 3.

Evaluation Period

Implementation of Pilot Project 2 is expected on July 1, 2023. The evaluation will examine performance July 1, 2023 through December 31, 2025. If a pre/post enrollment design is employed, the pre-enrollment period will be 12-months.

Evaluation Measures

Evaluation measures, data sources and analytic approach for each question and hypothesis are presented in Exhibit 3-2, on the following page.

Exhibit 3-2. Pilot Project 2 Evaluation Questions, Hypotheses, Measures and Analytic Approach

| Measure/Steward* | Numerator | Denominator | Data Source | Analytics/Frequency | | |
|--|--|---|-------------------------------|---------------------------|--|--|
| Evaluation Question 1. Does the ABC pilot re | esult in improved family stability (e.g., child | ren remaining in the family home)? | | | | |
| Hypothesis 1. Children whose caregivers participate in ABC services will be maintained in the home for at least nine months following program completion. | | | | | | |
| Percent of children who remain in the home after the completion of ABC services | The number of children who remain in the home for at least nine months following parent/caregiver involvement in the ABC program | The number of children whose parent/caregiver is participating in the ABC program | KATAHDIN | PSM w/t-test; annually | | |
| Evaluation Question 2. Does the ABC pilot in | mprove access to primary or preventive car | e for children whose parents complet | e the program | ? | | |
| Hypotheses 1. Children whose caregivers pa | articipate in ABC services will increase the n | umber of well child visits during the r | measurement p | period | | |
| Percent of children who receive a well- child visit in the 12-months following Pilot Project participation (HEDIS® W30) | The number of children who receive a well-child visit in the year following participation in the ABC program | The number of children whose parent/caregiver is participating in the ABC program | MIHMS | PSM w/t-test; annually | | |
| Evaluation Question 3. Does the visit coaching pilot result in family reunification when a child(ren) has been removed from the home pursuant to State law | | | | | | |
| Hypothesis 1. The number of children who are reunified with their caregivers will increase for parents who complete Visit Coaching services | | | | | | |
| Percent of children involved in the pilot program who are returned to the home during the measurement period | The number of families with one or more children returned to the home during the measurement period | The number of families participating in the Pilot during the measurement period | KATAHDIN | PSM w/t-test; annually | | |
| Hypothesis 2. Children who were returned t | to the home will not re-enter the program is | n the nine (9) months after the comp | letion of Visit C | Coaching services | | |
| The percent of children returned home during the demonstration period who were maintained in the home setting for at least nine months after reunification | The number of families whose children were maintained in the home for at least nine months after reunification | The number of families with one or more children returned to the home during the measurement period | KATAHDIN | PSM w/t-test; annually | | |
| Evaluation Question 4. Do parenting skills improve after participation in visit coaching? | | | | | | |
| Hypothesis 1. Members who participate in V | | | visit coaching s | services | | |
| The percent of parents reporting satisfaction | The number of parents who report they are satisfied with the visit coaching service | The number of parents who complete a Parent Survey (post Visit Coaching services) | Vendor Quarterly Report | Descriptive | | |

^{*} Unless otherwise noted, all measures are state-specific and developed by the evaluation team

IV. Pilot Project 3 Home-Based Skill Development

The Home-Based Skills Development Pilot Project will support Medicaid members with an SUD who may benefit from therapeutic services to restore and improve the skills necessary to maintain community living, promote healthy child development and maintain safe and stable housing. The program is focused on preventing the need for more intensive inpatient, residential and ED utilization, when avoidable. It is anticipated that approximately 200 Medicaid members per year will be served in the pilot, which is expected to begin July 1, 2023.

The OCFS case worker will complete an UNCOPE assessment to determine if substance use risk factors are present in the home. For all UNCOPE screens that are positive the caseworker will provide information to the caregivers regarding their eligibility in Pilot Project 3, as applicable. Members will be referred by OCFS to the vendor for final determination of eligibility and enrollment in the pilot. The vendor is required to track all enrollments, level of engagement and retention in program services.

Evaluation Questions and Hypotheses

The Home-Based Skills Development program is expected to support parents in gaining the skills they need to maintain community living, promote healthy child development, and address their own substance use risk factors as applicable. The evaluation activities for Pilot Project 3 will consider two primary evaluation questions and five hypotheses. An overview of the evaluation questions and hypotheses associated with Pilot Project 3 is presented in Exhibit 4-1 below.

Exhibit 4-1. Pilot Project 3 Evaluation Questions and Hypotheses

| | Evaluation Question | | Hypothesis |
|----|--|----|---|
| 1. | Does Pilot Project 3 support community living by avoiding more | 1. | Inpatient admissions for SUD will be controlled or reduced for participants in Pilot Project 3 |
| | intensive residential, hospital or ED services for parents who have an SUD | 2. | The use of residential SUD treatment will decrease for participants in Pilot Project 3 |
| | and their child(ren) | 3. | Out of home placements for children of participants in Pilot Project 3 will be decreased |
| | | 4. | The number of children who are reunified with their caregivers will increase for parents who are participating in Pilot Project 3 |
| 2. | Do parent/caregivers who participate in Pilot Project 3 have lower ED use for SUD? | 1. | Visits to the ED for SUD will be controlled or reduced for participants in Pilot Project 3 |

Methodology

This section describes the evaluation design for Pilot Project 3. It also includes a description of the population, evaluation period, measures. Data sources, cleaning and validation and the expected analytical method. for each Pilot is presented in Section V.

Evaluation Design

The evaluation for Pilot Project 3 will rely on quasi-experimental methods. The evaluator will work with OMS and OCFS to determine if a comparison strategy is feasible. If feasible, the design will employ

Propensity Score or Coarsened Exact Matching to create a treatment and comparison group. If the comparison strategy is not feasible or matching does not yield balanced groups, the design will employ pre/post methods to measure change before and after parent/caregiver enrollment in Pilot Project 3.

Target and Comparison Populations

The evaluation study group will include all Medicaid members who are enrolled in Pilot Project 3 services through the State's vendor(s). To the extent possible the evaluation team will work with OMS and OCFS to identify a comparison sample of Medicaid enrolled families working with child protective services who are not receiving pilot program services. Variables considered for matching include:

- UNCOPE score at time of CPS involvement or removal from the home
- Age of child at time of CPS involvement (for ABC program and children who are not removed from the home)
- Age of child at time of out-of-home placement pursuant to State law (for visit coaching)
- Age of parent/caregiver at time of CPS involvement or removal of child(ren) from the home
- County of residence for the caregiver participating in Pilot Project 3

Members will be excluded from the comparison sample if they received treatment services under Pilot Projects 2.

Evaluation Period

Implementation of Pilot Project 3 is expected on July 1, 2023. The evaluation for examine performance July 1, 2023 through December 31, 2025. If a pre/post enrollment design is employed, the pre-enrollment period will be 12 months.

Evaluation Measures

Evaluation measures, data sources and analytic approach for each question and hypothesis are presented in Exhibit 4-2 on the following page. In addition to the target measures, OMS is interested in understanding the implementation experience for State staff and providers in developing this new program. The evaluation team will conduct a survey (through focus groups, facilitated interview or electronic methods) related to the development and implementation of Pilot Project 3.

Evaluation will include a survey of State staff and vendors at two points in time. The first will occur in the first year of operation and include questions related to

- Implementation success and challenges
- Enhancements that could be made to the program to support effectiveness in subsequent years

The second interview will be conducted at the end of the Demonstration and focus on identifying program outcomes, successes and considerations for program continuation or expansion.

The State is currently in the process of procuring a vendor through a competitive RFP. As part of the procurement the vendor will be required to conduct a survey of parental satisfaction. The evaluation team will work with OMS to determine if the parental survey, once developed, be used to augment findings in the interim and/or summative reports.

Exhibit 4-2. Pilot Project 3 Evaluation Questions, Hypotheses, Measures and Analytic Approach

| Measure/Frequency/Steward* | Numerator | Denominator | Data Source | Analytics/Frequency | | |
|--|--|---|------------------|---------------------------|--|--|
| Evaluation Question 1. Does Pilot Project 3 | support community living and avoid more i | ntensive residential, hospital or ED se | ervices for pare | nts who have an SUD | | |
| and their child(ren) | | | | | | |
| Hypothesis 1. Inpatient admissions for SUD | will be controlled or reduced for participan | ts in Pilot Project 3 | | | | |
| The rate of hospitalization for SUD per 1,000 member months for parents/caregivers | The number of inpatient admissions for SUD for parents/caregivers | Number of member months divided by 1,000 for parents/caregivers | MIHMS | PSM w/t-test; annually | | |
| Hypothesis 2. Use of residential SUD treatm | ent will decrease for participants in Pilot Pi | roject 3 | | | | |
| Percent of parent/caregivers participating in the pilot who receive residential SUD treatment | The number of parent/caregivers who receive residential treatment for SUD | The number of parent/caregivers participating in the Pilot | MIHMS | PSM w/t-test; annually | | |
| Hypothesis 3. Out of home placements for o | children of participants in Pilot Project 3 wil | ll be decrease | | | | |
| Percent of children who remain in the home during parent/caregiver participation in Pilot Project 3 | The number of children who remain in the home during parent/caregiver involvement in the pilot | The number of children whose parent/caregiver is participating in the Pilot program | KATAHDIN | ANOVA w/t-test; annually | | |
| Hypothesis 4. The number of children who a | are reunified with their caregivers will incre | | • | | | |
| Percent of children involved in the pilot program who are returned to the home during the measurement period | The number of families with one or more children returned to the home during the measurement period | The number of families participating in the Pilot during the measurement period | KATAHDIN | PSM w/t-test; annually | | |
| The percent of children returned home during the demonstration period who were maintained in the home setting for at least nine months after reunification | The number of families whose children were maintained in the home for at least nine months after reunification | The number of families with one or more children returned to the home during the measurement period | KATAHDIN | PSM w/t-test; annually | | |
| Evaluation Question 2. Do parent/caregivers who participate in Pilot Project 3 have lower ED use for SUD? | | | | | | |
| Hypothesis 1. Visits to the ED for SUD will be | e controlled or reduced for participants in I | Pilot Project 3 | | | | |
| The rate of ED visits for SUD per 1,000 member months for parents/caregivers | The number of visits to the ED for SUD for parents/caregivers | Number of member months divided by 1,000 for parents/caregivers | MIHMS | PSM w/t-test; annually | | |

^{*} Unless otherwise noted, all measures are state-specific and developed by the evaluation team

V. Data Sources, Cleaning, Validation and Analytical Methods

The evaluation will rely on administrative data collected by OMS, OFI and OCFS. The primary sources of data will be the Maine Integrated Health Management Solution (MIHMS); the Automated Client Eligibility System (ACES) maintained by the OFI; and the Maine Automated Child Welfare Information System (KATAHDIN). These data sources are described in Exhibit 5-1.

Exhibit 5-1. Evaluation Design Data Sources

| Data Source | Description |
|---|---|
| Maine Integrated Health Management Solution (MIHMS) | Medicaid payment information and claims data submitted to the State by providers used to support service utilization and trends analysis |
| Automated Client Eligibility System (ACES) | Eligibility and enrollment detail for Medicaid beneficiaries including race and ethnicity, aid category and other demographics used to identify pilot participants and stratify data into sub-groups, when applicable |
| Maine Child Welfare Information System (KATAHDIN) | Child custody, placement and risk information including dates of reunification, parental compliance with treatment programs and termination of parental rights as applicable. |

Data Cleaning and Validation

The evaluator will schedule ad hoc meetings with State subject matter experts if anomalies are found in the data. For example, results or sample size that represent a significant departure from the prior year without clear explanation will prompt individual meetings with data and program experts. In addition, the evaluation team inventories changes in the measure specifications, if any, and any changes in program operations or policy that may have occurred since the last data submission. Processes for each data set are described below.

The measures identified for the evaluation rely on Medicaid claims (paid, suspended, and denied) and Medicaid eligibility information from ACES.

- Medicaid Claims: The evaluator receives a standardized monthly claims extract maintained by
 the State for contractors and partners doing health care research. The evaluator will perform a
 data audit to identify problems and inconsistencies with the data received. This includes
 comparisons to previous claims extracts and sample trends. The evaluator will work with the
 State to answer questions and provide feedback to resolve discrepancies in output.
- Member Eligibility: A recipient aid category code is being developed to identify those Medicaid
 members who retain eligibility under Pilot Project 1. The evaluator will identify all members
 participating in the Pilot Project 1, their start date and ends dates. In addition, the eligibility
 system will provide information on other aid category codes for use in Propensity Score
 Matching as applicable.

Maine Automated Child Welfare Information System: The evaluator will receive information on child placements from the KATAHDIN for all participants. Vendors providing services under Pilot Projects 2

and 3 provide quarterly updates, participant tracking and level of engagement in pilot services through the KATAHDIN. The evaluation team will ensure the data is complete and address any gaps in information or anomalies with the OCFS and the vendor(s) as needed.

Analytic Methods

To address the relatively small number of participants expected under each pilot. The evaluation will use a pooled sample approach for each Pilot Project. Members whose eligibility was terminated due to non-compliance or termination of parental rights will be removed from the study group.

The evaluation data analysis will consist of both exploratory and descriptive strategies and incorporate univariate and multi-variate techniques. The analysis will be performed to systematically apply statistical and/or logical techniques to describe, summarize, and compare data across time. The evaluation questions and hypotheses will use member-level data to draw program level conclusions.

Descriptive statistics will be used to describe the basic features of the data and what they depict, and to provide simple summaries about the sample and the measures. They also will be used to provide summaries about the participants and their outcomes. An exploratory data analysis will be employed to compare many variables in the search for organized patterns. Data will be analyzed as rates, proportions, frequencies, and measures of central tendency (e.g., mean, median, mode), and/or qualitatively analyzed for themes. Where feasible, based on sample size and availability of data, the analysis will be stratified by racial and ethnic sub-populations.

As appropriate, analysis methods will include t-test, and ANOVA. These tests are useful for comparing population means and standard deviations over time and the objective is to determine whether the mean of a certain outcome variable of interest is significantly different between two time periods. An overview of the analytic methods expected for each pilot is provided in Exhibit 5-2 below, followed by a detailed description of each method.

Exhibit 5-2 Overview of Analytic Methods by Pilot Project

| Pilot Project | Design | Analytics |
|--|-------------------------------|---------------|
| Pilot 1 (Continued Coverage) | Pre/post | |
| Pilot 2 (Parenting Support Services: ABC and Visit Coaching) | Propensity Score Matching (if | ANOVA; T-test |
| Pilot 3 (Home-based Skill | not feasible, pre/post) | |
| Development) | | |

Propensity Score Matching

Propensity Score Matching with t-test will be used for evaluating members who are engaged in Pilot Projects 2 and 3 and a comparison group of enrollees who are not engaged with the Pilot Projects. Propensity Score Matching is intended to reduce confounding variables associated with the observational data. Variables examined will include age (child and parent), geography (recipient county of residence), aid category code, gender, and UNCOPE risk score. Geography is characterized as "Urban" and "Rural" using Maine county classifications as Metropolitan Statistical Areas as illustrated in Exhibit 5-3.

Exhibit 5-3. Propensity Score Matching Geographical Categories

| PSM Geographic Category | Maine County (Recipient Place of Residence) | | | | |
|----------------------------|---|--|--|--|--|
| Geographic Category | (Necipient Flace of Nesidence) | | | | |
| Urban | Cumberland, York, Sagadahoc, Androscoggin, Penobscot, Kennebec | | | | |
| Rural | Aroostook, Oxford, Hancock, Somerset, Knox, Waldo, Lincoln, Washington, Franklin, Piscataquis | | | | |

The analysis will account for these variables by selecting similar-looking comparison and treatment groups from the larger population such that the groups look comparable across the demographic factors. A logit regression will be used to estimate the propensity scores and to match using the propensity score. After the matching, sample means will be compared between the treatment and control groups to verify that they are indeed comparable before regressing the outcome of interest. This allows for an estimate of the effect of the treatment on the outcome.

The evaluator will use propensity score matching in alignment with Rosenbaum and Rubin (1983)¹ where the propensity score collapses many observable demographic factors that could contribute to the outcome metric of interest to a one-dimensional score that can be used to compare member characteristics and create a comparison group comparable to the treatment group. This allows the evaluator to attribute more of the differences in the metrics of interest across these two groups to their treatment (or lack thereof in the case of the comparison group) and not to one of the demographic factors which could also explain some or all of the differences between the groups' outcomes. The observed baseline covariates include gender, age, geography, UNCOPE risk score and the aid category codes (enumerated below). The evaluator will perform a pooled analysis for all members participating in the pilot being studied.

Since propensity score is a common but not the only method of comparing multi-dimensional/multi-attributed objects by collapsing the many dimensions to a one-dimensional score, the evaluator will also look at the coarsened exact matching to produce good covariate balancing between the treatment and comparison groups. After matching, the evaluator will compare the two groups on the aforementioned demographic factors to determine if there are statistically significant differences in any of those factors. Ideally, the evaluator should not find such differences, thereby attributing greater explanatory power to the variation in the metrics of interest to the member's association with the comparison or the treatment group. Propensity Score Matching is a nonparametric method of estimating treatment effect in situations where we cannot randomize which subjects receive the comparison or treatment group assignment.

The propensity score provides balancing such that conditional on a propensity score, the distribution of the demographic variables enumerated above is not statistically significantly different. After deriving the propensity scores, the control and treatment groups are matched using the "nearest neighbor" search. Then the design will verify that covariates above are all balanced in the postmatching groups and then compare the results using a t-test.

If the evaluator cannot find appropriately balanced comparison and treatment groups, the hypothesis being studied will be evaluated using a pre/post enrollment design.

¹ The central role of the propensity score in observational studies for causal effects. Rosenbaum P.R., Rubin D. B., Biometrika (1983), 70, 1, pp. 41-55

Qualitative Analysis of Parent Surveys

The vendor is required to conduct a parent survey following the completion of the Visit Coaching program under Pilot Project 2. The survey is aimed at understanding parental satisfaction with the services they received under the pilot. The evaluation of Pilot Project 2 will track and trend parental responses over the course of the Demonstration using descriptive statistics.

Concurrent or Sequential Enrollment in Other Pilot Projects

To account for the effects of concurrent or sequential enrollment in multiple pilots, the evaluator will identify, to the extent possible, those participants that receive services from multiple Pilot Projects. In addition, it is possible for a current participant to have received services under one of the two existing programs offering parenting support services (members will be asked during intake). Participants in Pilot Projects will be identified as receiving support from one, two or three additional pilots or in pre-existing programs. The evaluator will perform the analysis as stated in the design with and without participants who participate in multiple or pre-existing programs. Results will be compared for changes in directionality (e.g., changes in statistical significance).

Isolation from other Initiatives

It may be possible for ABC (Pilot Project 2) or Home-based Skill Development (Pilot Project 3) program participants to also receive MaineMom services. MaineMOM, is funded by CMS outside of the Demonstration. MaineMOM involves providing integrated care management, social service supports, and MAT for Medicaid members who are pregnant and postpartum.

To account for the effects of concurrent enrollment in MaineMOM services, the evaluator will perform the analysis as stated in the design with and without MaineMOM participants. If there are no statistically significant differences between the findings, the evaluator will show the results of the analysis including MaineMOM participants. Otherwise, the evaluator will present the results of the analysis on the population with and without and discuss changes in directionality (e.g., changes in statistical significance).

VI. Methodological Limitations

Due to the quasi-experimental nature of the design and the limitations identified below, the evaluation results cannot be attributed to causal inference. The findings may suggest an association or correlation with various aspects of the Demonstration. However, language suggesting causation or analyses of counterfactuals may not be appropriate when describing results.

Pilot Projects with unique limitations are presented in Exhibit 6-1.

Exhibit 6-1. Methodological Limitations

| Pilot Project | Limitation | Mitigation |
|-----------------------|---|--------------------------------|
| Pilot 1 (Continued | Medicaid members who had children | The design will employ a |
| Coverage) | removed from the home during the | pre/post design to analyze the |
| | baseline period were able to retain | utilization of services before |
| | continuous eligibility due to the novel | and after enrollment in the |
| | coronavirus PHE, thus confounding the | pilot |
| | potential impact of the Pilot Project | |
| Pilot 2 (Parenting | ABC and Visit Coaching are each currently | Members living in regions with |
| Support Services: ABC | offered in one region of the State. | programs operating before the |
| and Visit Coaching) | Evaluators will not be able to discern if a | pilots begin will be excluded |
| | member of the comparison group has | from the potential comparison |
| | received services in the past | group |

VII. Special Methodological Considerations

Maine OMS, OCFS and OBH continue to work out implementation details and a competitive procurement for Pilot Project 3 is still in development. In addition, Maine has not received final CMS approval of its Pilot Projects Implementation Protocol as required under the STCs. Changes in implementation details, timelines or state wideness of the programs may require adjustments to the evaluation design. OMS and the evaluation team will work with CMS to identify any changes that may be necessary due to modified or new implementation activities or procurements.

In addition, the methodology is limited by procurement timelines. Pilots are not expected to begin until July 1, 2023, for Pilot Projects 2 and 3 and October 1, 2023, for Pilot Project 1. This limits the length of the potential intervention period and the number of Medicaid members expected to participate in each pilot. Any delay in procurement or program "go live" dates will further limit the number of Medicaid members in the study groups.

Attachments

Independent Evaluator

As part of the original SUD Demonstration approved in 2021, DHHS partnered with the New England States Consortium Systems Organization (NESCSO) to conduct a procurement for this project. NESCSO issued a Request for Proposals (RFP) on October 2, 2020, on behalf of the State. One RFP was released for all evaluation activities (evaluation design development and implementation) and the production of required CMS reports. Bidders were given the option of working with a subcontractor on the design or implementation components of the procurement. The successful bidder demonstrated, at a minimum, the following qualifications:

- The extent to which the evaluator can meet the RFP's minimum requirements, including an
 assurance that the firm does not have a conflict of interest in designing and performing the
 SUD evaluation;
- The extent to which the evaluator has sufficient capacity to conduct the proposed evaluation, in terms of technical experience and the size/scale of the evaluation;
- The evaluator's prior experience with similar evaluations;
- Past references; and
- Value (i.e., the evaluator's capacity to conduct the proposed evaluation, with consideration given to those that offer higher quality at a lower cost).

Four proposals were received, and Pacific Health Policy Group has been retained to develop the SUD Demonstration Evaluation Design and implement the final evaluation activities in compliance with CMS requirements.

Timeline and Major Milestones

| | 2023 | | | 2024 | | | | 2025 | | | | 2026 | | | | 2027 | |
|--|------|----|----|------|----|----|----|------|----|----|----|------|----|----|----|------|----|
| Pilot Project Evaluation Activity | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 |
| Evaluation Design Addendum and Approval | | | | | | | | | | | | | | | | | |
| Submit Draft Evaluation Design to CMS | | | | | | | | | | | | | | | | | |
| Review CMS feedback and collaborate on | | | | | | | | | | | | | | | | | |
| revisions | | | | | | | | | | | | | | | | | |
| Submit revised Final Evaluation Design to CMS | | | | | | | | | | | | | | | | | |
| Data Collection, Cleaning and Analysis | | | | | | | | | | | | | | | | | |
| Identify and execute data-sharing agreements | | | | | | | | | | | | | | | | | |
| Define data extraction specifications for each | | | | | | | | | | | | | | | | | |
| data source | | | | | | | | | | | | | | | | | |
| Define data extraction timelines for each data | | | | | | | | | | | | | | | | | |
| source | | | | | | | | | | | | | | | | | |
| Revise data tracking tool for pilots as needed | | | | | | | | | | | | | | | | | |
| Clean and validate data received | | | | | | | | | | | | | | | | | |
| Analyze data | | | | | | | | | | | | | | | | | |
| Reporting and CMS Follow-up | | | | | | | | | | | | | | | | | |
| Annual summary of evalautionprogress | | | | | | | | | | | | | | | | | |
| Submit Draft Interim Report to CMS | | | | | | | | | | | | | | | | | |
| Review CMS feedback and collaborate on | | | | | | | | | | | | | | | | | |
| revisions | | | | | | | | | | | | | | | | | |
| Submit Final Interim Evaluation Report to CMS | | | | | | | | | | | | | | | | | |
| Submit Draft Summative Evaluation Report | | | | | | | | | | | | | | | | | |
| Review CMS feedback and collaborate on | | | | | | | | | | | | | | | | | |
| revisions | | | | | | | | | | | | | | | | | |
| Submit Final Summative Evaluation Report | | | | | | | | | | | | | | | | | |
| Post Final Summative Evaluation Report | | | | | | | | | | | | | | | | | |

Pilot Project Evaluation Budget

The original evaluation design contemplated some level of effort for the evaluation of the pilot projects as part of the larger SUD Demonstration design. However, DHHS anticipated that the pilot design would be completed as part of the overall evaluation design originally submitted to CMS in 2021 and not as an addendum. The additional tasks associated with developing and implementation of the pilot project evaluation will add \$49,890 to the exiting approved Demonstration evaluation budget.