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

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) completed its review of the Implementation Plan, which is required by the Special Terms and Conditions (STCs), specifically, STC # 18, of Maine's section 1115 demonstration, "Maine Substance Use Disorder Care Initiative" (Project No: 11-W-003381), effective through December 31, 2025. CMS determined that the Implementation Plan, meets the requirements set forth in the STCs, and thereby approves the state's Implementation Plan.

The Implementation Plan is approved as of the date of this letter through December 31, 2025 and is hereby incorporated into the demonstration STCs as Attachment C (see attached). We appreciate our continued partnership with Maine on the Maine Substance Use Disorder Care Initiative section 1115.

Your project officer for this demonstration is Ms. Wanda Boone-Massey. She is available to answer any question concerning your section 1115 demonstration. Ms. Boone-Massey's contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
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Sincerely,

7/26/2021

X Andrea J. Casart

Signed by: Andrea J. Casart -A

Andrea J. Casart
Director
Division of Medicaid Expansion Demonstrations

Enclosure

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

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: **11-W-003381**

TITLE: **Maine Section 1115 Substance Use Disorder Care Initiative**

AWARDEE: **Maine Office of MaineCare Services**

Under the authority of section 1115(a)(2) of the Social Security Act ("the Act"), expenditures made by Maine for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from January 1, 2021 through December 31, 2025 unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

As discussed in the Centers for Medicare & Medicaid Services' (CMS) approval letter, the Secretary of Health and Human Services has determined that the Maine Section 1115 Substance Use Disorder Care Initiative demonstration, including the granting of the expenditure authority described below, is likely to assist in promoting the objectives of title XIX of the Act.

The following expenditure authority may only be implemented consistent with the approved Special Terms and Conditions (STC) and shall enable Maine to operate the above-identified section 1115(a) demonstration.

1. **Residential and Inpatient Treatment for Individuals with Substance Use Disorder (SUD).** Expenditures for otherwise Medicaid services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD).

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: **11-W-003381**

TITLE: **Maine Section 1115 Substance Use Disorder Care Initiative**

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

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the "Section 1115 Substance Use Disorder Care Initiative" section 1115(a) Medicaid demonstration (hereinafter "demonstration"), to enable the Maine Department of Health and Welfare (hereinafter "state") to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authority authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on the expenditure authority, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS related to the demonstration. The demonstration will be statewide and is approved for a five-year period, from January 1, 2021 through December 31, 2025.

The STCs have been arranged into the following subject areas:

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

II. PROGRAM DESCRIPTION AND OBJECTIVES

This 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). Through this demonstration, the state will test whether this authority improves access to and the affordability of care for such beneficiaries. The state expects additional SUD residential treatment facilities will begin providing these services or expand their current services to the extent they qualify as an IMD, when allowable under state law and in accordance with any state requirements. The state expects that reimbursement for these services will fill a gap in the continuum of care and improve coordination with MaineCare's existing array of community-based services available to individuals otherwise eligible for MaineCare and provide access to evidence-based services at different levels of intensity across a continuum of care, based on individual needs and goals. Maine is committed to maintaining support for community-based SUD treatment options and sought the authority approved under this demonstration in order to better ensure that appropriate treatment options are accessible across the continuum.

During the demonstration period, the state seeks to achieve the following goals:

SUD Demonstration Goals:

1. Increased rates of identification, initiation, and engagement in treatment for SUD;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of emergency departments and inpatient hospital settings for treatment, where the utilization is preventable or medically inappropriate, through improved access to other continuum of care services;
5. Fewer readmissions to the same or higher level of care, where the readmission is preventable or medically inappropriate; and
6. Improved access to care for physical health conditions among beneficiaries with SUD.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).

2. **Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and policy statement, not expressly waived or identified as not

applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state thirty (30) business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
    a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7) as a result of the change in FFP.
    b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

5. **State Plan Amendments.** The state will not be required to submit title XIX or XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP state plans govern.

6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:
    a. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;
    b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
    c. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
    d. An up-to-date CHIP allotment worksheet, if necessary;
    e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

8. **Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer of the state in accordance with the requirements of 442 Code of Federal Regulations (CFR) 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit phase-out plan consistent with the requirements of STC 9.

9. **Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.
    a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a thirty (30) day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the thirty (30) day public comment period has ended, the state must

provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.

c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.

d. Transition and Phase-out Procedures. The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210 and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR §431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

e. Exemption from Public Notice Procedures 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).

f. Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.

g. Federal Financial Participation (FFP). If the project is terminated or any relevant waivers are suspended by the state, FFP must be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

10. Withdrawal of Waiver or Expenditure Authority. CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waiver or

expenditure authorities would no longer be in the public interest or promote the objectives of title XIX and title XXI. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

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

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

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

13. **Federal Financial Participation (FFP).** No federal matching funds for expenditures for this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.

14. **Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, MCOs, and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

15. **Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and

procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(d)(5).

IV. ELIGIBILITY AND ENROLLMENT

16. **Eligibility Groups Affected by the Demonstration.** Under the demonstration, there is no change to Medicaid eligibilityand standards and methodologies for eligibility remain set forth under the state plan. This demonstration will apply to otherwise-eligible Medicaid beneficiaries who are short-term residents in institutions for mental diseases (IMD) primarily to receive SUD treatment or withdrawal management services.

V. SUBSTANCE USE DISORDER PROGRAM AND BENEFITS

17. **SUD Program Benefits.** Effective upon CMS' approval of the SUD Implementation Plan, the demonstration benefit package for Medicaid beneficiaries will include SUD treatment services, including services provided in residential and inpatient treatment settings that qualify as an IMD, which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Medicaid beneficiaries who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance, including OUD/SUD services, that would otherwise be matchable if the beneficiary were not residing in an IMD once CMS approves the state's Implementation Plan. The state will aim for a statewide average length of stay of 30 days or less in residential treatment settings, to be monitored pursuant to the SUD Monitoring Protocol as outlined in STC 19, to ensure short-term residential stays.

    Under this demonstration beneficiaries will have access to high quality, evidence-based OUD/SUD treatment services across a comprehensive continuum of care, ranging from residential and inpatient treatment to ongoing chronic care for these conditions in cost-effective community-based settings.

18. **SUD Implementation Plan and Health IT Plan.**
    a. The state must submit the SUD Implementation Plan within ninety (90) calendar days after approval of this demonstration. The state must submit the revised SUD Implementation Plan within sixty (60) days after receipt of CMS's comments. The state may not claim FFP for services provided in IMDs to beneficiaries who are primarily receiving SUD treatment and withdrawal management services until CMS has approved the SUD Implementation Plan. Once approved, the SUD Implementation Plan will be incorporated into the STCs as Attachment C and, once incorporated, may be altered only with CMS approval. After approval of the applicable implementation plans required by these STCs, FFP will be available prospectively, not retrospectively.
    b. Failure to submit a SUD Implementation Plan will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SUD

program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral as described in STC 24.

c. At a minimum, the SUD Implementation Plan must describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives for the program:

1. Access to Critical Levels of Care for OUD and other SUDs. Coverage of OUD/SUD treatment services across a comprehensive continuum of care including: outpatient; intensive outpatient; medication assisted treatment (medication as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state); intensive levels of care in residential and inpatient settings; and medically supervised withdrawal management, within 12-24 months of demonstration approval.
2. Use of Evidence-based SUD-specific Patient Placement Criteria. Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of demonstration approval;
3. Patient Placement. Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of demonstration approval;
4. Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities. Currently, under state law, residential treatment service providers must be a licensed organization, pursuant to the residential service provider qualifications described in the MaineCare Benefits Manual (e.g., Regulations/provider manual/policy guidance/etc). The state must establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;
5. Standards of Care. Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;
6. Standards of Care. Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of demonstration approval;

7. Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for SUD/OUD. An assessment of the availability of providers in the critical levels of care throughout the state, or in the regions of the state participating under this demonstration, including those that offer MAT within 12 months of demonstration approval;
8. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and SUD/OUD. Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;
9. Improved Care Coordination and Transitions between levels of care. Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of demonstration approval.
10. SUD Health IT Plan. Implementation of the milestones and metrics as detailed in STC 18(d) [or Attachment C].

d. SUD Health Information Technology Plan ("Health IT Plan"). The SUD Health IT plan applies to all states where the Health IT functionalities are expected to impact beneficiaries within the demonstration. As outlined in SMDL #17-003, states must submit to CMS the applicable Health IT Plan(s), to be included as a section(s) of the associated Implementation Plan(s) (see STC 18(a) and 18(c)), to develop infrastructure and capabilities consistent with the requirements outlined in each demonstration-type.

   The Health IT Plan must detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The plans will also be used to identify areas of health IT ecosystem improvement. The Plan must include implementation milestones and projected dates for achieving them (see Attachment C), and must be aligned with the state's broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state's Behavioral Health (BH) IT Health Plan.

   1. The state must include in its Monitoring Protocol (see STC 19(d)) an approach to monitoring its SUD Health IT Plan which will include performance metrics to be approved in advance by CMS.
   2. The state must monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in an addendum to its Annual Report (see STC 28).
   3. As applicable, the state should advance the standards identified in the 'Interoperability Standards Advisory—Best Available Standards and Implementation Specifications' (ISA) in developing and implementing the state's SUD Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.

4. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state should use the federally-recognized standards, barring another compelling state interest.
5. Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally-recognized ISA standards, barring no other compelling state interest.
6. Components of the Health IT Plan include:
    A. The Health IT Plan must describe the state's goals, each DY, to enhance the state's prescription drug monitoring program (PDMP).[1]
    B. The Health IT Plan must address how the state's PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[2] This must also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan must describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients' history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.
    C. The Health IT Plan will, as applicable, describe the state's capabilities to leverage a master patient index (or master data management service, etc.) in support of or SUD care delivery. Additionally, the Health IT Plan must describe current and future capabilities regarding PDMP queries—and the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.
    D. The Health IT Plan will describe how the activities described in (i), (ii) and (iii) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.[3]
    E. The Health IT Plan will describe the state's current and future capabilities to support providers implementing or expanding Health IT functionality in the following areas: 1) Referrals, 2) Electronic care plans and medical records, 3) Consent, 4) Interoperability, 5) Telehealth, 6) Alerting/analytics, and 7) Identity management.

[1] Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance prescriptions in states. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the "opioid" epidemic and facilitate a nimble and targeted response.

[2] *Ibid*.

[3] Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*. MMWR Morb Mortal Wkly Rep 2017;66.

F. In developing the Health IT Plan, states should use the following resources:
    i. States may use federal resources available on Health IT.Gov (https://www.healthit.gov/topic/behavioral-health) including but not limited to "Behavioral Health and Physical Health Integration" and "Section 34: Opioid Epidemic and Health IT" (https://www.healthit.gov/playbook/health-information-exchange/).
    ii. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.

G. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP interoperability, electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.

19. SUD Monitoring Protocol. The state must submit a Monitoring Protocol for the SUD programs authorized by this demonstration within one hundred fifty (150) calendar days after approval of the demonstration. The Monitoring Protocol Template must be developed in cooperation with CMS and is subject to CMS approval. The state must submit a revised Monitoring Protocol within sixty (60) calendar days after receipt of CMS's comments. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs as Attachment D. Progress on the performance measures identified in the SUD Monitoring Protocol must be reported via the quarterly and annual monitoring reports. Components of the SUD Monitoring Protocol must include:

a. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 18(a) and 18(c) and reporting relevant information to the state's Health IT Plan described in STC 18(d);
b. A description of the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Section VIII of the demonstration; and
c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.

20. Evaluation. The SUD Evaluation will be subject to the same requirements as the overall demonstration evaluation, as described in Sections VIII (General Reporting Requirements) and X (Evaluation of the Demonstration) of these STCs.

21. **Unallowable Expenditures Under the SUD Expenditure Authority.** In addition to the other unallowable costs and caveats already outlined in these STCs, the state may not receive FFP under any expenditure authority approved under this demonstration for any of the following:

    a. Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

VI. COST SHARING

22. **Cost Sharing.** Cost sharing imposed upon individuals enrolled in the demonstration is consistent with the provisions of the approved state plan.

VII. DELIVERY SYSTEM

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

VIII. GENERAL REPORTING REQUIREMENTS

24. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement. The following process will be used: 1) Thirty (30) days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) Thirty (30) days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:
    a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
    b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state's written extension request.

c. If CMS agrees to an interim corrective plan in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.
d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement with respect to required deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified in these STCs, the deferral(s) will be released.
e. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

25. Deferral of Federal Financial Participation (FFP) from IMD Claiming for Insufficient Progress Toward Milestones. Up to $5,000,000 in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones and goals as evidenced by reporting on the milestones in the Implementation Plan and the required performance measures in the Monitoring Plan agreed upon by the state and CMS. Once CMS determines the state has not made adequate progress, up to $5,000,000 will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made.

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

27. Compliance with Federal Systems Updates. As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state will work with CMS to:
a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
c. Submit deliverables to the appropriate system as directed by CMS.

IX. MONITORING

28. Monitoring Reports. The state must submit three (3) Quarterly Monitoring Reports and one (1) Annual Monitoring Report each DY. The fourth quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual Report. The Quarterly Monitoring Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The Annual Monitoring Report is due no later than ninety (90) calendar days following the end of the DY. The

reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

a. Operational Updates. The operational updates will focus on progress toward meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; updates on the state's financing plan and maintenance of effort described in STC 18(e); legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
b. Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.
c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately.
d. Evaluation Activities and Interim Findings. Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.
e. SUD Health IT. The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 18(d).

29. SUD Mid-Point Assessment. The state must conduct an independent mid-point assessment by July 1, 2023. In the design, planning and conduction of the mid-point assessment, the

state must require that the independent assessor consult with key stakeholders including, but not limited to: SUD treatment providers, beneficiaries, and other key partners.

The state must require that the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than sixty (60) days after July 1, 2023. This timeline will allow for the assessment report to capture approximately the first two-and-a-half years of demonstration program data, accounting for data run-out and data completeness. The state must brief CMS on the report.

For milestones and measure targets at medium to high risk of not being achieved, the state must submit to CMS modifications to the SUD Implementation Plan, and the SUD Monitoring Plan for ameliorating these risks. Modifications to the applicable Implementation, Financing, and Monitoring Protocol are subject to CMS approval. Elements of the mid-point assessment include:

a. An examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plans, and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol;
b. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date;
c. A determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets;
d. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state's SUD Implementation Plans or to pertinent factors that the state can influence that will support improvement; and
e. An assessment of whether the state is on track to meet the budget neutrality requirements.

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

31. Close-Out Report. Within one hundred twenty (120) calendar days after the expiration of the demonstration, the state must submit a Draft Close-Out Report to CMS for comments.

a. The draft close-out report must comply with the most current guidance from CMS.
b. The state will present to and participate in a discussion with CMS on the close-out report.
c. The state must take into consideration CMS' comments for incorporation into the final close-out report.
d. The final close-out report is due to CMS no later than thirty (30) calendar days after receipt of CMS' comments.
e. A delay in submitting the draft or final version of the close-out report may subject the state to penalties described in STC 24.

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

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

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

X. EVALUATION OF THE DEMONSTRATION

34. Cooperation with Federal Evaluators. As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 24.

35. Independent Evaluator. Upon approval of the demonstration, the state must begin to arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party to sign an agreement that the independent party will conduct the demonstration evaluation in an independent manner in accordance with the CMS-approved draft Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

36. **Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after the approval of the demonstration. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The draft Evaluation Design must be developed in accordance with the following CMS guidance (including but not limited to):
    a. All applicable Evaluation Design guidance, including guidance about SUD. Hypotheses applicable to the demonstration as a whole, and to all key policies referenced above, will include (but will not be limited to): the effects of the demonstration on health outcomes; the financial impact of the demonstration (for example, such as an assessment of medical debt and uncompensated care costs).
    b. Attachment A (Developing the Evaluation Design) of these STCs, technical assistance for developing SUD Evaluation Designs (as applicable, and as provided by CMS), and all applicable technical assistance on how to establish comparison groups to develop a Draft Evaluation Design.

37. **Evaluation Budget.** A budget for the evaluations must be provided with the draft Evaluation Designs. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluations such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the designs are not sufficiently developed, or if the estimates appear to be excessive.

38. **Evaluation Design Approval and Updates.** The state must submit the revised draft Evaluation Designs within sixty (60) calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design*s*, the documents will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design to the state's website within thirty (30) calendar days of CMS approval. The state must implement the evaluation designs and submit a description of its evaluation implementation progress in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in these STCs. Once CMS approves the evaluation designs, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

39. **Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality

Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

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

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

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

a. Unless otherwise agreed upon in writing by CMS, the state must submit the final Summative Evaluation Report within sixty (60) calendar days of receiving comments from CMS on the draft.
b. The final Summative Evaluation Report must be posted to the state's Medicaid website within thirty (30) calendar days of approval by CMS.

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

43. State Presentations for CMS. CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the Interim Evaluation Report, and/or the Summative Evaluation Report.

44. Public Access. The state shall post the final documents (e.g., Monitoring Reports, Close Out Report, the approved Evaluation Design, Interim Evaluation Reports, and Summative Evaluation Reports) on the state's website within thirty (30) calendar days of approval by CMS.

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

XI. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

46. Allowable Expenditures. This demonstration project is approved for expenditures applicable to services rendered during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.[4]

47. Standard Medicaid Funding Process. The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within thirty (30) days after the end of each quarter, the state shall submit form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made

[4] For a description of CMS's current policies related to budget neutrality for Medicaid demonstration projects authorized under section 1115(a) of the Act, see State Medicaid Director Letter #18-009.

available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

48. **Extent of Federal Financial Participation for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole for the following, subject to the budget neutrality expenditure limits described in Section XI:
    a. Administrative costs, including those associated with the administration of the demonstration;
    b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
    c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.

49. **Sources of Non-Federal Share.** The state certifies that its match for the non-federal share of funds for this demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.
    a. The state acknowledges that CMS has authority to review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.
    b. The state acknowledges that any amendments that impact the financial status of the demonstration must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

50. **State Certification of Funding Conditions.** The state must certify that the following conditions for non-federal share of demonstration expenditures are met:
    a. Units of government, including governmentally operated health care providers, may certify that state or local monies have been expended as the non-federal share of funds under the demonstration.
    b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
    c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration

expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR 433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.

d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments.
e. Under all circumstances, health care providers must retain one hundred (100) percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

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

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

Table 1: Master MEG Chart

MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description
Non Expansion Adults	Hypo 1	X		X	Medicaid beneficiaries diagnosed with a SUD
Expansion Adults	Hypo 2	X		X	Expansion adult Medicaod beneficiaries diagnosed with a SUD

53. Reporting Expenditures and Member Months. The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget

neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00381). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

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

months, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.

f. Budget Neutrality Specifications Manual. The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state's Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

Table 2: MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
Non Expansion Adults	Non-Expansion Medicaid beneficiaries diagnosed with a SUD	STC# 21	Follow CMS-64.9 Base Category of Service Definition	Date of service	MAP	Y	1/1/2021	12/31/2025
Expansion Adults	Expansion Medicaid beneficiaries diagnosed with a SUD	STC# 21	Follow CMS-64.9 Base Category of Service Definition	Date of service	MAP	Y	1/1/2021	12/31/2025

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

Table 3: Demonstration Years

Demonstration Year 1	January1, 2021 to December 31, 2021	12 months
Demonstration Year 2	January1, 2022 to December 31, 2022	12 months
Demonstration Year 3	January1, 2023 to December 31, 2023	12 months
Demonstration Year 4	January1, 2024 to December 31, 2024	12 months
Demonstration Year 5	January1, 2025 to December 31, 2025	12 months

55. Budget Neutrality Monitoring Tool. The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the Performance Metrics Database and

Analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing demonstration's actual expenditures to the budget neutrality expenditure limits described in Section XI. CMS will provide technical assistance, upon request.[5]

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

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

a. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments, CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.

c. The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject to review and audit,

[5] 42 CFR §431.420(a)(2) provides that states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and §431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS's current approach is to include language in STCs requiring, as a condition of demonstration approval, that states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget neutrality limit. CMS has obtained Office of Management and Budget (OMB) approval of the monitoring tool under the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and in states agree to use the tool as a condition of demonstration approval.

and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

XII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

58. Limit on Title XIX Funding. The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit may consist of a Main Budget Neutrality Test, and one or more Hypothetical Budget Neutrality Tests, as described below. CMS's assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.

59. Risk. The budget neutrality expenditure limits are determined on either a per capita or aggregate basis. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions; however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.

60. Calculation of the Budget Neutrality Limits and How They Are Applied. To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.

61. Main Budget Neutrality Test. This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests. Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS.

62. Hypothetical Budget Neutrality. When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be "hypothetical;" that is, the expenditures would have been

eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS's current view that states should not have to "pay for," with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state's WW hypothetical spending exceeds the supplemental test's expenditure limit, the state agrees (as a condition of CMS approval) to refund the FFP to CMS.

63. Hypothetical Budget Neutrality Test 1: SUD Services (see Expenditure Authority #1). The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

Table 4: Hypothetical Budget Neutrality Test

MEG	TREND	DY 1-PMPM	DY 2-PMPM	DY 3-PMPM	DY 4-PMPM	DY 5-PMPM
Non-Expansion Adults	5.7%	$5,230	$5,528	$5,843	$6,176	$6,528
Expansion Adults	5.6%	$4,765	$5,032	$5,313	$5,611	$5,925

64. Composite Federal Share. The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to

method. Each Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

65. Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from January 1, 2021 to December 31, 2025. If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

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

Table 5: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations

Demonstration Year	Cumulative Target Definition	Percentage
DY 1	Cumulative budget neutrality limit plus:	2.0 percent
DY 1 through DY 2	Cumulative budget neutrality limit plus:	1.5 percent
DY 1 through DY 3	Cumulative budget neutrality limit plus:	1.0 percent
DY 1 through DY 4	Cumulative budget neutrality limit plus:	0.5 percent
DY 1 through DY 5	Cumulative budget neutrality limit plus:	0.0 percent

XIII. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION PERIOD

Table 6: Schedule of Deliverables for the Demonstration Period		
Date	**Deliverable**	**STC**
30 calendar days after approval date	State acceptance of demonstration STCs, and Expenditure Authorities	Approval letter
90 calendar days after approval date	SUD Implementation Plan (including Health IT Plan)	STC 18(a)
60 calendar days after receipt of CMS comments	Revised SUD Implementation Plan (including Health IT Plan)	STC 18(a)
150 calendar days after Implementation Plan Completeness	Monitoring Protocol	STC 19
60 calendar days after receipt of CMS comments	Revised Monitoring Protocol	STC 19
180 calendar days after approval date	Draft Evaluation Design	STC 36
60 days after receipt of CMS comments	Revised Draft Evaluation Design	STC 38
No later than 60 calendar days after July 1, 2023	SUD Mid-Point Assessment	STC 28
June 30, 2024 or with renewal application	Draft Interim Evaluation Report	STC 40 (c)
60 calendar days after receipt of CMS comments	Final Interim Evaluation Report	STC 40 (d)
Within 18 months after June 30, 2025	Draft Summative Evaluation Report	STC 40
60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	STC 40 (a)
Monthly Deliverables	Monitoring Calls	STC 32
Quarterly monitoring reports due 60 calendar days after end of each quarter, except 4th quarter.	Quarterly Monitoring Reports, including implementation updates	STC 28
	Quarterly Expenditure Reports	STC 28 (c)
Annual monitoring reports due 90 calendar days after end of each 4th quarter	Annual Monitoring Reports	STC 28

ATTACHMENT A
Developing the Evaluation Design

Introduction

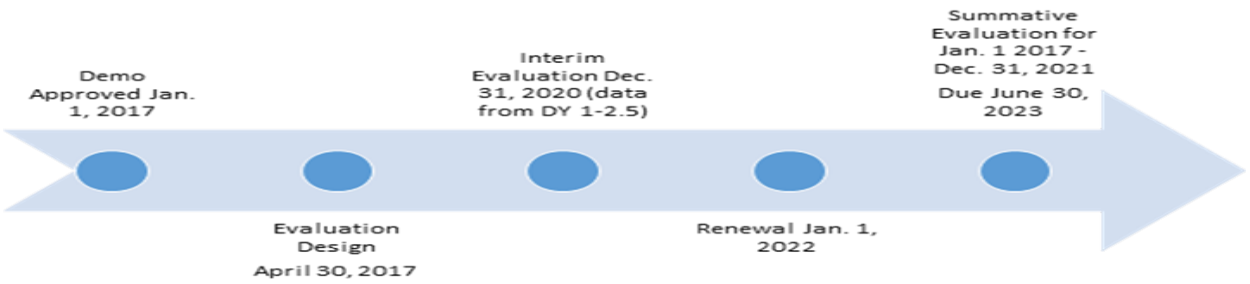
For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs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

Expectations for Evaluation Designs

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

The format for the Evaluation Design is as follows:
General Background Information;
Evaluation Questions and Hypotheses;
Methodology;
Methodological Limitations;
Attachments.

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



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

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

1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).

2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;

4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

5) Describe the population groups impacted by the demonstration.

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

1) Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.

2) Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf

3) Identify the state's hypotheses about the outcomes of the demonstration:

4) Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;

5) Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

C. Methodology – In this section, the state is to describe in detail the proposed research methodology.

The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

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

1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?

2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.

3) *Evaluation Period* – Describe the time periods for which data will be included.

4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:

    a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.

    b. Qualitative analysis methods may be used, and must be described in detail.

    c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.

    d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

    e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).

    f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

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

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

6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:

    a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.

b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.

c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).

d. The application of sensitivity analyses, as appropriate, should be considered.

7) *Other Additions* – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

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

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

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

1) When the state demonstration is:
   a. Long-standing, non-complex, unchanged, or
   b. Has previously been rigorously evaluated and found to be successful, or
   c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)
2) When the demonstration is also considered successful without issues or concerns that

would require more regular reporting, such as:

a. Operating smoothly without administrative changes; and
b. No or minimal appeals and grievances; and
c. No state issues with CMS-64 reporting or budget neutrality; and
d. No Corrective Action Plans (CAP) for the demonstration.

E. Attachments

1) **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include "No Conflict of Interest" signed by the independent evaluator.

2) **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.

3) **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

ATTACHMENT B
Preparing the Interim and Summative Evaluation Reports

Introduction

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

Expectations for Evaluation Reports

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

Intent of this Guidance

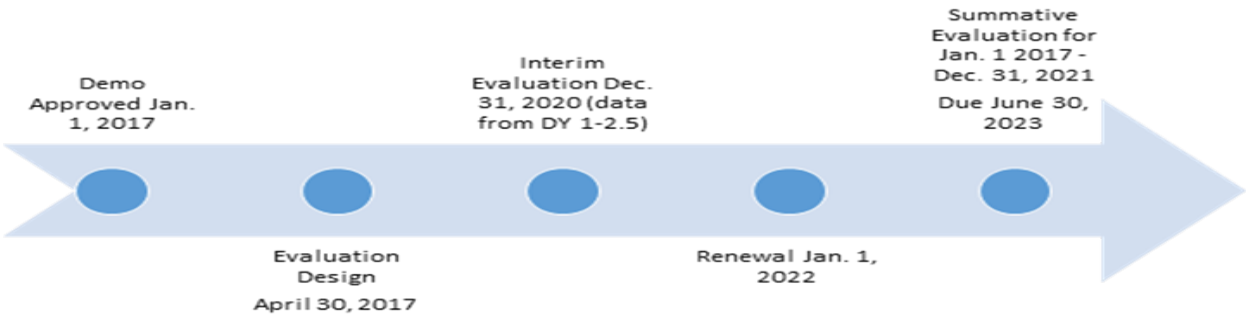
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved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

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

A. Executive Summary;
B. General Background Information;
C. Evaluation Questions and Hypotheses;
D. Methodology;
E. Methodological Limitations;
F. Results;
G. Conclusions;
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
I. Lessons Learned and Recommendations; and
J. Attachment(s).

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish to the state's website the evaluation design within thirty (30) days of CMS approval, and publish reports within thirty (30) days of submission to CMS , pursuant to 42 CFR 431.424. CMS will also publish a copy to Medicaid.gov.



Required Core Components of Interim and Summative Evaluation Reports

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

A. Executive Summary – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.

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

1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.

2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;

4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.

5) Describe the population groups impacted by the demonstration.

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

1) Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.

2) Identify the state's hypotheses about the outcomes of the demonstration;
   a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
   b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
   c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

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

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

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

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

1. *Evaluation Design* – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?
2. *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.
3. *Evaluation Period* – Describe the time periods for which data will be collected
4. *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?
5. *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data.
6. *Analytic methods* – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
7. *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.

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

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

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

1) In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?

2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:

   a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

D. Interpretations, Policy Implications and Interactions with Other State Initiatives – In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long range planning. This should include interrelations of the demonstration with other aspects of the state's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretation of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

E. Lessons Learned and Recommendations – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

1. What lessons were learned as a result of the demonstration?

2. What would you recommend to other states which may be interested in implementing a similar approach?

F. Attachment - Evaluation Design: Provide the CMS-approved Evaluation Design

ATTACHMENT C
SUD Implementation Plan and Financing Plan

Maine Department of Health and Human Services: Substance Use Disorder Care Initiative 1115 Waiver Implementation Plan

Contents

Introduction

The State of Maine, including the Department of Health and Human Services ("the Department"), have dedicated significant resources to developing a coordinated response to the opioid epidemic and to the needs of Maine people with Substance Use Disorders (SUD) more broadly. This 1115 waiver is one component of this response, and will play a pivotal role in increasing capacity for residential treatment facility services, and serve as a framework for specific goals and milestones that the Department shares with the Centers for Medicare and Medicaid Services (CMS).

It is important to note that there are many additional assessments, planning projects/awards, and funding opportunities in which the State is involved that intersect and align with this Implementation Plan, including:

- The Governor's Office Maine Opioid Response Strategic Action Plan which lays out strategies to reduce the negative health and economic impacts of SUD and Opioid Use Disorder (OUD) on individuals, families, and communities in Maine. This plan is overseen by the Maine Director of Opioid Response.
- MaineCare's SUPPORT ACT 1003 award ("SUPPORT for ME") to increase the treatment capacity of MaineCare providers to deliver SUD treatment and recovery services.
- MaineCare's Maternal Opioid Misuse model ("MaineMOM") to improve care for pregnant and postpartum women with OUD and their infants by integrating maternal and substance use treatment services.
- Numerous assessments of the SUD treatment and recovery system, through Pew Charitable Trust and the Urban Institute, and many other related efforts within the Department.
- The Family First Prevention Services Act (FFPSA) provides opportunities for collaboration across state systems to identify primary, secondary, and tertiary prevention services that can support families in being safe, healthy, and successful by reducing risk and safety factors. FFPSA includes federal support for evidenced based mental health, substance use, and in home support services in an effort to prevent out of home placements for children at imminent risk of entering foster care.
- Several federal awards to the Department with activities spanning prevention, use of health information technology, harm reduction, treatment, etc.

These efforts, and others, represent moving parts of the SUD response in Maine. This Implementation Plan is intended to highlight key Department activities that advance the specific objectives of the 1115 waiver and does not comprise an exhaustive list of activities taking place currently, or planned, with the Department's SUD response; this Plan will need to be updated over time. Additionally, this Plan does not highlight activities with primary responsibility/oversight outside of the Department; further, there is a focus on activities that relate to MaineCare policies and procedures. Lastly, while the Department considers recovery support services to be integral to effective SUD care, discussions of these efforts fall outside the scope of this Implementation Plan. Please refer to the above linked reports and initiatives for information on these efforts.

Milestones to be Addressed in Maine's 1115 Waiver Implementation Plan

Milestones
Access to critical levels of care for OUD and other SUDs;
Widespread use of evidence-based, SUD-specific patient placement criteria;
Use of nationally recognized, evidence-based, SUD program standards to set residential treatment provider qualifications;
Sufficient provider capacity at each level of care, including MAT;
Implementation of comprehensive treatment and prevention strategies to address opioid misuse and OUD; and
Improved care coordination and transitions between levels of care.

Milestone Implementation Plan

This section contains information detailing Maine's strategies for meeting CMS' six stated milestones over the course of the demonstration, including which party/office is lead for the planned actions.

Access to Critical Levels of Care for OUD and Other SUDs

Current State: MaineCare offers broad SUD and OUD service coverage across the continuum of care. Generally, these services align with an American Society of Addiction Medicine (ASAM) level of care. These covered services include, but are not limited to, the following (see Attachment A for a full description of covered services and their page in the Maine Medicaid State Plan):

- Early Intervention Services
- Outpatient Services
- Intensive Outpatient Services;
- Medication Assisted Treatment (MAT)
- Intensive levels of care in residential and inpatient settings; and
- Medically supervised withdrawal management

As it specifically relates to access to care, the Office of Behavioral Health has partnered with Maine Medical Association's Quality Improvement team to provide training on implementation of rapid induction services in Emergency Departments (EDs), along with supports and trainings for the warm-handoff to community-based treatment. Through their work, 23 of Maine's 33 EDs now offer rapid induction, with four more expected to implement in spring/summer 2021. Funding for this initiative will end September 2022.

The Department is not proposing to add any additional SUD services at this time; however, the Department has identified utilization management limits for residential care that will be removed to ensure that there is no administrative barrier to clinically appropriate admissions for this level of

care (see Table 1). Table 1 outlines specific activities that will improve access to services across the continuum of care within 12-24 months of demonstration approval.

Table 1. Future State: Plan for Access Improvements

Action Items	Implementation Timeframe /Parties Responsible
Early Intervention	
Incorporate Screening, Brief Intervention, and Referral to Treatment (SBIRT) in MaineCare's new primary care alternative payment model.	Rule provision to be effective December 2022/MaineCare Value-Based Purchasing
Outpatient Services	
Clarify through MaineCare rulemaking that partial hospitalization services are approved outpatient services for psychiatric and non-psychiatric hospitals. The rulemaking will be proposed by August 2021 and will follow the process for public comment, response to comment with any necessary amendments, and adoption.	Rule to be effective November 2021/MaineCare Policy
Continue to support the goal of all EDs in Maine offering MAT by offering training on implementation of rapid induction, along with supports and trainings for the warm-handoff to community-based treatment through the ongoing work of the Office of Behavioral Health and the Maine Medical Association's Quality Improvement team.	September 2022/Office of Behavioral Health
Intensive Outpatient Program	
Finalize an independent rate evaluation of SUD Intensive Outpatient Programs. Rate evaluations consist of policy review, literature review, review of similar services reimbursed through Medicaid and private insurers, stakeholder sessions, provider surveys including review of cost reports, drafting rate models, reviewing draft models with stakeholders, public comment, and final revision. Currently, the rate evaluation comment period has closed and the final revision is pending. Following the final rate proposal, the decision to amend rates will be considered as part of MaineCare's comprehensive rate system evaluation and subject to the availability of funds.	July 2021/MaineCare Rate Setting
Medication Assisted Treatment	

Update the Maine Medicaid State Plan to reflect the required CMS templates in accordance with the provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) relating to mandatory coverage of MAT for OUD.	Submitted 3/31/21, anticipated effective 10/1/2020/ MaineCare Policy
Residential and Inpatient Treatment (including medically supervised withdrawal management)	
Finalize an independent rate evaluation of SUD residential treatment facilities. Rate evaluations consist of policy review, literature review, review of similar services reimbursed through Medicaid and private insurers, stakeholder sessions, provider surveys including review of cost reports, drafting rate models, reviewing draft models with stakeholders, public comment, and final revision. Currently, the rate evaluation comment period has closed and the final revision is pending. Following the final rate proposal, the decision to amend rates will be considered as part of MaineCare's comprehensive rate system evaluation and subject to the availability of funds.	July 2021/MaineCare SUPPORT for ME and Rate Setting
Propose rulemaking to remove single admission limitation from Clinically Managed Low Intensity Services and Clinically Managed Population-Specific High Intensity Residential Programs as well as increasing the number of allowable days per admission in Clinically Managed Residential Services from 30 to 45 days in Residential Rehabilitation Type I and from 45 to 60 days in Residential Rehabilitation Type II.	Rule to be effective by October 2021/MaineCare Policy

Use of Evidence-based, SUD-specific Patient Placement Criteria

Current State: MaineCare already requires that providers assess treatment needs based on ASAM Criteria for nearly all SUD services; these requirements are stated in the MaineCare Benefits Manual which is the State regulation for the MaineCare program (Title 22 M.R.S, Chapter 855), for nearly all SUD services. The exception to this is that the Opioid Health Home (OHH) policy does not currently require ASAM placement tools, though it is common practice among providers of the OHH service. The OHH policy does require the documentation of an OUD as part of the eligibility process.

For residential SUD treatment services, the current MaineCare regluations references version 2 of ASAM; however, MaineCare is updating this reference to read "the most current edition"of ASAM through a rulemaking (to be effective October 2021 – see Table 3); this is the only instance where MaineCare rule references an outdated version. No other ASAM related changes are needed across other SUD services in the MaineCare Benefits Manual.

Currently, there is limited utilization management by an Administrative Services Organization (ASO) to assess patient placement for SUD services and to ensure interventions are approrpriate for the diagnosis and level of care; this occurs only as described in Table 2 below. Currently, there is no systematized, routine/ongoing, utilization management approach to ensuring members have timely access to SUD services at the appropriate levels of care outside of the Office of Behavioral Health's Substance Abuse Prevention and Treatment block grant requirements.

(Legend: Prior Authorization Review: Requires clinical review; **Initial Registration:** Clinical review for appropriate diagnosis(es) and duplication and non-concurrent services; **Continued Stay Review:** Requires clinical review for continuation of care; and/or **Discharge Review:** Required for all services on last date of service)

Table 2: Current Utilization Management of SUD services

Service	Type of Utilization Management	Frequency/Description of Review
Targeted Case Management	Initial Registration, Continued Stay Review, Discharge Review	Initial authorization of 30 days with a maximum continued stay of 90 days
Outpatient Services (Comprehensive Assessment, Therapy and Counseling Services)	Initial Registration, Continued Stay Review, Discharge Review	Initial authorization of 365 days with a maximum continued stay of 180 days
Medication Management Services	Initial Registration, Continued Stay Review, Discharge Review	Initial authorization of 180 days with a maximum continued stay of 180 days
Medication Assisted Treatment (Methadone/Opioid Treatment Programs)	Initial Registration, Continued Stay Review, Discharge Review	Initial authorization of 180 days with a maximum continued stay of 180 days
Opioid Health Homes	Initial Registration, Continued Stay Review, Discharge Review	Initial authorization of 180 days with a maximum continued stay of 180 days

Intensive Outpatient Services	Prior Authorization, Continued Stay Review, Discharge Review	Initial authorization of 30 days with a maximum continued stay of 7 days
Clinically Managed Low Intensity Residential Services	N/A	Limited to a single admission of 180 covered days on an annual basis, unless a member has a documented need to exceed that limit. Any stay in excess of 180 days requires documented need in the member's service plan. *See Table 1, Future State
Clinically Managed Residential Services: 1. Residential Rehabilitation I 2. Residential Rehabilitation II 3. Adolescent Residential Rehabilitation	N/A	1. Limited to 30 days for any single admission, with a limit of 2 admissions and 30 covered days on an annual basis. Any continuous stay in excess of 28 days requires documented need in the member's treatment plan *See Table 1, Future State 2. The term of residency shall not exceed 45 days *See Table 1, Future State 3. Designed to last at least 3 months and limited to 12 months per single admission.

Clinically Managed Population-Specific High Intensity Residential Programs	N/A	Limited to a single admission of 270 covered days on an annual basis unless a member has a documented need to exceed that limit. Any stay in excess of 270 days requires documented need in the member's treatment plan.*See Table 1, Future State
Medically Monitored Inpatient Programs	N/A	Limited to 7 days for each admission episode, with no limit on the number of admissions or covered days on an annual basis.
Inpatient	Prior Authorization, Initial Registration, Continued Stay Review, Discharge Review (Varies based on the hospital and services provided)	All hospital admissions and continued stays must be certified for medical necessity and length of stay through an appropriate utilization review plan.
Psychiatric Residential Treatment Facility Services	Prior Authorization, Continued Stay Review, and Discharge Review for limited services	Must meet Clinical Certificate of Need criteria

The Department will implement the following activities and utilization management approaches to ensure that members have access to SUD services at the appropriate level of care, interventions are appropriate for the diagnosis and level of care, and that there is an independent process for reviewing placement in residential settings. This milestone will be met within 12-24 months of demonstration approval.

Table 3. Future State: Plan for Improvements in Evidence-Based Patient Placement Criteria

Action Items	Timeframe/Parties Responsible
Establishment of a Utilization Management Approach for Appropriate Access and Level of Care, Including an Independent Process for Reviewing Placement in Residential Treatment	
Require residential SUD providers to submit admissions to the Department's behavioral health utilization management ASO including the ASAM assessment used for placement purposes. The ASO will use the ASAM assessments to do post utilization review for appropriate level of care, starting with a sampling of admissions. Providers will have a window of time, upon admission, to submit the data to the ASO to avoid potential interruption with timely access to services. The Department and the ASO will meet in July 2021 to establish this process (including any ASO contract amendments needed, provider trainings, provider communications, etc.). By December 2021, the Departments contract with the ASO will be updated, if needed, to encompass this effort. The timeframe for full implementation of this process is March 2022.	March 2022/ASO/MaineCare Policy/Office of Behavioral Health
Evaluate options with our ASO to enhance clinical review of placements across the continuum of care and based on the ASAM assessment tools and the incorporation of waitlist/timely access tracking functionality (as currently used for some mental health services). The Department and the ASO will meet in June 2021 to begin these conversations. By September 2021, the Department and ASO will finalize a proposal for incorporation of timely access tracking for SUD services and appropriateness of care assessment. This will include a review of other Medicaid programs' best practices. By December 2021, the Departments contract with the ASO will be updated, if needed, to encompass this effort. Beginning December 2021, the Department will hold provider trainings to initiate a soft-roll out of this	March 2022/ASO/MaineCare Policy/Office of Behavioral Health

new functionality and review process. This process will be piloted until March 2022, when it will become required for all impacted SUD services.	
Use of Evidence-based SUD-specific Patient Placement Criteria	
Amend MaineCare regulations for residential SUD treatment providers to reference the most recent ASAM version.	Rule to be effective October 2021/MaineCare policy
Evaluate the structure of MaineCare policy to identify and recommend changes to more clearly outline program descriptions and provider qualifications and their relationship to ASAM criteria. Amend MaineCare policy, offer provider training, and/or offer sub-regulatory guidance, as needed.	Work to commence October 2021 to target rule effective date of December 2022 or guidance/training date of July 2022.
Amend the OHH policy, through rulemaking, to require the use of ASAM criteria to assess patient placement and as treatment guidelines.	Rule to be effective December 2021/MaineCare Policy/MaineCare Value-Based Purchasing
Establish an incentive within MaineCare's new value-based primary care model for primary care providers to offer MAT services in alignment with ASAM guidelines for appropriate level of care, have a cooperative referral process with specialty behavioral health providers including a mechanism for co-management for the provision of MAT as needed, or be co-located with a MAT provider.	Rule to be effective December 2021/MaineCare Policy/MaineCare Value-Based Purchasing
Assess training needs in the community that would facilitate improvements in the utilization of ASAM assessment tools for placement purposes. Subsequently, the Department will provide training support,namely, through the launch of the SUPPORT for ME Learning Community which is a statewide learning network for provider training around behavioral health issues, set to launch by January 2022.	January 2022/Office of Behavioral Health
Provide users (health care providers, consumers, case managers, families, etc.) of the service locator tool, an online placement assessment tool (based on ASAM criteria) to inform service	May 2021 (Service Locator Contract finalized)/ September 2021 (Service Locator

outreach. While this is not a clinical assessment, it furthers the impact of this waiver milestone. Utilize information from the service locator tool to assess access to SUD services at the appropriate level of care.	Implemented)/MaineCare Support for ME

Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities

Current State: The MaineCare Benefits Manual, which outlines the State's regulation for the Medicaid program, utilizes ASAM criteria as a basis for the provider qualifications of residential services and ASAM assessments are required for placement in residential treatment programs; additionally, state residential licensing regulations also already includes ASAM-aligned SUD-specific program standards regarding the types of services, hours of clinical care and credentials of staff. Currently, responsibility for review and quality assurance of residential treatment facilities is divided across the different Department offices, as described in Table 4. While, the regulatory oversight of residential treatment programs already includes chart reviews, technical assistance, and site visits, the Department is exploring ways to strengthen programmatic oversight of these processes, including whether there are areas of improvement around the assessment of ASAM standards (e.g. types of services, hours of clinical care, and credentials of staff). One area identified is that if a residential treatment provider is MaineCare enrolled, but does not hold a contract with the Office of Behavioral Health for block grant funding, there is currently a gap in programmatic quality assurance activities (e.g. site visits) (please note that regulatory standards of residential treatment providers is already in place, as described above). Additionally, the Office of Child and Family Services is seeking greater involvement in oversight of all behavioral health services for individuals under 21 years of age as part of their specialized Children's Behavioral Health team.

Table 4: Current Process for Assurance of Residential Treatment Facility Program Standards

Office of MaineCare Services	Division of Licensing and Certification	Office of Behavioral Health	Office of Child and Family Services

MaineCare regulations (see MaineCare Benefits Manual, Chapters II and III, Section 97, Private Non-Medical Institution Services) outline ASAM-aligned program expectations and conducts reviews, when necessary, as part of Medicaid program integrity efforts.	As outlined in the SUD facility licensing regulations, the Division of Licensing and Certification assesses programs for the following items: • Program descriptions for residential services; • Clinical assessments; • Admission and discharge dates to ensure compliance with program length limits; • Progress notes and treatment plans indicating number of counseling hours and types of treatment/support provided, including group and individual counseling, living skills/vocation training; • Discharge summaries and treatment follow up plans; • Credentials of employees providing services and supervision to ensure compliance with regulatory requirements for clinical licensure.[6]	As outlined in manuals and contracts with residential treatment providers,[7] the Office of Behavioral Health conducts annual site visits with residential treatment facilities which hold contract under the Substance Abuse Prevention and Treatment block grants. As part of these site visits, client charts are reviewed, as well as other program documents, to ensure compliance with block grant requirements, which include utilizing ASAM placement criteria to determine eligibility.	Currently not involved in quality assurance or licensing.

[6] 14-118 CMR Chapter 5, Regulations for Licensing and Certifying of Substance Abuse Treatment Programs:

[7] These contracts/manuals are not available online.

Maine also seeks to improve access to medications for OUD for individuals in residential treatment programs. Currently, MaineCare and licensing regulations require that residential treatment providers facilitate access to any specialized service beyond their capabilities; however, through recent outreach, the Department understands that there are some potential policy and reimbursement challenges to facilitating access to medications for OUD. While facilitation of MAT services for patients residing in residential treatment is already in MaineCare regulation, this language is stronger within the Department's state-funded contracts. Additionally, the language in the MaineCare Benefits Manual could be improved to align with ASAM on the use of MAT and to reduce stigmatizing language; for example, discussion of a "substance free lifestyle." In alignment with MaineCare's value-based purchasing efforts, there is interest in exploring a gradual transition to rewarding the direct provision of MAT in these settings through a combination of financial incentives (e.g. assessment of continuous pharmacotherapy, higher payments for facilities that offer MAT onsite) and regulatory changes. Lastly, recent reports suggest additional training/education may support evidence-based integration of medications for OUD into residential settings.

The Department plans to implement the following activities to strengthen program standards and provider qualifications for residential treatment facilities, including establishing a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12 to 24 months of demonstration approval.

Table 5. Future State: Plan for Residential Treatment Provider Program Standards and Qualifications

Action Items	**Timeframe/Parties Responsible**
Establishment of a Residential Provider Review Process	
Improve the integrated oversight processes for residential treatment providers to assure compliance with ASAM standards across the Division of Licensing and Certification, the Office of MaineCare Services, the Office of Behavioral Health, and the Office of Child and Family Services. All relevant parties will participate in a cross-Department meeting series to establish clear rules and responsibilities for an improved integrated oversight process in July 2021. This will include documentation of types of oversight activities, scope of reviews/areas of focus, frequency, follow-up actions, and communication protocols between parties.	July 2021/DHHS wide

Beginning July 2021, the Office of Behavioral Health will take responsibility for the programmatic oversight for all adult residential treatment facilities enrolled in MaineCare, regardless of whether they hold a contract specifically with their office, effective July 2021. This will ensure site visits occur at all facilities.	July 2021/Office of Behavioral Health
Amend MaineCare Policy to support the Office of Child and Family Services quality assurance activities by requiringprovider participation in the quality assurance activities.	Rule to be effective October 2021/MaineCare Policy
Beginning October 2021, the Office of Child and Family Services will take responsibility for the quality oversight of the limited number of adolescent treatment facilities by reviewing and providing feedback and technical assistance to providers related to reportable events, trauma-informed care agency assessments, clinical records, and fidelity monitoring.	October 2021/Office of Child and Family Services
Establishment of a Requirement that Residential Treatment Providers Offer MAT On-site or Facilitate Access to MAT Off-site	
Amend the MaineCare regulations to replace general language that is misaligned with ASAM regarding the use of MAT and include language to specifically require the facilitation of MAT off-site if that is not a service offered within the facility.	October 2021/MaineCare Policy
Assess current policies and practices, including duplication concerns, reimbursement, administrative issues and the current counseling waivers, aimed at reducing barriers and improving integration of MAT in existing residential programs. The assessment will occur through provider surveys, stakeholder groups, and internal review/decision-making.	December 2021/MaineCare Policy
Establishment of Residential Treatment Provider Qualifications in Medicaid policy that align with ASAM standards.	
Evaluate the structure of MaineCare policy to identify and recommend changes to more clearly outline program descriptions and provider qualifications and their relationship to ASAM criteria. Amend MaineCare policy, offer provider training, and/or offer sub-regulatory guidance, as needed.	Work to commence October 2021 to target rule effective date of

	December 2022 or guidance/training date of July 2022.
Amend MaineCare regulations for residential SUD treatment providers to reference the most recent ASAM version.	Rule to be effective October 2021/MaineCare policy

Sufficient Provider Capacity at each Level of Care, including MAT

Current State: The Department participated in various internal and external inquiries regarding capacity of Medicaid-covered providers to meet the SUD-related needs of MaineCare members both as a whole and with a focus on the recent MaineCare expansion population. This ranged from external reviews of the full service delivery system informed by key informant interviews and review of publicly available data, efforts to map service capacity using administrative data on licensed and unlicensed SUD treatment providers, to internal assessments for various federal grant applications that involved compiling both high-level and detailed data for the SUD system and priority subpopulations in Maine. As a result of one of the funding applications, OMS was awarded over $2M through the Section 1003 Demonstration Project to Increase Substance Use Provider Capacity through a federal cooperative agreement with CMS after a thorough assessment of MaineCare members' SUD-related needs and the capacity of our treatment and recovery system (SUPPORT for ME). The results of the SUPPORT for ME assessment, concluding in September 2021, will provide the basis of additional actions that may be unidentified at this time. SUPPORT for ME's capacity assessment includes key informant interviews with providers, community listening sessions for individuals accessing treatment and recovery services, and quantitative analysis.

Table 6 outlines specific activities that will improve provider capacity across the continuum of care within 12 months of demonstration approval.

Table 6: Future State: Plan for Provider Capacity Improvements

Action Items	Implementation Timeframe /Parties Responsible
Impacting all levels of care	

Produce assessments of SUD service provider capacity relative to need across the service continuum and including recovery supports. This will include a discussion of barriers to provider capacity, including willingness to offer these services, and how to fill gaps in MaineCare coverage (e.g. eligibility gaps, workforce constraints).	Ongoing through September 2021/ MaineCare SUPPORT for ME
Conduct an evaluation of MaineCare rates and rate setting system and develop and implement a plan for the creation of a comprehensive, streamlined, and coherent system that will support MaineCare members' access to high value-services.	Ongoing through November 2021/MaineCare Rate Setting
Deploy a service locator tool which will assist the public, including health care providers and consumers, to search for local behavioral health providers with capacity to provide SUD/OUD care. This tool will go beyond the existing MaineCare provider directly by offering a straightforward way to identify treatment providers and treatment options, including provider capacity/appointment availability. This tool will produce ongoing assessment of the number of SUD service providers accepting new patients.	May 2021 (Service Locator Contract encumbered)/ September 2021 (Service Locator Implemented)/MaineCare Support for ME
Fund SUD specific telehealth support through the North East Telehealth Resource Center to expand effective utilization of telehealth services.	Ongoing through September 2021/ MaineCare SUPPORT for ME
Establish an incentive within MaineCare's new value-based primary care model for primary care providers to offer MAT services in alignment with ASAM guidelines for appropriate level of care, have a cooperative referral process with specialty behavioral health providers including a mechanism for co-management for the provision of MAT as needed, or be co-located with a MAT provider.	Rule to be effective December 2021/MaineCare Policy/MaineCare Value-Based Purchasing
Residential Treatment (including medically supervised withdrawal management)	

Implement Maine's approved 1115 IMD Exclusion Waiver for SUD services and work with current and prospective residential treatment providers to understand their options for serving MaineCare members in facilities that have more than 16 beds.	January 2021-December 2025/MaineCare Policy
MAT	
Amend the OHH rule to improve access to treatment, reduce administrative barriers to providing MAT, promote evidence-based treatment standards, and reinforce integration with primary care. This includes more flexibility and clarity around counseling expectations and the inclusion of methadone as a form of MAT under this model (all forms of buprenorphine, buprenorphine derivatives, and naltrexone are already used in the model). MaineCare is also assessing feasibility and appropriateness of expanding the OHH model to allow additional SUD chronic condition eligibility, such as stimulant use disorder. Stimulant use is reportedly on the rise in Maine both in cases of polysubstance use and independently.	Rule to be effective December 2021 /MaineCare Value-Based Purchasing Ongoing/MaineCare Value-Based Purchasing
Review all MAT policies for policy and utilization management restrictions that may impact access to evidence-based and low-barrier care.	Ongoing through September 2021/MaineCare Policy and Pharmacy
Explore mobile MAT options in order to reach vulnerable populations statewide.	Ongoing through December 2022/ Office of Beahvioral Heatlh
Gather data on barriers and gaps to accessing SUD treatment for youth Conduct online survey for youth and young adults (ages 12-21) who have been impacted by SUD to better understand their perspective on SUD capacity and treatment and recovery needs in Maine.	Ongoing through September 2021/MaineCare SUPPORT for ME

Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Misuse and OUD

Current State: Over the past five years, the Department has focused heavily on the implementation of revised opioid prescribing guidelines as well as implementation of strategies to increase utilization and improve functionality of Maine's Prescription Drug Monitoring Program (PDMP). This work included the implementation of legislation (P.L. 488, 127th Legislature) titled "An Act to Prevent Opiate Abuse by Strengthening the Controlled Substances Prescription Monitoring Program," numerous benefit changes within the MaineCare program to promote alternative treatments to pain management, and sustained academic detailing to support safe prescribing. There is also a PDMP Advisory Committee, consisting of external stakeholders (e.g. providers, pharmacists, health care organizations) and state personnel, which meets bimonthly, to increase utilization and improve functionality of the PDMP.

As of the beginning of Governor Mills' Administration, there has also been a focus on expanded coverage of and access to naloxone for overdose reversal. MaineCare coverage for naloxone is already in place with low-barrier access and additional efforts are underway to incentivize and/or require co-prescribing of naloxone with MAT. There are also many initiatives through the Office of Behavioral Health to deploy various distribution networks, including exploring ways to fund more direct distribution and leave-behind doses of naloxone.

Table 7. Future State: Plan for Additional Comprehensive Treatment and Prevention Strategies to Address OUD

Action Items	Timeframe/Parties Responsible
Expand Coverage of and Access to Naloxone	
Consider implementing a standing order for naloxone.	September 2021/ MaineCare Pharmacy
Implementation of Strategies to Increase Utilization and Improve Functionality of the PDMP	
Improve functional and data analytic capacity of the PDMP (see Attachment B)	Ongoing through November 2021/Office of Behavioral Health
Other Strategies to Prevent Prescription Drug Misuse and Overdose Risk	

Assess concurrent use of opioids and benzodiazapines in MaineCare's Medicaid Accountable Care Organizations, as part of this program's performance-based payments. This data will be evaluated collaboratively with these entities and with the 1115 monitoring reports to identify areas of intervention for improvement.	December 2021 and Ongoing/MaineCare Value-Based Purchasing
Implementation of Opioid Prescribing Guidelines	
N/A already in place.	

Improved Care Coordination and Transitions between Levels of Care

Current State: MaineCare regulations (MaineCare Benefits Manual, Section 97) require residential treatment providers to deliver scheduled therapeutic and rehabilitative treatment consisting of transitional services that are designed to facilitate a member's return to the community. Additionally, programs are required to have written policies and procedures to facilitate client referrals and coordination of services internally and externally. Residential treamtnt providers are also required by MaineCare to have written policies and procedures regarding discharge and treatment follow-up.

In addition to the residential treatment provider requirements around care coordination and transitions of care, MaineCare covers a limited set of populations with SUD through Targeted Case Management (TCM, MaineCare Benefits Manual, Section 13), offers an OHH program to serve individuals with OUD (MaineCare Benefits Manual, Section 93), and allows SUD as a qualifying condition in their primary care Health Home model (MaineCare Benefits Manual, Section 91). The MaineCare provider requirements for these (and other non-SUD specific) care coordination and/or case management services include specific expectations around transitions of care. The Health Home programs includes a service called Comprehensive Transitional Care which includes assisting members and family/guardian/caregivers, as appropriate, with the discharge process. For the OHH model, this specifically includes requirements of outreach to assist the member in returning to treatment for OUD, connecting or re-connecting members to other providers or community-based services post-discharge, and working to prevent avoidable readmissions. While care transition support is considered a basic element of all case management services, including TCM, OHH, Behavioral Health Homes (BHH), primary care Health Homes, and Community Integration services for members with serious mental illness, there is a need to assess and improve the experience and effectiveness of these services for members with SUD. Part of this work includes creating clear expectations and accountability for discharging as well as receiving providers. Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities will be

aggressively addressed through this 1115 waiver. This milestone will be achieved within 24 months of demonstration approval and will be tracked through the 1115 monitoring measures consistently and on an ongoing basis.

Of note, the Department has additional initiatives to improve care transitions out of state prisons and local jails, including processes to ensure active/full MaineCare upon release for eligible MaineCare members, and state-funded MAT and care coordination transition services to facilitate transitions to MaineCare-covered community services.

The Department has also partnered with community providers to implement and continuously improve the BHH and OHH programs (from 2014 and 2017, respectively) to improve coordination of mental and physical health. These efforts are critical to ensure that providers involved in care transitions account for all of an individuals health and social needs during transitions, including establishing or re-establishing primary and specialty physical health services. Health Home providers participate in regular peer learning and technical assistance convenings with the Department to continuously improve these efforts.

The BHH program, which serves adults with serious mental illness and children with serious emotional disturbance (and many individuals having co-occuring SUD), has core competencies surrounding integration of physical and behavioral health and requires formal agreements between BHH organizations and primary care practices in their service area. This program has a pay-for-performance measure focused on the intersection of physical and behavioral health, specifically assessing metabolic screening for individuals on antipsychotic medications.

Building upon the BHH program and the integrated team-based approach to care, the Department introduced OHHs in 2017 to improve the quality and availability of integrated MAT services statewide. This program currently serves over 2,600 MaineCare members with OUD monthly, with utilization increasing monthly due to increasing provider capacity and increased Medicaid eligibility. This program also focuses on whole-person care and requires the MAT provider to connect members to primary care and establish releases of information with the members' primary care provider, with member consent.

Lastly, the SUPPORT for ME team recently conducted a care integration assessment adapted from the Maine Health Access Foundation (MeHAF) Site Self-Assessment tool across various provider types serving MaineCare members with SUD. The purpose of the assessment is to collect information from organizations to help MaineCare better understand the level of care within their organization and across several dimensions of care. A full analysis of these results will be reported in Spring 2021. In Table 8, we highlight that this program's focus on integration with physical health will be strengthened by a pay-for-performance provision within the next 12 months that is aligned with this 1115 performance measure of ensuring individuals with SUD access physical health care.

Table 8. Future State: Plan for Improved Care Coordination and Transitions between Levels of Care

Action Items	Timeframe/Parties Responsible
Implementation of Policies to Ensure Residential and Inpatient Facilities Link Beneficiaries with Community-Based Services	
Assess transitions of care (through provider surveys, stakeholder groups, and internal review/decision-making), including a specific focus on plans and procedures of residential treatment facilities (including medically supervised withdrawal facilities) to support effective/safe discharges (through incorporation of this in site visits and quality assurance activities).	December 2021/Office of Behavioral Health/Office of Child and Family Services
Develop mechanism for performance monitoring for residential treatment facilities, behavioral health inpatient facilities, and community providers to assess follow-up after a residential stay (e.g. seven days or less). The first step is to develop internal or contracted vendor support to routinely assess performance on designated follow-up care quality measures. MaineCare or it's vendor, will review data and work with internal and external stakeholders to share provider-level performance on this metric. MaineCare will consider opportunities to incorporate financial incentives/penalties related to this effort and other key metrics.	January 2022/MaineCare Value-Based Purchasing
Evaluate whether current duplication or other policies restrict provider's ability to engage in effective care transitions. The state will conduct an assessment through provider surveys, stakeholder groups, and internal review/decision-making.	Ongoing through April 2022/ MaineCare Policy
Amend MaineCare residential treatment facilities regulations to be more specific around requirements that these providers must coordinate with the member's treatment team, including but not limited to the member's case management, behavioral health home, or opioid health home providers to coordinate care and facilitate access to any identified services and supports, considering their physical and mental health needs.	Rule to be effective October 2021/MaineCare Policy

Additional Policies to Ensure Coordination of Care for Co-Occurring Physical and Mental Health Conditions	
Share targeted results of the Maine Health Access Foundation (MeHAF) Site Self-Assessment/care integration assessment with providers to seek feedback on opportunities for future technical assistance offerings or other supports needed to improve integration of SUD with other mental and physical health services.	July 2021/MaineCare SUPPORT for ME
Incorporate a pay-for-performance provision into the OHH model that includes a measure on annual primary care or ambulatory visits.	Rule to be effective December 2021/MaineCare Policy/ MaineCare Value-Based Purchasing
Convene residential treatment and BHH/OHH providers in a working group around transitions and integration of physical and behavioral health.	November 2021/MaineCare Value-Based Purchasing
Assess TCM and OHH eligibility for opportunity to include additional SUD conditions aimed at developing a more robust care management/care coordination system for individuals with SUD.	Ongoing through March 2022/ MaineCare Policy
Amend MaineCare Policy clearly state providers must coordinate with the member's treatment team, including but not limited to the member's case management, behavioral health home, or opioid health home providers to coordinate care and facilitate access to any identified services and supports, considering their physical and mental health needs.	Rule to be effective October 2021/MaineCare policy

Implementation Administration

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Attachment A: MaineCare Covered SUD Services

Service	Brief Description	SPA Page
Community-based Services		
Early Intevention Services	Services include screening and health risk assessment, Screening, Brief Intervention and Referral to Treatment (SBIRT), and evidence-based parenting interventions.	Attachment 3.1-A Page 2; item 5a
Targeted Case Management	Services consist of assessment, planning, referral and related activities, and monitoring and follow-up activities for individuals with a diagnosed SUD who are currently seeking treatment and are either pregnant, living with minor children, or an intravenous drug user.	Supplement 1 to Attachment 3.1-A Page 6a-6f
Outpatient Services (Comprehensive Assessment, Therapy and Counseling Services)	Services include comprehensive assessment, individual and group therapy for children and adults with mental health and co-occurring disorders.	Attachment 3.1-A Page 5; item 13a-Diagnostic Services: Attachment 3.1-A Page 5(a) and Attachment 3.1-A Page 6, item 13d-Rehabilitative Services: Attachment 3.1-A Page 5(a)(xii)
Medication Management Services	Services directly related to the psychiatric evaluation, prescription, administration, education and/or monitoring of medications intended for the treatment of mental health disorders, SUD, and/or co-occurring disorders.	Attachment 3.1-A Page 6, item 13d-Rehabilitative Services: Attachment 3.1-A Page 5(a)(xxi)
Medication Assisted Treatment	Treatment for SUD that includes the use of methadone delivered in accordance with the Substance Abuse and Mental Health Services Administration (SAMHSA)	SPA # 21-0003 - Attachment 3.1-A Page 6, item 13d- Rehabilitative

	regulations. Services include assessment, planning, counseling, drug use disorder testing, and medication administration. Also includes MAT services that are delivered in an office-based setting, (e.g. OBOT or a certified Opioid Treatment Program (OTP).	Services: Attachment 3.1-A Page 5(a)(x)
Opioid Health Homes	Integrated MAT services, including office visits with a MAT prescriber, prescription medication for OUD, OUD counseling, comprehensive care management/care coordination/health promotion, urine drug screening, and peer recovery support services provided through a bundled rate.	Section 3.1-H
Intensive Outpatient Services	Intensive and structured service of alcohol and drug assessment, diagnosis, and treatment services in a non-residential setting for members who meet ASAM criteria level II.1 or II.5. Services include co-occurring mental health and SUD. Available to adults and children.	Attachment 3.1-A Page 6, item 13d-Rehabilitative Services: Attachment 3.1-A Page 5(a)(xiv)
Residential		
Clinically Managed Low Intensity Residential Services	Services delivered according to ASAM level 3.1, including scheduled therapeutic and rehabilitative treatment designed to enable the member to sustain a substance free lifestyle in an unsupervised community situation. Available to adults.	Attachment 3.1-A Page 6, item 13d-Rehabilitative Services: Attachment 3.1-A Page 5(a)(xix)
Clinically Managed Population-Specific High Intensity Residential Programs	Services delivered according to ASAM level 3.3, Category II, including scheduled therapeutic plan consisting of treatment services designed to enable the member to sustain a substance free life style within a supportive environment. The treatment mode may vary with the member's needs and	Attachment 3.1-A Page 6, item 13d-Rehabilitative Services: Attachment 3.1-A Page 5(a)(xviii)

	may be in the form of individual, group or family counseling. Available to adults.	
Clinically Managed Residential Services	Services delivered according to ASAM level 3.5, including therapeutic treatment and planning consisting of assessment, diagnostic, and counseling services. Available to adults and children.	Attachment 3.1-A Page 6, item 13d-Rehabilitative Services: Attachment 3.1-A Page 5(a)(xvi)
Medically Monitored Inpatient Programs	Services delivered according to ASAM level 3.7, including a planned structured regimen of 24-hour professionally directed evaluation, observation, medical monitoring, and addiction treatment in an inpatient setting. Services provide immediate diagnosis and care to members having acute physical problems related to substance use disorder. Available to adults and children.	Attachment 3.1-A Page 6, item 13d-Rehabilitative Services: Attachment 3.1-A Page 5(a)(xvii)
Inpatient		
Psychiatric Residential Treatment Facility (PRTF) Services	Comprehensive mental health treatment and/or SUD treatment to children and adolescents who, due to mental illness, SUD, or Serious Emotional Disturbance (SED), meet level of care requirements for a PRTF.	Attachment 3.1-A Page 7, item 16

Attachment B: Health IT Plan

As a component of Milestone 5,[8] Implementation of Strategies to Increase Utilization and Improve Functionality of Prescription Drug Monitoring Programs (PDMP), please find Maine's SUD Health IT Plan. In summary, Maine has a robust PDMP, administered by Appriss, that has been supported through legislative and programmatic effort; however, this plan will focus on three main areas of improvement that are based on user feedback and best practice review:

- Complete work to integrate Maine's PDMP and Health Information Exchange (HIE) systems
- Provider, pharmacy and health system engagement and education around PDMP-based SUD assessment and decision support, PDMP compliance, and workflow optimization
- Implementation of enhanced PDMP data analytics capabilities

Table 1. State Health IT / PDMP Assessment & Plan

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Prescription Drug Monitoring Program (PDMP) Functionalities			
Enhanced interstate data sharing in order to better track patient-specific prescription data	Maine's PDMP is currently connected with 34 state PDMPs and the Military Health System, and connections with an additional 15 states are currently pending. We are integrating with another interstate data sharing tool, RxCheck that will allow us to connect with those PDMP's that are not currently able to connect	• Finalize connections between Maine's PDMP system and the 15 states currently pending • Explore establishing PDMP connections with US Territories and the Canadian province of New Brunswick	• The Office of Behavioral Health (OBH) administers the PDMP system in Maine. OBH's PDMP Coordinator will check in with the 15 pending states on a monthly basis to assess technological readiness for intrastate data sharing and establish these connections as the

[8] Milestone 5. Implementation of comprehensive treatment and prevention strategies to address Opioid Abuse and OUD, that is:

- Enhance the state's health IT functionality to support its PDMP; and
- Enhance and/or support clinicians in their usage of the state's PDMP.

	through the NAPD PMPi Interconnect.		technological progress allows. • OBH is managing a re-engagement with the Appriss AWARxE PDMP system, which includes RxCheck for intrastate data sharing. RxCheck will be implemented upon "Go Live" with Appriss (planned date 4/4/21). • OBH's PDMP Coordinator will communicate on a monthly basis with US Territories and New Brunswick, Canada to assess progress towards procuring and implementing PDMP systems; OBH will pursue connections as technological dependencies are clarified.
Enhanced "ease of use" for prescribers and other state and federal stakeholders	Prescribers (clinicians) and dispensers (pharmacies) are currently able to access Maine's PDMP directly as a stand-alone application or via established interoperability with over 150 different electronic health record (EHR) and pharmacy management systems. Prescribers can allow their delegates (clinical staff with special permissions set through the PDMP and connected to a specific	• Inclusion of scheduled I through V substances to provide authorized users with a broad set of information and tools required to support clinical decision-making at the time of prescribing or dispensing • Enhanced data integration, analytic, and reporting capabilities encompassing diverse SUD-related data sets to enable outcome measurement and actionable insights for treatment purposes.	The future state requires legislative changes and the request for these rule changes will be heard in the current legislative session running through July 2021.

	prescriber's DEA) to run Batch Patient Reports.		
Enhanced connectivity between the state's PDMP and any statewide, regional or local health information exchange	The State of Maine has a robust HIE infrastructure developed and operated by HealthInfoNet. HealthInfoNet was launched in 2006 and has since carried out a range of projects and functions in collaboration with and under contract to Maine DHHS. HealthInfoNet connects providers to other providers through a secure online network to share patients' electronic health record data, allowing doctors, hospitals, and other providers to share important health information required to improve the quality and safety of patient care in the state. HealthInfoNet is an independent, nonprofit 501(c)(3) organization, warehousing electronic health record data for almost all (98%) of Maine residents. HealthInfoNet is connected to the majority of healthcare facilities in the state, including all hospitals, over 750 ambulatory care sites, multiple reference laboratories, pathology laboratories, Federally Qualified Health Centers (FQHCs), long-term care and home health facilities, behavioral health providers, independent	By using the statewide PDMP, integrated with the statewide HIE and providers' EHR systems, prescribers will be able to view a patient's comprehensive prescription drug history (scheduled I-V substances) in context of their overall medical record to mitigate drug-to-drug interactions, ensure the co-prescription of Naloxone, and/or refer the patient to another authorized prescriber for education and/or treatment. Connection through the PDMP and HIE will occur through the current system.	The Office of Behavioral Health is managing the integration of Maine's PDMP with its HIE. Functionality for HIE connection will be implemented no later than December 2021. Maine recently made the determination to re-engage with the Appriss AWARxE PDMP system, which will allow the state to leverage work that has already been done by HealthInfoNet in other states to connect the HealthInfoNet HIE with the Appriss AWARxE PDMP. The first meeting between the HealthInfoNet and Appriss technology teams to begin work on the integration project is scheduled for 2/23/21.

	laboratories, social services providers, and the Veterans Administration (using both local connections and the Sequoia Project). Additionally, HealthInfoNet receives a routine claims data feed from the Office of MaineCare Services.		
Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns[9] (see also "Use of PDMP" #2 below)	The current PDMP system allows prescribers to connect through their EHR to view patients' comprehensive prescription drug history. Prescribers are able to assign a delegate to assist with bulk patient reports for review prior to the patient's visit to ensure better provider/patient communication regarding their level of care.	By using the statewide PDMP, integrated with the statewide HIE and providers' EHR systems, prescribers would be able to view a patient's comprehensive prescription drug history (scheduled I-V substances) in context of their overall medical record to mitigate drug-to-drug interactions, ensure the co-prescription of Naloxone, and/or refer the patient to another authorized prescriber for education and/or treatment. With an advanced analytic and reporting infrastructure, the State's program would easily be able to assist with the Administration's policy efforts by combining diverse data sources (e.g., PDMP, HIE clinical, Medicaid claims, a SUD Treatment Services application, VITAL Signs, etc.) to deliver timely reporting and data-sharing of opioid-related outcomes.	The Office of Behavioral Health is managing the integration of Maine's PDMP with its HIE. Functionality for HIE connection will be implemented no later than December 2021. Maine recently made the determination to re-engage with the Appriss AWARxE PDMP system, which will allow the state to leverage work that has already been done by HealthInfoNet in other states to connect the HealthInfoNet HIE with the Appriss AWARxE PDMP. The first meeting between the HealthInfoNet and Appriss technology teams to begin work on the integration

[9] Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015. MMWR Morb Mortal Wkly Rep 2017;66:265–269. DOI: http://dx.doi.org/10.15585/mmwr.mm6610a1.

			project is scheduled for 2/23/21.
Current and Future PDMP Query Capabilities			
Facilitate the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP (i.e. the state's master patient index (MPI) strategy with regard to PDMP query)	Appriss currently uses a unique patient identifying algorithm that merges patients well and also allows the Maine PDMP Administrators the ability to manually merge patients if desired.	The State will assess the clinical, analytic and workflow outcome value of upgrading the HIE MPI to ensure a more complete representation of a patient's medication use history, as well as to associate the PDMP data with other clinical encounters and data available through the HIE. Patient matching is important to safety in the Maine PDMP and for PDMP interstate data sharing as required in the PARTNERSHIP Act. Patient matching is central to getting the right and complete information for a patient's medication use prescription history to a provider making clinical decisions when viewing the PDMP data.	While the PDMP system merges patients effectively, the state is considering are leveraging of the HIE MPI as an additional resource when users are connecting through their EMR. Future plans to leverage the HIE MPI center around constructing a comprehensive multi-source state database of linked client records that would allow a more encompassing view of how individuals are served by various DHHS services and systems, including MaineCare, OBH, Office of Child and Family Services, Office of Aging and Disability Services, Emergency Management Services, Syndromic Surveillance (hospital ED data), Department of Corrections, Department of Public Safety, etc.
Use of PDMP – Supporting Clinicians with Changing Office Workflows / Business Processes			

Develop enhanced provider workflow / business processes to better support clinicians in accessing the PDMP prior to prescribing an opioid or other controlled substance to address the issues which follow	Appriss allows prescribers to view a patient record either through their own EHR, via the HealthInfoNet portal, or through its AWARxE program. Appriss allows the provider to review the patient's record by accessing the EHR, assigning a delegate to print prior to the appointment in the bulk print feature or to view prior to the visit in the PMP and print the record to add to the patient's chart when appropriate. Prescribers have access to the patient's record from another PMP (out-of-state) to help identify any doctor-shopping, doctor-cycling, or co-prescribing habits.	Appriss currently utilizes PMP Gateway for point-of-care integration prescribers' EHR systems. In addition, the Office of Behavioral Health is managing the ongoing work to integrate the AWARxE PDMP with HealthInfoNet such that providers who participate with the HIE will be able to access PDMP data within the HIE portal. (Please see above for description of this project.) PMP Gateway increases utilization of PDMP data at the point-of-care through integration with 150+ different EHR and pharmacy management systems. PMP Gateway delivers PDMP data and NarxCare analytics within the PDMP workflow. The information provided to clinicians is provided in clinically meaningful ways using the NarxCare system and with clinician benchmark reporting comparing clinicians' prescribing patterns to those of their peers.	As part of Maine's re-engagement with the Appriss AWARxE PDMP system, the state will maintain provider EHR integrations via the Appriss PMP Gateway. In addition, the OBH will be investing in a provider outreach and education campaign as part of the AWARxE re-engagement to facilitate EHR integration work and assist health care organizations in implementing and reinforcing PDMP best practices. This outreach and engagement work is planned to occur beginning in April 2021 and will continue through December 2021.
Develop enhanced supports for clinician review of the patients' history of controlled substance prescriptions provided through the PDMP—prior to the issuance of an opioid prescription	Appriss allows prescribers to view the record either through their own EHR, via the HealthInfoNet portal or through the AWARxE interface. Appriss allows the provider to review the patient's record by accessing the EHR, assigning a delegate to print prior to the appointment in the bulk print feature or to view prior to the visit in the PMP and print the record to add to the patient's chart when appropriate. Prescribers have	Prescribers will have the ability to access patient PDMP data through the AWARxE platform, via the HealthInfoNet portal, or through the Gateway integration with their own EHR. The clinician will have access to clinical profiles of patients and historical information of the patient's prior use of controlled substances. The Appriss NarxCare module provides clinicians with clinical decision support related to risk of overdose based on an underlying predictive algorithm.	As part of Maine's re-engagement with the Appriss AWARxE PDMP system, the state will maintain provider EHR integrations via the Appriss PMP Gateway. The Office of Behavioral Health is managing the integration of Maine's PDMP with its HIE. Functionality for HIE connection will be implemented no later than December 2021. The first

	access to the patient's record from out-of-state PDMPs to help identify any doctor-shopping, doctor-cycling, or co-prescribing habits.	PMP Gateway increases utilization of PDMP data at the point-of-care through integration with various electronic health record and pharmacy management systems. PMP Gateway delivers PDMP data and NarxCare analytics within the PDMP workflow. The information provided to clinicians is provided in clinically meaningful ways using the NarxCare system and with clinician profiling reporting comparing clinicians to their peers.	meeting between the HealthInfoNet and Appriss technology teams to begin work on the integration project is scheduled for 2/23/21.
Master Patient Index / Identity Management			
Enhance the master patient index (or master data management service, etc.) in support of SUD care delivery.	Provider compliance with Web Infrastructure for Treatment Services (WITS) data entry requirements for SUD treatment services has been suboptimal, resulting in SUD treatment episode data and client-level data that is under-reported and often incomplete.	OBH is expanding its existing relationship with Kepro, the Administrative Services Provider for both OBH and MaineCare, to replace the WITS system. The Kepro data collection system, Atrezzo, will be used by all SUD providers to both collect client-level data and also process authorizations for treatment. Combining these two functionalities in one system will reduce administrative burden on providers and incentivize compliance with SUD treatment episode data collection by tying this function to authorization/invoicing for services.	OBH is managing the Kepro expansion project. The planned completion date for this project is 4/31/21. Tasks remaining include: Complete review and validation of the development work done by Kepro; • Historical data transfer from WITS to Atrezzo; • User Acceptance Testing and System Testing; and, • Provider engagement/education on the new system.
Overall Objective for Enhancing PDMP Functionality & Interoperability			

Leverage the above functionalities / capabilities / supports (in concert with any other state health IT, TA or workflow effort) to implement effective controls to minimize the risk of inappropriate opioid overprescribing—and to ensure that Medicaid does not inappropriately pay for opioids	Currently, Appriss provides within its system the payment type associated with dispensations. The prescriber checks the system prior to prescribing an opioid or benzothiazepine per state statue §7253.Prescribers and dispensers required to check PDMP information, as per the dispenser prior to dispensing a opioid or benzothiazepine.	The Appriss NarxCare system serves as an alert to prescribers regarding potentially risky/inappropriate opiate prescriptions.	OBH administers Maine's PDMP and is managing the provider education and engagement campaign as part of the state's re-engagement with the Appriss AWARxE system. Planned activities include: with provider education on the NarxCare tool and its underlying algorithm to better enable providers to make informed and appropriate prescribing decisions at the point of care in the upcoming fiscal year (July 2021 – Sept 2022). The term provider encompasses prescribing providers with DEA numbers (MD, DO, NP)

Attachment C: Implementation Administration

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ATTACHMENT D
Reserved for SUD Monitoring Protocol

ATTACHMENT E
Reserved for SUD Evaluation Design