

State Demonstrations Group

June 25, 2025

William Halsey State Medicaid Director Connecticut Department of Social Services 55 Farmington Avenue Hartford, CT 06105

Dear Director Halsey:

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

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

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

Updates to Demonstration Monitoring

Below are the updated aspects of demonstration monitoring for the Connecticut Substance Use Disorder (SUD) (Project Number 11-W-00372/1 and 21-W-00069/1) demonstration.

Reporting Cadence and Due Date

CMS determined that, when combined with monitoring calls, an annual monitoring reporting cadence will generally be sufficient to monitor potential risks and vulnerabilities in demonstration implementation, performance, and progress toward stipulated goals. Thus, pursuant to CMS's authority under 42 CFR 431.420(b)(1) and 42 CFR 431.428, CMS is updating the cadence for this demonstration to annual monitoring reporting (see also section 1115(d)(2)(D)-(E) of the Act). This transition to annual monitoring reporting is expected to

alleviate administrative burden for both the state and CMS. In addition, CMS is extending the due date of the annual monitoring report from 90 days to 180 days after the end of each demonstration year to balance Medicaid claims completeness with the state's work to draft, review, and submit the report timely.

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

The Connecticut SUD demonstration will transition to annual monitoring reporting effective June 25, 2025. The annual monitoring report for the current demonstration year will be due on September 28, 2026 which reflects the first business day following 180 calendar days after the end of the demonstration year. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect the new reporting cadence and due date.

Structured Monitoring Report Template

As noted in STC 28, "Monitoring Reports," 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." Pursuant to that STC, CMS is introducing a structured monitoring report template to minimize variation in content of reports across states, which will facilitate drawing conclusions over time and across demonstrations with broadly similar section 1115 waivers or expenditure authorities. The structured reporting framework will also provide CMS and the state opportunities for more comprehensive and instructive engagement on the report's content to identify potential risks and vulnerabilities and associated mitigation efforts as well as best practices, thus strengthening the overall integrity of demonstration monitoring.

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

Some of the metrics currently required for SUD) and Serious Mental Illness (SMI)/Serious Emotional Disturbance (SED) demonstrations will no longer be required.

CMS is also removing the requirement for a Monitoring Protocol deliverable, which has been required under certain types of section 1115 demonstration, including but not limited to the SUD, SMI/SED, Health-Related Social Needs (HRSN), and reentry demonstrations. Removal of the Monitoring Protocol requirement simplifies and streamlines demonstration monitoring activities for states and CMS.

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Demonstration Monitoring Calls

As STC 32 "Monitoring Calls" describes, CMS may "convene periodic conference calls with the state," and the calls are intended "to discuss ongoing demonstration operation, including (but not limited to) any significant actual or anticipated developments affecting the demonstration." Going forward, CMS envisions implementing a structured format for monitoring calls to provide consistency in content and frequency of demonstration monitoring calls across demonstrations. CMS also envisions convening quarterly monitoring calls with the state and will follow the structure and topics in the monitoring report template. We anticipate that standardizing the expectations for and content of the calls will result in more meaningful discussion and timely assessment of demonstration risks, vulnerabilities, and opportunities for intervention. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect that monitoring calls will be held no less frequently than quarterly.

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

In the coming weeks, CMS will reach out to schedule a transition meeting to review templates and timelines outlined above. As noted above, the pertinent Connecticut SUD section 1115 demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect these updates.

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

Sincerely,

Karen LLanos Acting Director

Enclosure cc: Marie DiMartino, State Monitoring Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES

EXPENDITURE AUTHORITY

NUMBER: 11-W-00372/1 and 21-W-00069/1

TITLE: Connecticut Substance Use Disorder Demonstration

AWARDEE: Connecticut Department of Social Services

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Connecticut for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from April 1, 2022, through March 31, 2027, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

The Secretary of Health and Human Services (HHS) has determined that the Connecticut Substance Use Disorder Demonstration, including the granting of the expenditure authorities described below, is likely to assist in promoting the objectives of title XIX of the Act.

The following expenditure authorities may only be implemented consistent with the approved special terms and conditions (STC), and shall enable Connecticut to operate this section 1115(a) demonstration.

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

<u>Title XXI Expenditure Authority:</u>

1. **Residential and Inpatient Treatment for Individuals with Substance Use Disorder.** Expenditures for otherwise covered services that are furnished to otherwise eligible individuals of the Children's Health Insurance Program (CHIP) who are primarily receiving treatment and withdrawal management services for SUD as short-term residents in facilities that meet the definition of an IMD.

Under the authority of section 1115(a)(2) of the Act as incorporated into Title XXI by section 2107(e)(2)(A), state expenditures described below, shall, for the period of this demonstration (April 1, 2022 through March 31, 2027) and based on state's available allotment under section 2104 of the Act, be regarded as match-able expenditures under the state's Title XXI plan. All requirements of Title XXI will be applicable to such expenditures for children who are residing in an IMD at the time of application or at the time of renewal and would be ineligible for coverage under CHIP pursuant to 2110(b)(2)(A).

CENTERS FOR MEDICARE & MEDICAID SERVICES

EXPENDITURE AUTHORITY

NUMBER:	11-W-00372/1 and 21-W-00069/1
TITLE:	Connecticut Substance Use Disorder Demonstration
AWARDEE:	Connecticut Department of Social Services

I. PREFACE

The following are the special terms and conditions (STCs) for the "Connecticut Substance Use Disorder" section 1115(a) Medicaid demonstration (hereinafter, "demonstration"), to enable the Connecticut Department of Social Services (hereinafter "state") to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authorities authorizing federal matching of demonstration costs not otherwise match-able, which are separately enumerated. These STCs set forth conditions and limitations on those expenditure authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration, and the state's obligations to CMS related to the demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted. The demonstration will be statewide and is approved for a five-year period, from April 1, 2022 through March 31, 2027, unless otherwise specified.

The STCs have been arranged into the following subject areas:

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

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

Attachment A: Developing the Evaluation Design

Attachment B: Preparing the Interim and Summative Evaluation Reports Attachment C: SUD Implementation Plan and SUD Health IT Plan Attachment D: SUD Monitoring Protocol Attachment E: SUD Evaluation Design

II. PROGRAM DESCRIPTION AND OBJECTIVES

This demonstration will provide the state with authority to provide clinically appropriate treatment to individuals diagnosed with a SUD while they are short-term residents in treatment facilities that qualify as IMDs. This demonstration will address currently unmet needs, support a continuum of treatment options, and provide access to a comprehensive and coordinated system of evidence-based SUD services at varied levels of intensity for Medicaid and Children's Health Insurance Program (CHIP) enrollees. Through coverage for CHIP enrollees, this demonstration will provide access to essential healthcare for children who are diagnosed with a SUD and require treatment in an IMD, and who would otherwise be ineligible for services under Medicaid or for enrollment in CHIP.

The demonstration—in alignment with the demonstration goals outlined in the State Medicaid Director Letter (SMDL) #17-003, entitled "Strategies to Address the Opioid Epidemic"^[1] and published on November 1, 2017—is expected to:

- Increase identification, initiation, and engagement of Medicaid beneficiaries diagnosed with SUD;
- Increase beneficiary adherence to, and retention in, SUD treatment programs;
- Reduce overdose deaths, particularly those due to opioids;
- Reduce inappropriate or preventable utilization of emergency departments and inpatient hospital settings through improved access to a continuum of care services;
- Reduce readmissions to the same or higher level of care; and
- Provide a continuum of care to increase the chances of Medicaid beneficiaries having a successful recovery process, and improve access to care for physical health conditions among beneficiaries.

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 CHIP Law, Regulation, and Policy. All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and policy statement,

^{[1] &}lt;u>https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd17003.pdf</u>.

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 for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
- b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.
- **5. State Plan Amendments**. The state will not be required to submit title XIX or XXI state plan amendments (SPA) 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 of Health & Human Services (HHS) in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance

expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.

- 7. Amendment Process. Requests to amend the demonstration must be submitted to CMS for approval no later than one hundred twenty (120) calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny (or delay approval of) a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit required must be submit required to the 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 that 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 "withwaiver" 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. Updates provided by the state 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. If the state intends to request an extension of the demonstration, it must apply to CMS from the Governor or Chief Executive Officer of the state in accordance with the requirements of 42 CFR §431.412(c). If the state does not intend to request an extension of a demonstration beyond the period authorized in these STCs, it must submit a phase-out plan consistent with the requirements of STC 9.
- **9. Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.

- a. <u>Notification of Suspension or Termination:</u> 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 (6) months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.
- b. <u>Transition and Phase-out Plan Requirements:</u> 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. <u>Transition and Phase-out Plan Approval.</u> 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 fourteen (14) calendar days after CMS approval of the transition and phase-out plan.
- d. <u>Transition and Phase-out Procedures:</u> 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 redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to termination, 42 CFR 435.916. 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. <u>Exemption from Public Notice Procedures 42 CFR Section 431.416(g)</u>. CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
- f. <u>Enrollment Limitation during Demonstration Phase-Out.</u> If the state elects to suspend, terminate, or not extend this demonstration, during the last six (6) 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. <u>Federal Financial Participation</u>. 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 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 431.408 prior to applying 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.** 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, managed care organizations (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 the only involvement of human subjects in research activities authorized and/or required by this demonstration is for projects 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 eligibility. Standards and methodologies for eligibility remain as set forth under the state plan. This demonstration will apply to otherwise-eligible Medicaid beneficiaries who are short-term residents in IMDs for a SUD diagnosis.

Under the demonstration, an individual eligible for CHIP, except for if the individual is residing in an IMD for diagnoses of SUD at the time of application or renewal, will continue to be eligible for CHIP. All other standards and methodologies for eligibility remain as set forth under the state plan.

17. Applicability of title XXI Maintenance of Effort to Demonstration Populations. The maintenance of effort provision at section 2105(d)(3)(A) of the Act applies to title XXI eligible children enrolled in this demonstration. This provision requires that, with certain exceptions, as a condition of receiving FFP for Medicaid, states must maintain CHIP "eligibility standards, methodologies, and procedures" for children that are no more restrictive than those in effect on March 23, 2010. See STCs 72 and 73 related to the title XXI funding limits and shortfalls.

V. SUBSTANCE USE DISORDER PROGRAMS AND BENEFITS

18. SUD Program Benefits. Effective upon CMS' approval of the SUD Implementation Plan, the demonstration benefit package for Medicaid beneficiaries will include SUD treatment services, such as services provided in residential and inpatient treatment settings that meet the definition of an IMD, which are not otherwise match-able expenditures under section 1903 of the Act. The state must achieve a statewide average length of stay of no more than thirty (30) days in residential and inpatient treatment settings, to be monitored pursuant to the SUD Monitoring Protocol as outlined in STC 27 below.

Under this demonstration, beneficiaries will have access to high-quality, evidence-based opioid use disorder (OUD) and 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.

19. 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 for CMS review and comment. The state must submit the revised SUD Implementation Plan within sixty (60) calendar days after receipt of CMS' 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:
 - i. Access to Critical Levels of Care for OUD and other SUDs: Coverage of SUD/OUD treatment services across a comprehensive continuum of care, within 12-24 months of SUD demonstration approval, including: outpatient; intensive outpatient; medication-assisted treatment (medication as well as counseling and other services, with sufficient provider capacity to meet the needs of Medicaid beneficiaries); intensive levels of care in residential and inpatient settings; and medically supervised withdrawal management;
 - ii. 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;

- iii. **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;
- iv. Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities: Currently, residential treatment service providers must be a licensed organization, pursuant to the residential service provider qualifications described in the provider manual at: <u>http://www.abhct.com/Customer-</u> <u>Content/WWW/CMS/files/BHRP_Provider_Manual_2013.pdf</u>. 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;
- v. **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;
- vi. **Standards of Care:** Establishment of a requirement that residential treatment providers offer medication assisted treatment (MAT) on-site or facilitate access to MAT off-site within 12-24 months of demonstration approval;
- vii. Sufficient Provider Capacity at Each Level of Care Including MAT 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 twelve (12) months of demonstration approval;
- viii. 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;
 - ix. 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 twenty-four (24) months of demonstration approval.

- x. **SUD Health IT Plan:** Implementation of the milestones and metrics as detailed in STC 19(d).
- d. **SUD Health Information Technology Plan.** The SUD Health Information Technology (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 19.a. and 19.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 plan 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.

- i. The state must include in its Monitoring Protocol (see STC 27) an approach to monitoring its SUD Health IT Plan which will include performance metrics to be approved in advance by CMS.
- ii. The state must monitor progress, each demonstration year (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 in an addendum to its Annual Report (see STC 28).
- iii. 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.
- iv. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or accountable care organization 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.
- v. 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.

- A. Components of the Health IT Plan include:
 - 1. The Health IT Plan must describe the state's goals, each DY, to enhance the state's prescription drug monitoring program (PDMP).¹
 - 2. The Health IT Plan must address how the state's PDMP will enhance ease of use for prescribers and other state and federal stakeholders.^{1 above} 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.
 - 3. 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 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.
 - 4. 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.²
 - 5. 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.
 - 6. In developing the Health IT Plan, states should use the following resources.
 - States may use federal resources available on Health IT.Gov (<u>https://www.healthit.gov/topic/behavioral-health</u>) including but not limited to "Behavioral Health and Physical Health Integration" and "Section 34: Opioid Epidemic and Health IT." (<u>https://www.healthit.gov/playbook/health-information-exchange/</u>).

¹ PDMPs 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 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.

- 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 <u>https://www.medicaid.gov/medicaid/data-and-</u><u>systems/hie/index.html</u>. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.
- 7. 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.
- **20. 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

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

VII. DELIVERY SYSTEM

22. Delivery System. All demonstration beneficiaries will continue to receive services through the same delivery system arrangements as currently authorized in the state.

VIII. GENERAL REPORTING REQUIREMENTS

23. 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) calendar 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 calendar 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.

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.

- 24. Deferral of Federal Financial Participation 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.
- **25. Submission of Post-approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.

- **26. Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional 1115 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.
- **27. SUD Monitoring Protocol(s).** The state must submit a draft Monitoring Protocol for the SUD programs authorized by this demonstration no later than one hundred fifty (150) calendar days after the effective date of the demonstration. The SUD Monitoring Protocol 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' comments. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs, as Attachment D. Progress on the performance measures identified in the Monitoring Protocol must be reported via the Quarterly and Annual Monitoring Reports. Components of the Monitoring Protocol 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 19(c) and reporting relevant information to the state's Health IT plan described in STC 19(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 (General Reporting Requirements) 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.
- **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 monitoring 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 state must submit a revised monitoring report within sixty (60) calendar days after receipt of CMS' comments, if any. 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 systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.
 - a. <u>Operational Updates.</u> 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. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. In addition, monitoring reports should describe key achievements, as well as the conditions and efforts to which these successes can be attributed. Monitoring reports should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

- b. <u>Performance Metrics.</u> The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration's milestones and/or goals and must cover all key policies under this demonstration. Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration on beneficiaries' outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, and if conducted, grievances and appeals. The required monitoring and performance metrics must be included in the monitoring reports, and will follow the framework provided by CMS to support federal tracking and analysis.
- c. <u>Budget Neutrality and Financial Reporting Requirements.</u> Per 42 CFR 431.428, the monitoring reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every monitoring report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately.
- d. <u>Evaluation Activities and Interim Findings</u>. 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. <u>SUD Health IT</u>. The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 19.d.
- **29. SUD Mid-Point Assessment.** The state must contract with an independent entity to conduct a mid-point assessment by March 31, 2025. This timeline will allow for the mid-point assessment report to capture approximately the first two-and-a-half years of demonstration program data, accounting for data run-out and data completeness. 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: representatives of MCOs, if applicable, SUD treatment providers, beneficiaries, and other key partners.

The state must require that the assessor provide a mid-point assessment 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) calendar days after March 31, 2025. The state must brief CMS on the report, if requested. The state must submit a revised mid-point assessment report within sixty (60) calendar days after receipt of CMS' comments, if any.

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 Protocol for ameliorating these risks. Modifications to the applicable Implementation Plan and Monitoring Protocol are subject to CMS approval.

Elements of the mid-point assessment report 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 Plan 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 Plan Related to Monitoring. 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. A state corrective action plan could include a temporary suspension of implementation of demonstration programs in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS will withdraw an authority, as described in STC 10, when metrics indicate substantial and sustained directional change inconsistent with the state's demonstration goals, and the state has not implemented corrective action. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

- **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 23.
- 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) calendar 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 Monitoring Report.

IX. 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; providing data and analytic files to CMS; entering into a data use agreement that explains how the data and data files will

be exchanged; and providing a technical point of contact to support specification of the data and files to be disclosed as well as relevant data dictionaries and record layouts. The state shall include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they make data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 23.

- **35. Independent Evaluator.** Upon approval of the demonstration, the state must 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 state must submit, for CMS comment and approval, a draft evaluation design with implementation timeline no later than one hundred eighty (180) calendar days after the approval of the demonstration.

The draft evaluation design must be developed in accordance with:

- a. Attachment A (Developing the Evaluation Design) of these STCs;
- b. CMS' evaluation design guidance for SUD, including guidance for approaches to analyzing associated costs; and
- c. All applicable CMS guidance on applying robust evaluation approaches, including establishing valid comparison groups and assuring causal inferences in demonstration evaluations.

The draft Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STCs 39 and 40.

37. Evaluation Design Approval and Updates. The state must submit to CMS a revised draft evaluation design within sixty (60) calendar days after receipt of CMS' comments. Upon CMS approval of the evaluation design, the document will be included as Attachment E 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 design and submit a description of its evaluation implementation progress in each of the quarterly and annual monitoring reports, including any required rapid cycle assessments specified in these STCs. Once CMS approves the evaluation design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for

approval if the changes are substantial in scope; otherwise, in consultation with CMS, the state may include updates to the evaluation design in monitoring reports.

38. Evaluation Questions and Hypotheses. Consistent with Attachments A and B (Developing the Evaluation Design; Preparing the Interim and Summative Evaluation Reports) of these STCs, the evaluation design must include a discussion of the evaluation questions and hypotheses that the state intends to test. The evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact and also its effectiveness in achieving the goals. Each demonstration component should have at least one evaluation question and hypothesis. The state must also conduct a demonstration cost assessment. Additionally, the state should accommodate data collection and analyses stratified by key subpopulations of interest to inform a fuller understanding of existing disparities in access and health outcomes, and how the demonstration's policies might support bridging any such inequities.

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' 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).

The findings from each evaluation component must be integrated to help inform whether the state met the overall demonstration goals, with recommendations for future efforts regarding all components.

- **39. Evaluation Budget.** A budget for the evaluations must 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 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.
- **40. Interim Evaluation Report.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When applying for extension, the Interim Evaluation Report should be posted to the state's website with the application for public comment.
 - a. The interim evaluation report will discuss evaluation progress and present findings to date as per the approved evaluation design.

- b. For demonstration authority that expires prior to the overall demonstration's expiration date, the interim evaluation report must include an evaluation of the authority as approved by CMS.
- c. If the state is seeking to extend the demonstration, the draft interim evaluation report is due when the application for extension is submitted. If the state made changes to the demonstration in its application for extension, 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 a revised interim evaluation report within sixty (60) calendar days of receiving CMS comments on the draft interim evaluation report.
- e. Once approved by CMS, the state must post the final interim evaluation report to the state's Medicaid website within thirty (30) calendar days of approval by CMS.
- f. The interim evaluation report must comply with Attachment B (Preparing the Interim and Summative Evaluation Reports) of these STCs.
- **41. Summative Evaluation Report.** The state must submit a 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 a revised summative evaluation report within sixty (60) calendar days of receiving comments from CMS on the draft.
 - b. Once approved by CMS, the final summative evaluation report must be posted to the state's Medicaid website within thirty (30) calendar days of approval by CMS.
 - c. The summative evaluation report must be developed in accordance with Attachment B (Preparing the Interim and Summative Evaluation Reports) of these STCs.
- **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 an extension process when associated with the state's interim evaluation report, or as part of the review of the summative evaluation report. A corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC

10. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

- **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 report, and summative evaluation report) on the state's Medicaid 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 deliverables, CMS will be notified prior to presentation of these reports or their findings, including in related publications (e.g., journal articles), by the state, contractor, or any other third party directly connected to the demonstration over which the state has control. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment 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.

X. 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.³
- **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 match-able 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 available to the

³ For a description of CMS' 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.

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 approval 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.** As a condition of demonstration approval, the state certifies that the non-federal share is obtained from permissible state and/or local funds that, unless permitted by law, are not other federal funds. The state further certifies that such funds must not be used to match any other federal grant or contract, except as permitted by law. CMS approval of this demonstration does not constitute direct or indirect approval of any underlying source of non-federal share or associated funding mechanisms and all sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, CMS reserves the right to prohibit the use of any sources of non-federal share funding that it determines impermissible.
 - a. If requested, the state must submit for CMS review and approval documentation of any sources of non-federal share that would be used to fund the demonstration.
 - b. If CMS determines that any funding sources are not consistent with applicable federal regulations, the state must address CMS' concerns within the time frames allotted by CMS.
 - c. Without limitation, CMS may request information about the non-federal share sources for any amendments that CMS determines may financially impact the demonstration.
- **50. State Certification of Funding Conditions.** As a condition of demonstration approval, the state certifies that the following conditions for non-federal share funding of demonstration expenditures have been met:
 - a. Units of state or local government, including health care providers that are units of state or local government, 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, the state must obtain CMS approval for a cost reimbursement methodology. This methodology must include a detailed explanation of the process, including any necessary cost reporting protocols, 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 be used as the non-federal 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 revenues and are transferred by units of government within the state. Any transfers from units of government must be made in an amount not to exceed the non-federal share of title XIX payments.
- e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local governments 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. Financial Integrity for Managed Care and Other Delivery Systems.** As a condition of demonstration approval, the state attests to the following, as applicable:
 - a. All risk-based MCO, prepaid inpatient health plan (PIHP), and prepaid ambulatory health plan (PAHP) payments, comply with the requirements on payments in 42 CFR §438.6(b)(2), 438.6(c), 438.6(d), 438.60 and/or 438.74.
 - b. For non-risk-based PIHPs and PAHPs, arrangements comply with the upper payment limits specified in 42 CFR §447.362, and if payments exceed the cost of services, the state will recoup the excess and return the federal share of the excess to CMS.
- **52. Requirements for health care related taxes and provider donations.** As a condition of demonstration approval, the state attests to the following, as applicable:

- All health care-related taxes as defined by Section 1903 (w)(3)(A) of the Social Security Act and 42 CFR § 433.55 are broad-based as defined by Section 1903 (w)(3)(B) of the Social Security Act and 42 CFR § 433.68 (c).
- b. All health care-related taxes are uniform as defined by Section 1903 (w)(3)(C) of the Social Security Act and 42 CFR § 433.68 (d).
- c. If the health care-related tax is either not broad-based or not uniform, the state has applied for and received a waiver of the broad-based and/or uniformity requirements as specified by 1903 (w)(3)(E)(i) of the Social Security Act and 42 CFR § 433.72.
- d. The tax does not contain a hold harmless arrangement as described by Section 1903 (w)(4) of the Social Security Act and 42 CFR § 433.68 (f).
- e. All provider related-donations as defined by 42 CFR § 433.52 are bona fide as defined by Section 1903 (w)(2)(B) of the Social Security Act, 42 CFR § 433.66, and 42 CFR § 433.54.
- **53. 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.
- **54. Medicaid Expenditure Groups.** Medicaid expenditure groups (MEGs) are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The master MEG Chart table provides a master list of MEGs defined for this demonstration. The column titled *MEG* in the below table reflects the state's terminology for their distinct eligibility groups. The table does not include Husky B, which is the eligibility group for children enrolled in CHIP.

Table 2: Master MEG Chart						
MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description	
Husky A	Нуро 1	Х		Х	Low-income Medicaid enrollees, parents/caregiver relatives, and children	
Husky C	Hypo 1	Х		Х	Aged, Blind, and Disabled	
Husky D	Нуро 1	Х		Х	Medicaid expansion enrollees	

- **55. 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-00372/1). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.
 - a. <u>Cost Settlements.</u> 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. <u>Premiums and Cost Sharing Collected by the State.</u> 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. <u>Pharmacy Rebates.</u> 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. <u>Administrative Costs.</u> 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. <u>Member Months.</u> As part of the Quarterly and Annual Monitoring Reports described in section VIII, 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 (3) months contributes three (3) eligible member months to the total. Two individuals who are eligible for two (2) months, each contribute two (2) eligible member months, for a total of four (4) eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.

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

	Table 3: MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date	
Husky A	Children and Caretaker adults (Non- Expansion Adult Medicaid beneficiaries) diagnosed with a SUD	See STC # 19	Follow CMS 64.9 Base Category of Service Definitions	Date of service	МАР	Y	April 1, 2022	March 31, 2027	
Husky C	Aged, Blind, and Disabled Medicaid beneficiaries diagnosed with a SUD	See STC # 19	Follow CMS 64.9 Base Category of Service Definitions	Date of service	МАР	Y	April 1, 2022	March 31, 2027	
Husky D	Medicaid Expansion adult beneficiaries diagnosed with a SUD	See STC # 19	Follow CMS 64.9 Base Category of Service Definitions	Date of service	МАР	Y	April 1, 2022	March 31, 2027	

56. Demonstration Years. Demonstration years for this demonstration are defined in the Demonstration Years table below.

Demonstration Year 1	April 1, 2022 to March 31, 2023	12 months
Demonstration Year 2	April 1, 2023 to March 31, 2024	12 months
Demonstration Year 3	April 1, 2024 to March 31, 2025	12 months
Demonstration Year 4	April 1, 2025 to March 31, 2026	12 months
Demonstration Year 5	April 1, 2026 to March 31, 2027	12 months

Table 4: Demonstration Years

- **57. 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.⁴
- **58.** 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.
- **59. 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

 $^{^{4}}$ 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' 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.

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

XI. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

- **60. 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' 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.
- **61. 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.

- **62.** 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 multiplied by 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.
- **63. 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.
- 64. 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' 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 Test, which subjects 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 offset that excess spending by savings elsewhere in the demonstration or to refund the FFP to CMS.
- **65. Hypothetical Budget Neutrality Test 1: SUD Services.** 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.

MEG	PC or Agg *	WOW Only, WW Only, or Both	BASE YEAR SFY2019	TRE ND	DY 1	DY 2	DY 3	DY 4	DY 5
Husky A	PC	Both	\$4,821.33	4.5%	\$5,562.82	\$5,813.15	\$6,074.74	\$6,348.10	\$6,633.76
Husky C	PC	Both	\$11,950.54	3.9%	\$13,532.8 1	\$14,060.5 9	\$14,608.9 5	\$15,178.7 0	\$15,770.6 7
Husky D	PC	Both	\$8,019.71	5.7%	\$9,602.90	\$10,150.2 7	\$10,728.8 4	\$11,340.3 8	\$11,986.7 8

- **66. Composite Federal Share.** The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Main or Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.
- **67. Exceeding Budget Neutrality.** CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from April 1, 2022 to March 31, 2027. 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.
- **68. Mid-Course Correction.** If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

Table 9: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations						
Demonstration Year	Demonstration YearCumulative Target DefinitionPercentage					

DY1	Cumulative budget neutrality limit plus:	2.0 percent
DY1 through DY2	Cumulative budget neutrality limit plus:	1.5 percent
DY1 through DY3	Cumulative budget neutrality limit plus:	1.0 percent
DY1 through DY4	Cumulative budget neutrality limit plus:	0.5 percent
DY1 through DY5	Cumulative budget neutrality limit plus:	0.0 percent

XII. MONITORING ALLOTMENT NEUTRALITY

- **69. Reporting Expenditures Subject to the Title XXI Allotment Neutrality Agreement.** The following describes the reporting of expenditures subject to the allotment neutrality agreement for this demonstration:
 - a. <u>Tracking Expenditures:</u> In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-21 reporting instructions outlined in section 2115 of the State Medicaid Manual.
 - b. <u>Use of Waiver Forms:</u> Title XXI demonstration expenditures will continue to be reported on separate Forms CMS-21 Waiver and/or CMS-21P Waiver, identified by the demonstration project number assigned by CMS (including project number extension, which indicates the demonstration year in which services were rendered or for which capitation payments were made).
 - c. <u>Claiming Period</u>: All claims for expenditures related to the demonstration (including any cost settlements) must be made within two years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state must continue to identify separately, on the Form CMS-21 Waiver, net expenditures related to dates of service during the operation of the demonstration.
- **70. Standard CHIP Funding Process.** The standard CHIP funding process will continue to be used during the demonstration. The state will continue to estimate match-able CHIP expenditures on the quarterly Form CMS-21B. On a separate CMS-21B, the state shall provide updated estimates of expenditures for the demonstration populations. CMS will make federal funds available based upon the state's estimate, as approved by CMS. Within thirty (30) calendar days after the end of each quarter, the state must submit the Form CMS-21 quarterly CHIP expenditure report. CMS will reconcile expenditures reported on the Form CMS-21 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

- **71. Title XXI Administrative Costs.** Administrative costs will not be included in the allotment neutrality limit, but the state must separately track and report additional administrative costs that are directly attributable to the demonstration. Total expenditures for outreach and other reasonable costs to administer the CHIP state plan and this demonstration that are applied against the state's title XXI allotment may not exceed ten percent of total title XXI net expenditures.
- **72. Limit on Title XXI Funding.** The state will be subject to a limit on the amount of federal title XXI funding that the state may receive on allowable demonstration expenditures during the demonstration period. Federal title XXI funds for the state's CHIP program (i.e., the approved title XXI state plan and this demonstration) are restricted to the state's available allotment and reallocated funds. Title XXI funds (i.e., that allotment or reallocated funds) must first be used to fully fund costs associated with CHIP state plan populations. Demonstration expenditures are limited to remaining funds.
- **73. Exhaustion of Title XXI Funds.** The state is eligible to receive title XXI funds for the demonstration population as described in STC 16, up to the amount of its title XXI allotment.

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 19			
60 calendar days after approval date	Revised SUD Implementation Plan (including Health IT Plan)	STC 19			
150 calendar days after demonstration effective date	Monitoring Protocol	STC 32			
60 calendar days after receipt of CMS comments	Revised Monitoring Protocol	STC 32			
180 calendar days after approval date	Draft Evaluation Design	STC 36			
60 calendar days after receipt of CMS comments	Revised Draft Evaluation Design	STC 36			
No later than 60 calendar days after March 31, 2025	SUD Mid-Point Assessment	STC 29			
60 calendar days after receipt of CMS comments	Revised SUD Mid-Point Assessment	STC 29			
March 31, 2026 or with extension application	Draft Interim Evaluation Report	STC 40			

XIII. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION PERIOD

60 calendar days after receipt of CMS comments	Revised Interim Evaluation Report	STC 40(d)
Within 18 months after March 31, 2027	Draft Summative Evaluation Report	STC 41
60 calendar days after receipt of CMS comments	Revised Summative Evaluation Report	STC 41(a)
Monthly Deliverables	Monitoring Calls	STC 32
Quarterly monitoring reports due 60 calendar days after end of each	Quarterly Monitoring Reports, including implementation updates	STC 28
quarter, except 4 th quarter	Quarterly Expenditure Reports	STC 28
Annual monitoring reports due 90 calendar days after end of each 4 th quarter	Annual Monitoring Reports	STC 28

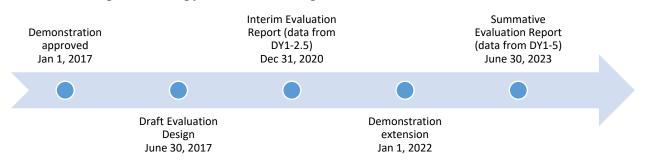
ATTACHMENT A Developing the Evaluation Design

Introduction

Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. To that end, for states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. 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 provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data. Evaluations should include findings about the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration (e.g., whether the outcomes observed in 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).

Submission Timelines

There is a specified timeline for the state's submission of its draft Evaluation Design and subsequent evaluation reports. The graphic below depicts an example of this timeline for a 5-year demonstration. 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) calendar days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Designs

CMS expects Evaluation Designs to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html. If the state needs technical assistance using this outline or developing the Evaluation Design, the state should contact its demonstration team.

All states with section 1115 demonstrations are required to conduct Interim and Summative Evaluation Reports, and the Evaluation Design is the roadmap for conducting these evaluations.

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. 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.

The format for the Evaluation Design is as follows:

- A. General Background Information;
- **B.** Evaluation Questions and Hypotheses;
- C. Methodology;
- **D.** Methodological Limitations;
- E. Attachments.
- **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 description of the population groups impacted by the demonstration.
 - 4. A brief description of the demonstration and history of its implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration.
 - 5. 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.
- **B.** Evaluation Questions and Hypotheses In this section, the state should:
 - 1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the evaluation questions align with the hypotheses and the goals of the demonstration.
 - 2. Address how the hypotheses and research questions promote the objectives of Titles XIX and/or XXI.
 - 3. 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 can be measured.
 - 4. 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, which includes information about the goals and features of the demonstration, is a particularly effective modeling tool when working to improve

health and health care through specific interventions. 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: <u>https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf</u>.

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, that the results are statistically valid and reliable, and that it builds upon other published research, using references where appropriate.

This section also provides evidence that the demonstration evaluation will use the best available data. The state should report on, control for, and make appropriate adjustments for the limitations of the data and their effects on results, and discuss the generalizability of results. This section should provide enough transparency to explain what will be measured and how, in sufficient detail so that another party could replicate the results. Table A below is an example of how the state might want to articulate the analytic methods for each research question and measure. Specifically, this section establishes:

- 1. *Methodological Design* Provide information on how the evaluation will be designed. For example, whether the evaluation will utilize pre/post data comparisons, pre-test or post-test only assessments. If qualitative analysis methods will be used, they must be described in detail.
- 2. *Target and Comparison Populations* Describe the characteristics of the target and comparison populations, incorporating 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. The state also should include information about how it will define the numerators and denominators. Furthermore, the state should ensure the measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval. When selecting metrics, the state shall identify opportunities for improving quality of care and health outcomes, and controlling cost of care. The state also should incorporate benchmarking and comparisons to national and state standards, where appropriate. The state also should 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.) Proposed health measures could include CMS' 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. 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.

- 5. Data Sources Explain from where the data will be obtained, describe any efforts to validate and clean the data, and discuss the quality and limitations of the data sources. If the state plans to collect primary data (i.e., data collected specifically for the evaluation), include the methods by which the data will be collected, the source of the proposed questions and responses, and the frequency and timing of data collection. Additionally, copies of any proposed surveys must be provided to CMS for approval before implementation.
- 6. *Analytic Methods* This section includes the details of the selected quantitative and/or qualitative analysis measures that will 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).
 - b. Explain how the state will isolate the effects of the demonstration from other initiatives occurring in the state at the same time (e.g., through the use of comparison groups).
 - c. Include a discussion of how propensity score matching and difference-indifferences designs may be used to adjust for differences in comparison populations over time, if applicable.
 - d. Consider the application of sensitivity analyses, as appropriate.
- 7. *Other Additions* The state may provide any other information pertinent to the Evaluation Design for the demonstration.

Research Question Hypothesis 1	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
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

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

D. Methodological Limitations – This section provides more detailed information about the limitations of the evaluation. This could include limitations about the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize these 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.

CMS also recognizes that there may be certain instances where a state cannot meet the rigor of an evaluation as expected by CMS. In these instances, the state should document for CMS why it is not able to incorporate key components of a rigorous evaluation, including comparison groups and baseline data analyses. For example, if a demonstration is long-standing, it may be difficult for the state to include baseline data because any pre-test data points may not be relevant or comparable. Other examples of considerations include:

- 1. When the demonstration is:
 - a. Non-complex, unchanged, or has previously been rigorously evaluated and found to be successful; or
 - b. 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;
 - b. No or minimal appeals and grievances;

- c. No state issues with CMS-64 reporting or budget neutrality; and
- d. No Corrective Action Plans 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 and prepare objective Evaluation Reports. The Evaluation Design should include a "No Conflict of Interest" statement 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 costs, 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, if CMS finds that the draft Evaluation Design is not sufficiently developed, or if the estimates appear to be excessive.
- 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 milestones for the development and submission of the Interim and Summative Evaluation Reports. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation Report is due.

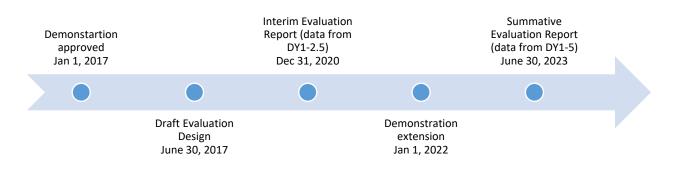
ATTACHMENT B Preparing the Interim and Summative Evaluation Reports

Introduction

Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. To that end, for states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. 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 provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data. Evaluations should include findings about the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration (e.g., whether the outcomes observed in 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).

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 a deliverable's timeline for a 5-year demonstration. 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 the Interim and Summative Evaluation Reports to the state's website within thirty (30) calendar days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Reports

All states with Medicaid section 1115 demonstrations are required to conduct evaluations that are 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). 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. When conducting analyses and developing the evaluation reports, every effort should be made to follow

the methodology outlined in the approved Evaluation Design. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

When applying 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.

CMS expects Interim and Summative Evaluation Reports to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: <u>https://www.medicaid.gov/medicaid/section-1115-</u> <u>demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-</u> <u>monitoring-evaluation-resources/index.html</u>. If the state needs technical assistance using this outline or developing the evaluation reports, the state should contact its demonstration team.

Intent of this Attachment

Title XIX of the Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's evaluation report submissions must provide comprehensive written presentations of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Attachment 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.

Required Core Components of Interim and Summative Evaluation Reports

The Interim and Summative Evaluation Reports present research and findings about the section 1115 demonstration. It is important that the reports 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. The evaluation reports 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.

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).

- 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 issue/s 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 description of the population groups impacted by the demonstration.
 - 4. 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.
 - 5. 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. Additionally, the state should explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable).

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

- 1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the goals of the demonstration align with the evaluation questions and hypotheses.
- 2. Address how the research questions / hypotheses of this demonstration promote the objectives of titles XIX and XXI.
- 3. 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.
- 4. 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.
- 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, (using references), meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An Interim Evaluation 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 Report.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used. The state also should report on, control for, and make 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, in sufficient detail so that another party could replicate the results. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

- 1. *Methodological Design* Whether the evaluation included an assessment of pre/post or post-only data, with or without comparison groups, etc.
- 2. *Target and Comparison Populations* Describe the target and comparison populations, describing inclusion and exclusion criteria.
- 3. *Evaluation Period* Describe the time periods for which data will be collected.
- 4. *Evaluation Measures* List the measures used to evaluate the demonstration and their respective measure stewards.
- 5. *Data Sources* Explain from where the data were obtained, and efforts to validate and clean the data.
- 6. *Analytic Methods* Identify specific statistical testing which was 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.
- **E.** Methodological Limitations This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.
- **F. Results** In this section, the state presents and uses the quantitative and qualitative data to demonstrate whether and to what degree the evaluation questions and hypotheses of the demonstration were addressed. The findings should visually depict the demonstration results, using tables, charts, and graphs, where appropriate. This section should include findings from the statistical tests conducted.
- **G. Conclusions** In this section, the state will present the conclusions about the evaluation results. Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically, the state should answer the following questions:
 - 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. If the state did not fully achieve its intended goals, why not?

- 3. What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?
- H. 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 interpretations 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.
- I. Lessons Learned and Recommendations This section of the evaluation report involves the transfer of knowledge. Specifically, it should include potential "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders. Recommendations for improvement can be just as significant as identifying current successful strategies. Based on the evaluation results, the state should address the following questions:
 - 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?

ATTACHMENT C SUD Implementation Plan

Connecticut Department of Social Services Implementation Plan

for

Substance Use Disorder Demonstration Waiver Pursuant to Section 1115 of the Social Security Act

Submitted to the U.S. Centers for Medicare and Medicaid Services Updated March 7, 2022

OVERVIEW

This Implementation Plan is submitted in conjunction with the Connecticut Department of Social Services (DSS) submission of a substance use disorder (SUD) demonstration waiver pursuant to Section 1115 of the Social Security Act. Connecticut is committed to providing a full continuum of care for people with opioid use disorder (OUD) and other SUDs and expanding access and improving outcomes in the most cost-effective manner possible. Consistent with the state's waiver application, except as otherwise specifically provided below or as required by federal law, all references in this Implementation Plan to Medicaid also apply to the state's Children's Health Insurance Program (CHIP).

Goals:

- 1. Increased rates of identification, initiation and engagement in treatment for OUD and other SUDs;
- 2. Increased adherence to and retention in treatment for OUD and other SUDs;
- 3. Reductions in overdose deaths, particularly those due to opioids;
- 4. Reduced utilization of emergency departments and inpatient hospital settings for OUD and other SUD 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 readmissions is preventable or medically inappropriate for OUD and other SUDs; and
- 6. Improved access to care for physical health conditions among beneficiaries with OUD or other SUDs.

Milestones:

- 1. Access to critical levels of care for OUD and other SUDs;
- 2. Widespread use of evidence-based, SUD-specific patient placement criteria;
- 3. Use of nationally recognized, evidence-based, SUD program standards to set residential treatment provider qualifications;
- 4. Sufficient provider capacity at each level of care, including medication assisted treatment (MAT);
- 5. Implementation of comprehensive treatment and prevention strategies to address opioid misuse and

OUD; and

6. Improved care coordination and transitions between levels of care.

Section I – Implementation Plan Milestone Completion

This section contains information detailing Connecticut's strategies for meeting the six milestones over the course of the Demonstration. Specifically, this section:

- 1. Includes a summary of how, to the extent applicable, Connecticut already meets each milestone, in whole or in part, and any actions needed to meet each milestone, including the persons or entities responsible for completing actions;
- 2. Describes the timelines and activities that Connecticut will undertake to achieve the milestones; and
- 3. Provides an overview of future plans to improve beneficiary access to SUD services and promote quality and safety standards

Milestones

1. Access to Critical Levels of Care for OUD and Other SUDs

Connecticut will improve access to OUD and SUD treatment services for Medicaid beneficiaries by offering a range of services at varying levels of intensity across a continuum of care because each type of treatment or level of care may be more or less effective depending on each beneficiary's individual clinical needs. To meet this milestone, Connecticut will provide coverage of the following services:

- Outpatient services;
- Intensive outpatient services;
- Medication-Assisted Treatment (MAT) (medications, as well as counseling and other services, with sufficient provider capacity to meet the needs of the Medicaid beneficiaries in the state);
- Intensive levels of care in residential and inpatient settings; and

• Medically supervised withdrawal management.

Below is a table that describes Connecticut's plans to meet Milestone 1, to improve access to SUD treatment services for Medicaid beneficiaries, including a variety of services at different levels of intensity across a continuum of care. This milestone will be met within 12 to 24 months of Demonstration approval.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current SUD treatment services covered by the state in each level of care. For services currently covered in the state plan, list the benefit category and page location; for services currently covered in a Demonstration, include the program name and Special Term and Condition number.	Provide an overview of planned SUD treatment services to be covered by the state in each level of care: indicate whether planned services will be added to the state plan or authorized through the 1115.	Provide a list of action items needed to be completed to meet milestone requirements, if any. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item.
Coverage of outpatient services	 Connecticut Medicaid covers SUD outpatient treatment services under the following sections of the Medicaid State Plan⁵: Outpatient hospital (Section 2.a of Attachment [Att.] 3.1-A, currently Att. 3.1-A Page 1 and Addendum [Add.] Page 1c to Att. 3.1-A) 	Connecticut plans to submit a SUD Medicaid State Plan Amendment (SPA) updating the State's standards to be consistent with the latest edition of the American Society of Addiction	The Department of Social Services (DSS) will submit a SPA in the rehabilitative services benefit category to update the State's

⁵ The CHIP State Plan substantively covers the same services listed here as covered by Medicaid, although they are reflected differently in the CHIP State Plan and EPSDT is a concept unique to federal Medicaid law that does not apply to CHIP.

Milestone	Current State	Future State	Summary of
Criteria			Actions Needed
	• FQHC (Section 2.c of Att. 3.1-A, currently Att. 3.1-	Medicine (ASAM).	standards to be
	A Page 1 and Add. Page 1d to Att. 3.1-A)		consistent with the
	• Physician services (Sec. 5 of Att. 3.1-A, currently		latest edition of
	Att. 3.1-A Page 2 and Add. Pages 2g and 3 to Att.		ASAM no later than
	3.1-A)		12 months following
	 Other licensed practitioner (OLP) Licensed 		Centers for Medicare
	Psychologist services (Sec. 6 of Att. 3.1-A,		and Medicaid
	currently Att. 3.1-A Page 3 and Add. Page 4b to		Services (CMS)
	Att. 3.1-A)		approval of the
	 OLP Licensed Clinical Social Worker services 		Demonstration (by
	(Sec. 6 of Att. 3.1-A, currently Att. 3.1-A Page 3		April 1, 2023).
	and Add. Page 4d to Att. 3.1-A)		
	 OLP Licensed Marital and Family Therapists 		
	services (Sec. 6 of Att. 3.1-A, currently Att. 3.1-A		
	Page 3 and Add. Pages 4d and 4d(i) to Att. 3.1-A)		
	OLP Licensed Professional Counselor Services		
	(Sec. 6 of Att. 3.1-A, currently Att. 3.1-A Page 3		
	and Add. Page 4e to Att. 3.1-A)		
	 OLP Licensed Alcohol and Drug Counselor 		
	Services (Sec. 6 of Att. 3.1-A, currently Att. 3.1-A		
	Page 3 and Add. Page 4e to Att. 3.1-A)		
	 OLP Nurse Practitioner Services, Certified 		
	Pediatric Nurse Practitioner Services, and Family		
	Nurse Practitioner Services (Secs. 6 and 23 of Att.		
	3.1-A, currently Att. 3.1-A Page 3 and Add. Pages		
	4c and 14 to Att. 3.1-A)		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Coverage of intensive outpatient services	 OLP Physician Assistants (Sec. 6 of Att. 3.1-A, currently Att. 3.1-A Page 3 and Add Page 4f to Att. 3.1-A) Clinic Free-standing clinic services (non-FQHC) Methadone Clinics or Chemical Maintenance Clinics (Sec. 9 of Att. 3.1-A, currently Att. 3.1-A Page 4 and Add. Page 7 to Att. 3.1-A) Rehabilitation Services Pursuant to EPSDT – Office-based off-site rehabilitation services (Sec. 13.d of Att. 3.1-A, currently Att. 3.1-A Page 6 and Supplement Page 2b to Add. Page 12 to Att. 3.1-A) Connecticut Medicaid covers SUD intensive outpatient treatment services, including partial hospitalization, under the following sections of the State Plan: Outpatient hospital (Section 2.a of Attachment [Att.] 3.1-A, currently Att. 3.1-A Page 1 and Add. Page 1 cto Att. 3.1-A FQHC (Section 2.c of Att. 3.1-A, currently Att. 3.1-A) Clinic Free-standing clinic services (non-FQHC) Behavioral Health Clinics/Mental Health and Substance Abuse Clinics (Sec. 9 of Att. 3.1-A, currently Att. 3.1-A, currently Att. 3.1-A) 	Connecticut plans to submit a SUD SPA updating the State's standards to be consistent with the latest edition of ASAM.	DSS will submit a Rehabilitative SPA to update the State's standards to be consistent with the latest edition of ASAM no later than 12 months following CMS approval of the Demonstration (by April 1, 2023).

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Coverage of MAT (medications as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the State)	OUD) and associated counseling/services under the following sections of the State Plan:	SUD SPA updating the State's standards to be consistent with the latest edition of ASAM.	DSS will submit a SPA in the rehabilitative services benefit category ("Rehabilitative SPA") to update the State's MAT standards for Non-OUD, as well as for services provided after the end-date of the 1905(a)(29) OUD MAT SPA to be consistent with the latest edition of ASAM no later than 12 months following CMS approval of the Demonstration (by April 1, 2023).

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Coverage of intensive levels of care in residential and inpatient settings	 Connecticut Medicaid does not cover residential SUD in a non-hospital setting. Connecticut Medicaid covers the following inpatient SUD treatment: Inpatient hospital services (Sec. 1 of Att. 3.1-A, currently Att. 3.1-A Page 1 and Add. Pages 1a and 1b to Att. 3.1-A) Inpatient hospital for individuals age 65 or older in institutions for mental diseases (Sec. 14 of Att. 3.1-A, currently Att. 3.1-A page 6) Inpatient psychiatric facility services for individuals under 22 years of age (Sec. 16 of Att. 3.1-A, currently Att. 3.1-A page 7) Connecticut reimburses providers outside of the Medicaid program using a Substance Abuse Prevention and Treatment (SAPT) block grant and State funds for residential programs. 	SUD SPA updating the State's standards to be consistent with the latest edition of ASAM and including residential SUD treatment for children and adults. Connecticut will reimburse SUD residential providers for children and adults in the Medicaid program in non-IMDs with the effective date of the SPA and for IMDs with the effective date of the	DSS will submit a Rehabilitative SPA to update the State's residential standards to be consistent with the latest edition of ASAM and to include coverage of residential SUD treatment no later than 12 months following CMS approval of the Demonstration (by April 1, 2023).
Coverage of medically supervised withdrawal management	 Connecticut Medicaid does not cover medically supervised withdrawal management in a non-hospital setting. Connecticut Medicaid covers the following detoxification: Inpatient detoxification in a general hospital setting (Inpatient hospital Services, Sec. 1 of Att. 3.1-A, currently Att. 3.1-A Page 1 and Add. Page 1 a to Att. 3.1-A) 	SUD SPA updating the State's standards to be consistent with the latest edition of ASAM and including coverage of medically supervised withdrawal management in a non-hospital setting.	DSS will submit a Rehabilitative SPA to update the State's standards to be consistent with the latest edition of ASAM and to include coverage of Medically supervised withdrawal

Milestone	Current State	Future State	Summary of
Criteria			Actions Needed
	detoxification under the following authorities:	outside of the Medicaid program using SAPT block grant and State funds for detoxification programs.	management in a non-hospital setting no later than 12 months following CMS approval of the Demonstration (by April 1, 2023).

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

Under this milestone, Connecticut will implement the latest edition of ASAM, which is evidence-based, SUD-specific patient placement criteria. To meet this milestone, Connecticut will ensure that:

- Providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools, linked to the ASAM Criteria; and
- Utilization management approaches are implemented to ensure that
 - (a) beneficiaries have access to SUD services at the appropriate level of care,
 - (b) interventions are appropriate for the diagnosis and level of care, and
 - (c) there is an independent process for reviewing placement in residential treatment settings.

Below, Connecticut identifies its plan to increase the use of ASAM's evidence-based, SUD-specific placement criteria to provide treatment that reflects diverse patient needs and evidence-based clinical guidelines. This table includes current and intended actions and associated timelines needed to meet Milestone 2 (*Use of evidence-based, SUD-specific patient placement criteria*). This milestone will be met within 12-24 months of Demonstration approval.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current state use of evidence-based, SUD-specific patient placement criteria and utilization management approach to ensure placement in appropriate level of care and receipt of services recommended for that level of care	Provide an overview of planned state implementation of requirement that providers use an evidence-based, SUD-specific patient placement criteria and use of utilization management to ensure placement in appropriate level of care and receipt of services	Specify a list of action items needed to be completed to meet milestone requirements. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item

		recommended for that level of care.	
Implementation of requirement that providers assess treatment needs based on SUD- specific, multi- dimensional assessment tools that reflect evidence-based clinical treatment guidelines	Connecticut providers are not required to utilize assessments that are directly tied to the ASAM criteria for treatment planning. DCF has cross-walked the GAIN (the current children's tool) to the ASAM placement criteria for children's assessment and treatment planning.	Connecticut will develop a universal training program for providers to assess treatment needs based on ASAM's multi- dimensional tools (or a tool cross-walked to ASAM criteria such as the GAIN for children) and to base treatment needs on those assessments. Connecticut will require all Medicaid SUD providers to sign an addendum to the Medicaid provider enrollment agreement that includes requirements for level of care (LOC) assessments using ASAM's most recent edition, consistent with provider training.	Department of Mental Health and Addiction (DMHAS)/Department of Children and Families (DCF) have statutory authority for SUD service provision. These agencies, or their designated contractor(s), will ensure that providers receive training necessary to implement the provider training portion of the Demonstration on behalf of DSS and the Medicaid program within 12 months of approval by April 1, 2023. Training would include utilization of State-approved provider assessment tools using, and/or cross-walked to the six dimensions of ASAM criteria, for treatment planning and implementation of most recent ASAM edition patient placement criteria and

			program standards.
			The Medicaid SPA (submitted by April 1, 2023) and related Medicaid provider manuals (completed by April 1, 2024) will establish the ASAM as requirements for providers to assess treatment needs and develop recommendations for placement in appropriate levels of care with the effective date of the Rehabilitative SPA compliant with the most recent edition of ASAM.
luculous sutation of a	Although Composition Madicaid's august		
	Although Connecticut Medicaid's current	Connecticut will ensure that	DMHAS/DCF have statutory
utilization		program standards are set for beneficiaries to have access to	authority for SUD service provision. These agencies
management approach such that	organization (ASO), which performs utilization management for all Medicaid BH services,	SUD services at the appropriate	
(a) beneficiaries	including SUD services, internally uses the latest		contractor(s), will work with
have access to		dimensions of care.	providers to ensure access
SUD services at	State's website is not consistent with that		for the Demonstration on
the appropriate	criteria. The state's non-Medicaid BH ASO,		behalf of DSS and the
level of care	which reviews residential placements, utilizes an older version of the ASAM placement criteria.	Connecticut will update contract language (BH ASO) to reflect requirements for utilization	Medicaid program within 12 months of Demonstration approval (by April 1, 2023). The DSS BH ASO will

		management using ASAM's most recent edition language consistent with provider training.	provide a website with a provider search function for Medicaid beneficiaries and providers at all LOCs (by April 1, 2023).
		Connecticut will use the most recent ASAM edition for utilization review. All website, provider information and internal documentation will be consistent with the latest ASAM edition.	DSS will direct the Medicaid BH ASO to use the most recent ASAM edition for utilization review and to update the website, provider information and internal documentation (by April 1, 2023).
Implementation of a utilization management approach such that (b) interventions are appropriate for the diagnosis and level of care	care, which is outside of the Medicaid system, utilizes an earlier version of ASAM for utilization	that providers' interventions are appropriate for the diagnosis and each ASAM LOC. All Medicaid websites, criteria, manuals, and provider	or their designated contractor(s), will work with providers to develop the program standards

	provision. These agencies,
	or their designated
	contractor(s), will ensure
	that providers are monitored
	and certified to provide the
	ASAM LOC for which the
	provider is enrolled in the
	Medicaid program within 24
	months of Demonstration
	approval (by April 1, 2024).
	appiovai (by April 1, 2024).
	With the effective date of the
	new SPA, DSS Provider
	enrollment standards will
	require certification by
	DMHAS/DCF (or their
	designated contractor(s))
	with an agreement also from
	DSS (or its designated
	contractor) to provide the
	ASAM LOC for which they
	are enrolled by April 1,
	2023. Provisional
	certification for no more than
	24 months will be granted to
	providers if they meet
	milestones for implementing
	the new requirements under
	the Demonstration by April
	1, 2024.

Implementation of	The current Medicaid BH ASO already uses the	Connecticut will use the most	DSS will direct the Medicaid
•			
a utilization	most recent ASAM edition for inpatient utilization		BH ASO to use the most
management	review.	utilization review of Medicaid	recent ASAM edition for
approach such that	DMHAS' ASO for the non-Medicaid Behavioral	inpatient and residential	utilization review, prior
(c) there is an	Health Recovery Program (BHRP) uses an older	placements. All website,	authorization, and to update
independent	edition of ASAM to review placements in non-	provider information and	the website, provider
process for	hospital residential treatment settings. The	internal documentation will be	information and internal
reviewing	residential placement criteria currently in use	consistent with the latest ASAM	documentation within 24
placement in	can be found at the following link:	edition.	months of Demonstration
residential	http://www.abhct.com/Customer-		approval by April 1, 2024.
treatment settings	Content/WWW/CMS/files/BHRP-		
	clinical/ABH_Clinical_Level_of_Care_Guidelines_2		
	<u>015.pdf</u>	Connecticut will update contract	
		language (BH ASO and	
		addendum to the Medicaid	
		provider enrollment agreement)	
		to reflect requirements for	
		utilization management and	
		LOC assessments using the	
		language in the most recent	
		ASAM edition, consistent with	
		provider training.	

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

Through this Demonstration, Connecticut will receive federal financial participation (FFP) for a continuum of SUD services, including services provided to Medicaid enrollees residing in residential treatment facilities that qualify as institutions for mental diseases (IMDs). To meet this milestone, Connecticut will ensure that the following criteria are met:

- Implementation of residential treatment provider qualifications (in licensure requirements, policy manuals, managed care contracts (in Connecticut, this reference refers to the Administrative Services Organization contracts), or other guidance) that meet the ASAM criteria or other nationally recognized, SUD-specific program standards regarding the types of services, hours of clinical care and credentials of staff for residential treatment settings;
- Implementation of a State process for reviewing residential treatment providers to assure compliance with these standards; and
- Implementation of a requirement that residential treatment facilities offer MAT on-site or facilitate access off site.

Below, Connecticut has outlined how it will incorporate nationally recognized, SUD-specific ASAM program standards into their provider qualifications for residential treatment facilities through their policy manuals and other guidance to meet Milestone 3 (*Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities*). This milestone will be met within 24 months of Demonstration approval.

Milestone Criteria	Current State	Future State	Summary of Actions
			Needed
Criteria for	Provide an overview of current provider	Provide an overview of	Specify a list of action
completion of	qualifications for residential treatment	planned use of nationally	items needed to be
milestone	facilities and how these compare to nationally	recognized SUD-specific	completed to meet
	recognized SUD-specific program standards,	program standards in	milestone requirements.
	e.g., the ASAM Criteria	improving provider	Include persons or entities
		qualifications for residential	responsible for completion
		treatment facilities.	of each action item.
			Include timeframe for
			completion of each action

			item
Implementation of residential treatment provider qualifications in licensure requirements, policy manuals, contracts, or other guidance. Qualification should 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	Connecticut Medicaid does not currently reimburse for SUD residential treatment for adults. Residential treatment is reimbursed by non- Medicaid SAPT block grant and State funds and includes ASAM 3.1, ASAM 3.5, ASAM 3.7 and ASAM 3.7D using the second edition of ASAM. The current standards can be found in Section 3 of the manual at the following linked website: http://www.abhct.com/Customer- Content/WWW/CMS/files/BHRP_Provider_Manual_ 2013.pdf Medicaid SUD treatment for children is reimbursed under EPSDT and roughly corresponds to an ASAM 3.5 LOC.	Connecticut plans to submit a SUD SPA updating the State's standards to be consistent with the latest edition of ASAM and including dresidential SUD treatment. Connecticut is currently conducting a public process for stakeholders to provide feedback on the types of services, hours of clinical care, and credentials of staff for residential treatment settings that will be Implemented under the Medicaid State Plan.	With the effective date of the SPA, DSS will update the Medicaid MMIS coding, rates, and billing guidance to support provider enrollment and billing under the new Medicaid Rehabilitative SPA (effective date of SPA). DSS, in conjunction with DMHAS and DCF, will update provider standards and certification developed by both State agencies within 18 months of Demonstration approval (by October 1, 2023). Other operational guidance will be updated by each State agency to support the latest edition of ASAM standards as needed to provide timely provider training in Milestone 2 (no later than 24 months after Demonstration approval

settings			or by April 1, 2024).
Implementation of a state process for reviewing residential treatment providers to ensure compliance with these standards	Currently SUD residential treatment providers are not enrolled in the Connecticut Medicaid program. All SUD residential providers are licensed by the Connecticut Department of Public Health (DPH). In addition: (1) SUD residential providers for children must also be licensed by DCF; and (2) SUD residential providers for adults that participate in BHRP must also be reviewed by DMHAS non-Medicaid BHRP ASO using criteria from the second edition of ASAM.	DMHAS/DCF have statutory authority for SUD service provision. These agencies, or their designated contractor(s), will ensure that providers are monitored and certified to provide the ASAM LOC for which the provider is enrolled in the Medicaid program.	Within 24 months of Demonstration approval, DSS provider enrollment standards will require certification by DMHAS/DCF (or their designated contractor(s)) with an agreement also from DSS (or its designated contractor) to provide the ASAM LOC for which they are enrolled: The monitoring of the providers will include both a review of the facility's infrastructure, as well as how the infrastructure is applied to ensure compliance with the new state standards consistent with the latest edition of ASAM. The monitoring will include initial certification, monitoring and recertification (by April 1, 2024).
Implementation of requirement that residential	5 1	None needed – Connecticut currently meets criteria.	None needed – Connecticut currently meets criteria.

treatment facilities	site or facilitate access off-site. All but one	
treatment facilities offer MAT onsite or facilitate access off-site	site or facilitate access off-site. All but one residential treatment provider already offers multiple versions of MAT on-site or facilitates access off-site. The one facility in question does not accept residents receiving methadone, but accepts placement of residents using Buprenorphine. The State has provided education to this facility and it will be accepting methadone residents in the future consistent with ASAM criteria and the	
	Demonstration requirements.	

4. Sufficient Provider Capacity at Critical Levels of Care Including for Medication Assisted Treatment for OUD

To meet this milestone, Connecticut will complete an assessment of the availability of providers enrolled in Medicaid and accepting new patients in the critical levels of care listed in Milestone 1. This assessment will determine the availability of treatment for Medicaid beneficiaries in each of these LOCs, as well as availability of MAT and medically supervised withdrawal management, throughout the State. This assessment will identify gaps in availability of services for beneficiaries in the critical LOCs and develop plans for enhancement of capacity based on assessments of provider availability

The table below summarizes the current and future actions, including associated timelines, to meet Milestone 4 (*Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment*). This milestone will be met within 24 months of Demonstration approval. *Note: It is necessary to ensure the complete implementation of the new service array in Medicaid prior to the capacity assessment being conducted*.

Milestone Criteria Current State	Future State	Summary of Actions Needed
completion of milestonecapacities throughout the state to provide SUD treatment at each of the critical levels of care listed in Milestone 1.plan 	lanned improvements to rovider availability and apacity intended to improve dedicaid beneficiary access to treatment throughout the state at each of the critical evels of care listed in dilestone 1.	Specify a list of action items needed to be completed to meet milestone requirements. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item

The anticipated penetration rate and geographic distributions of providers at each LOC is noted where available.

	I	1-	
Completion of assessment of the availability of providers enrolled in Medicaid and accepting new patients in the following critical levels of care throughout the state including those that offer MAT:	For non-residential levels of care, the state's behavioral health ASO currently tracks ambulatory/outpatient providers level of care and capacity. Except for situations such as fixed prescribing limits, the ASO does not otherwise track specific slots for open-access ambulatory levels of care. In the report entitled " <i>Connecticut Opioid and</i> <i>Other Substance Use Disorder Treatment and</i> <i>Recovery Service Capacity and Infrastructure</i> <i>Planning Support Act Semiannual Report</i> ," dated September 30, 2020, Connecticut reported on the capacity of the Medicaid SUD	Connecticut will examine the potential to enhance access monitoring reporting under the Demonstration. This initiative will leverage the DMHAS bed monitoring and the BH ASO bed monitoring for ongoing access monitoring and recruitment and enrollment of new facilities.	The Medicaid BH ASO in conjunction with DMHAS, or its designee, will complete an assessment of the availability of Medicaid SUD providers accepting new patients at ambulatory ASAM levels of care including MAT within 12 months of Demonstration approval (by April 1, 2023).
Outpatient Services; Intensive Outpatient Services; Medication Assisted Treatment (medications as well as counseling and other	system.		conjunction with DMHAS, or its designee, will complete an assessment of the availability of Medicaid SUD providers accepting new patients at residential ASAM levels of care within 24 months of Demonstration approval once all residential providers are enrolled in Medicaid and fully meet the latest edition of ASAM criteria (by April 1, 2024).

services);	prescribers of medications related to SUD,	
	including MAT for OUD and AUD).	
Intensive Care	MAT Providers	
in Residential		
and Inpatient	Cines different data as more ware ward to	
Settings;	Since different data sources were used to	
oottings,	determine providers for prescription drugs	
	(pharmacy claims) and all other service	
	categories (medical and behavioral health	
Medically	claims), there is substantial overlap between	
Supervised	the providers listed in the "prescription drugs"	
Withdrawal	category and the "other" service categories.	
Management.	The total number of State MAT providers	
	during dates of service from October 1, 2019	
	through December 31, 2019 was 711; of	
	which, 704 appeared as prescribers of MAT in	
	the pharmacy claims data. For other service	
	categories, providers appeared on medical	
	and behavioral health claims largely for	
	distributing methadone and, to a smaller	
	extent, non-pharmaceutical buprenorphine (i.e.	
	injectable). The service categories with the	
	most MAT providers, other than prescription	
	drugs, were physician services (162),	
	outpatient hospital services including ED	
	services (157), clinic services (146), and home	
	health services (129).	
l		

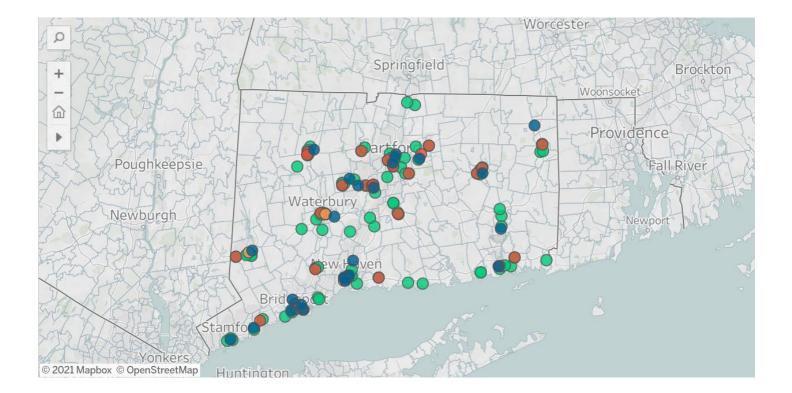
Overall, 42,322 members with SUD received care in at least one of the service categories outlined in the guidelines. The largest number of members with SUD (23,058) received care at a clinic, which includes FQHCs and methadone clinics.	
Many members also received physician services (14,525) and outpatient hospital services, including ED services (10,718).	
DMHAS maintains a real-time website listing the open residential and inpatient SUD treatment beds for the public and providers at <u>https://www.ctaddictionservices.com/</u> . This current online capacity system is working with real-time access.	
DMHAS' BHRP ASO also maintains residential data that tracks utilization and sends weekly updates (by provider by LOC by site) – on average capacity and bed count. This information calculates the rolling average capacity by fiscal year and is provided to DMHAS weekly.	

DDaP is the DMHAS data warehouse and is	
used to analyze actual utilization data. The	
DMHAS Evaluation Quality Metrics	
Improvement Division manages DDaP data.	
The Medicaid BH ASO maintains a search	
capacity for outpatient SUD treatment	
availability including an accessibility map for	
MAT. That search capacity and map can be	
found at the following link:	
https://public.tableau.com/views/CTBHPMedic	
aidMATProviderMap/TreatmentProviders?:em	
<u>bed=y&:display_count=yes&:showVizHome=n</u>	
<u>o</u>	
The Medicaid BH ASO SUD accessibility maps	
(current as of 6/16/2021) can be found below	
this chart. At this time, the search capacity and	
maps do not include an indicator of which	
providers are accepting new patients and must	
be used in combination with the DMHAS	
website.	

Sample Connecticut Medicaid BH ASO accessibility maps and search function (current as of June 16, 2021) – Search for a Behavioral Health Medicaid provider offering MAT services by name, city, or medication (http://www.ctbhp.com/medication-assisted-treatment.html)

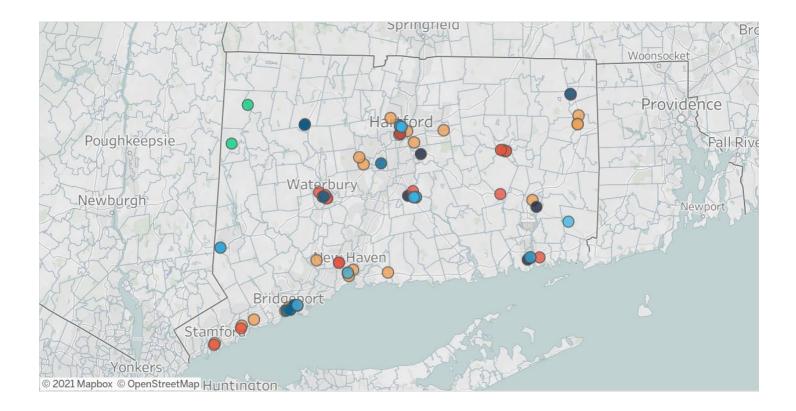
Select to Highlight (dots may be overlaid)

- Methadone Clinic
- Partial Hospital/IOP with Housing
- Intensive Outpatient (IOP)
- Behavioral Health Outpatient
- Partial Hospitalization (PHP)



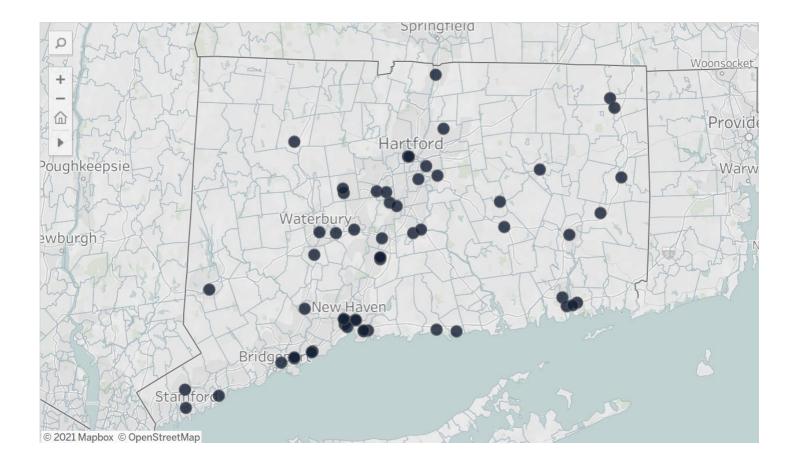
Search for other treatment services that support substance use recovery Select to Highlight

- Freestanding or State Hospital Detoxification
- SA 3.7 Intensive Residential Co-Occurring (30 to 45 days)
- SA 3.7 Intensive Residential (14 to 28 days)
- SA 3.5 Women's & Children's Programs (3 to 6 Months)
- SA 3.5 Intermediate Treatment (1 to 3 Months)
- SA 3.3 Long-Term Care (4 to 6 Months)
- SA 3.1R Halfway House (3 to 4 months)
- Walk-In Access Center



Medical data is provided and maintained with accuracy/integrity under the responsibility of the Medical ASO

Search for a MEDICAL Medicaid provider offering MAT services.



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

To meet this milestone, Connecticut will ensure that the following criteria are met:

- Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug misuse;
- Expanded coverage of and access to naloxone for overdose reversal; and
- Implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs.

Connecticut has detailed the strategies it has in place currently to address prescription drug misuse and opioid use disorders as well as plans to implement additional strategies. Attachment A describes the State's plans for improving its SUD health IT infrastructure to improve its prescription drug monitoring program (PDMP).

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current treatment and prevention strategies to reduce opioid abuse and OUD in the state.	Provide an overview of planned strategies to prevent and treat opioid abuse and OUD.	Specify a list of action items needed to be completed to meet milestone requirements as detailed above. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item
Implementation of opioid prescribing guidelines along with other	To address the opioid and prescription medication crisis, DPH has implemented prescribing guidelines to prevent opioid over-use through a number of updates to		None needed – Connecticut currently meets criteria.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
interventions to	Connecticut policy and law regulating the		
prevent opioid	prescribing of controlled substances and		
abuse	opioid medications. ⁶ Connecticut has		
	also collaborated with other State		
	agencies, legislators, and various		
	professional groups to improve the		
	Connecticut Prescription Monitoring and		
	Reporting System (CPMRS) – the		
	State's PDMP.		
	Effective October 1, 2010, Compositions		
	Effective October 1, 2019, Connecticut		
	amended the Medicaid State Plan to		
	reflect new drug utilization review		
	provisions required in federal law (Section 1004 of the Substance Use-		
	Disorder Prevention that Promotes		
	Opioid Recovery and Treatment for		
	Patients and Communities Act		
	[SUPPORT Act; P.L. 115-271]). These		
	provisions are designed to reduce		
	opioid-related overprescribing and		
	abuse. The required provisions include		
	the following: 136 separate opioid		

⁶ Rodrick Marriott, PharmD, Director, Department of Consumer Protection Drug Control Division, Connecticut Laws Impacting Prescribing and Practice, 2019, <u>https://portal.ct.gov/-/media/DCP/drug_control/PMP/Educational-Materials/Prescribing-Laws-2019-CM.pdf</u>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	prescription claim reviews at the point of sale as well as retrospective reviews, monitoring and management of antipsychotic medication in children, and identification of processes to detect fraud		
	and abuse. See a more complete listing below this chart.		
Expanded	Connecticut has taken a number of steps	None needed – Connecticut	None needed – Connecticut
coverage of, and	over the past eight years to make	currently meets criteria.	currently meets criteria.
access to,	naloxone more widely available. State		
naloxone for	legislation was first introduced in 2011 in		
overdose	the State's General Assembly and some		
reversal	of the subsequent legislative sessions		
	included new state legislation that has		
	made naloxone more accessible over		
	the years. A "Good Samaritan" law		
	passed in 2011 protects people, who call		
	911 seeking emergency medical		
	services for an overdose, from arrest for		
	possession of drugs/paraphernalia.		
	Legislation enacted in 2012, which		
	allowed prescribers (physicians,		
	surgeons, physician assistants,		
	advanced practice registered nurses,		
	dentists, and podiatrists) to prescribe,		
	dispense, or administer naloxone to any		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	person to prevent or treat a drug		
	overdose, protects the prescriber from		
	civil liability and criminal prosecution.		
	Protection from civil liability and criminal		
	prosecution was extended to the person		
	administering the naloxone in response		
	to an overdose in 2014. Legislation		
	enacted in 2015 allows pharmacists,		
	who have been trained and certified, to		
	prescribe and dispense naloxone directly		
	to customers requesting it. Most		
	recently, another State law (Public Act		
	18-166) allows prescribers to develop		
	agreements with organizations wishing		
	to train and distribute naloxone. This		
	legislation established new reporting		
	requirements, established a framework		
	for expanding distribution and availability		
	of naloxone, enacted limitations on		
	prescribing controlled substances, and		
	commissioned a feasibility study for		
	opioid intervention courts. All of these		
	changes have supported efforts to make		
	naloxone widely available.		
	In addition, Connecticut has established		
	other initiatives addressing OUD,		
	including expanding availability of		
	naloxone as outlined in the State's		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
and improve functionality of prescription drug monitoring programs	CPMRS, the State's PDMP, by prescribers in 2015, with additional provisions added in 2016. CPMRS is a tool to track the dispensing of controlled prescription drugs to patients. CPMRS is designed to monitor information for suspected misuse or diversion (i.e., channeling drugs into illegal use),	Medicaid Implementation Advanced Planning Document (IAPD) in 2019, 31,124 practitioners have controlled substance registrations, with some practitioners having more than one registration. CPMRS data have been integrated with 6,868 EHRs,	Needed See Attachment A
	critical information regarding a patient's controlled substance prescription history.	 including three major health systems. This initiative will allow the State to meet the following objectives: Further reduce the number of individuals who "doctor shop;" 	

Milestone Criteria	Current State		Future State	Summary of Actions Needed
	Since implementation, the use of CPMRS has grown. In 2018, CPMRS reported 1.9 million annual requests from law enforcement, pharmacists, and prescribers. This is nearly double the annual law enforcement, pharmacist, and prescriber requests from 2015 when there were one million requests. CPMRS has also documented a drop in Schedules IV and V controlled substances over time. Consistent with the overall data, the number of Medicaid- reimbursed opioid prescriptions have dropped, as well as Medicaid's percentage of payments for opioids dispensed.	•	Provide health care providers critical information regarding a patient's controlled substance prescription history and expand the availability of other data sources to support clinical decision making; Support clinician interventions for patients exhibiting high-risk behaviors; and Assist providers in achieving the medication reconciliation meaningful use objective and measure. ⁷	
	practitioners review a patient's controlled substance prescription history prior to prescribing controlled substances. The law also mandated that pharmacists	int pro po ca CF	additional goal of this egration initiative is to explore oviding as many avenues as ssible for an authorized health re provider to access the PMRS, including integrated cess through Health Information	

⁷ Stage 3 of meaningful use consolidates medication reconciliation into the HIE objective. The objective requires that eligible professionals provide a summary of the care record when transitioning or referring a patient to another setting of care, receive or retrieve a summary of care record upon the receipt of a transition or referral or upon the first encounter with a new patient, and incorporate summary of care information from other providers into their EHR using the functions of Certified EHR Technology. Providers must attest to all three measures and must meet the threshold for at least two measures to meet the objective.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	to continue to leverage opportunities described in State Medicaid Director Letter (SMDL) 16-003 to help professionals and hospitals eligible for the Medicaid Promoting Interoperability Program, formerly known as the Medicaid Electronic Health Record (EHR) Incentive Program connect to other Medicaid providers through the integration of CPMRS into EHRs and pharmacy dispensing systems. All hospitals and pharmacies now have the ability to have CPMRS integrated into their EHRs and pharmacy management systems.	Exchanges (HIEs).	

Connecticut Laws Impacting Prescribing and Practice

RODRICK MARRIOTT, PHARMD, Director, Department of Consumer Protection, Drug Control Division

There have been a number of updates to Connecticut law in past years that have an impact on the prescribing community, especially in regards to controlled substances and opioid medications. All of the changes have been small steps to help combat the opioid and prescription medication crisis. The changes for practitioners were made keeping in mind the effect they may have on their day to day work.

We have worked with sister agencies, legislators, and different professional groups to ensure we're taking thoughtful steps forward, and improving the Connecticut Prescription Monitoring and Reporting System (CPMRS), sometimes known as the Prescription Drug Monitoring Program (PDMP). Here are some of the changes:

2015

 Physicians are required to take continuing education courses in risk management, substance prescriit



risk management, in controlled substance prescribing, and pain management.

- Prescribers are required to review a patient's record on the CPMRS before prescribing any schedule II-V controlled substance meant to last more than 72 hours.
- Physicians must review patient records once every 90 days for a controlled substance prescription meant



for on-going treatment.

2016

In a major change, the law mandates a 7-day supply limit on opioid prescriptions for first time outpatient use. The law maintains professional judgment of the prescribing practitioner to prescribe more than a 7-day supply for on-going use when needed.





- The law requires education for patients under 18 and their guardian regarding the risks of addiction and overdose associated with opioids, and the dangers of combining them with alcohol, benzodiazepines, and other depressants. Patients should also understand the reason for the prescription.
- Also in 2016, practitioners were allowed to delegate an authorized agent to search the CPMRS.
- Under this law, patient records now only need to be reviewed once per year for on-going prescriptions that are Schedule V controlled substances. All other schedules remain at the 90-day level.

2017

 The number of days an opioid can be prescribed on a first visit is limited to five (5) days for patients who are minors.



 The law expands the educational requirement in the 2016 law update to include adults.



Patients are now allowed to opt-out of being prescribed opioids by filling out a voluntary nonopioid directive form.

2018

- Prescribers are no longer allowed to prescribe controlled substances to themselves or their family members, except in cases of emergency.
- This law expands the ability of telehealth professionals (practitioners who may not see you in person) to

prescribe Schedule II and III controlled substances in certain circumstances.



The law requires that prescribers begin to use electronic prescribing for controlled substance prescriptions if they haven't already, unless there is an emergency, or the proper technology is not available.

We look forward to making more improvements and updates to the systems we use to ensure public health and safety in conjunction with all of our great partners. We know that we always have more work to do, but numbers in recent years are encouraging. Opioid prescriptions are on a steady decline, more pharmacists are able to prescribe naloxone, and residents are using drug drop boxes in record numbers.

At the Drug Control Division, we always welcome questions, concerns, or ideas from the practitioners we work with. You can get in touch with us most easily by emailing dcp.drugcontrol@ct.gov.

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https://portal.ct.gov/-/media/DCP/drug_control/PMP/Educational-Materials/Prescribing-Laws-2019-CM.pdf?la=en

6. Improved Care Coordination and Transitions between Levels of Care

Connecticut will implement policies to ensure residential and inpatient facilities link beneficiaries, especially those with OUD and other SUDs, with community-based services and supports following stays in these facilities. The table below outlines Connecticut's current procedures for care coordination and transitions between LOCs to ensure seamless transitions of care and collaboration between services, including:

- Current content of specific policies to ensure these procedures;
- Specific plans to help beneficiaries attain or maintain a sufficient level of functioning outside of residential or inpatient facilities; and
- Current policies or plans to improve care coordination for co-occurring physical and mental health conditions.

Milestone Criteria	Current State	Future State	Summary of Actions
			Needed
Implementation	Provide an overview of current care	Provide an overview of	Specify a list of action
of policies to	coordination services and transition services	planned improvements	items needed to be
ensure	across levels of care.	to care coordination	completed to meet
residential and		services and transition	milestone requirements.
inpatient facilities		services across levels	Include persons or
link beneficiaries		of care	entities responsible for
with			completion of each action
community-base			item. Include
d services and			
supports			timeframe for completion
following stays in			of each action item
these facilities.			

This milestone will be met within 12 to 24 months of Demonstration approval.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Additional policies to ensure coordination of care for co-occurring	Connecticut has multiple interventions for coordinating the care of individuals with SUD and transitioning them between LOCs, including, but not limited to, facility credentialing, discharge planning requirements, and care management initiatives at DSS, DCF and DMHAS. These include, but are not limited to: Discharge planning; Referral and transition requirements; and Cross-departmental care management initiatives.	Under the Demonstration, DSS, DCF and DMHAS will create a clear delineation of responsibility for improved coordination and transitions between LOCs to ensure that individuals receive services and supports following stays in facilities and are retained in care; this includes efforts to align activities between	-
	 Medicaid behavioral health homes pursuant to section 1945 of the Social Security Act. Non-Medicaid DMHAS intensive case management (regions 1, 2, 4 and 5) for HUSKY D Medicaid beneficiaries. Case management support priority is given to 		enhance and improve the likelihood of engagement in treatment.

Milestone Criteria	Current State	Future State	Summary of Actions
	 those with a recent inpatient treatment for BH disorders with a focus on SUD diagnoses. Specific care management initiatives include an opioid antagonist treatment protocol. The model also utilizes a recovery specialist who works with the individual in the community to assist them in moving through the recovery continuum. Non-Medicaid DMHAS Region 3 intensive case management under the Eastern Region Service Center (ERSC). This collaborative effort between MH and SUD agencies offers person-centered care and develops recovery plans with the consumer to facilitate employment, independent living, housing, and use of social, 12 step and other community supports. 		Needed Within 12 months of Demonstration approval, DSS, DMHAS, and DCF will review all of the existing care management models reimbursed via State dollars, Medicaid administrative dollars and Medicaid fee-for-service payments across the State and ensure care management for the SUD population includes a strong transition management component between LOCs by April 1, 2023.
	 Medicaid Person-Centered Medical Home Plus (PCMH+) benefit. This Medicaid State Plan benefit is an integrated care program under section 1905(a)(30) of the Social Security Act that includes primary care case management services (PCCM) as defined in section 1905(t) and offers enhanced care coordination activities in several key areas, including integrating primary care and BH care, and promoting linkages to community supports, services and natural support systems. PCMH+ provider performance is 		Within 12 months, DSS will, based on the budget analysis, determine if the target population in the TCM SPA can be expanded to include SUD- only (i.e., TCM co-occurring

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	measured using various quality measures		SUD versus SUD-only) by
	and providers are encouraged to facilitate		April 1, 2023.
	improvement in transitions of care.		
	6. Connecticut Behavioral Health Partnership		
	Intensive Care Management (ICM) by the		
	Medicaid program's BH ASO, which is a		
	Medicaid administrative service.		
	7. Intensive Care Coordination (ICC) for		
	children in Child Welfare (CW) and		
	non-system-involved children by DCF's		
	contractor. This Integrated Family Care and		
	Support (IFCS) model engages families and		
	connects them to traditional and		
	non-traditional resources and services in		
	their community. The model also includes a		
	peer specialist and service delivery is		
	coordinated through family team meetings		
	(eight care coordinators who can serve CW		
	families and psychiatric residential		
	treatment facility transitions directly [staff		
	ratio 1:8-10]).		
	8. State-funded, non-Medicaid routine care		
	coordination for children (10 providers		
	including 75 care coordinators) –		
	wraparound process (staff ratio 1:10-12),		
	provided by DCF and its contractor.		
	9. Intensive family care including case		
	management by DCF and its contractor		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	 (unsubstantiated families at risk [staff ratio 1:20-25}) 10. Intensive Care Management (ICM) by the Medicaid program's medical ASO, which is a Medicaid administrative service. This program includes outreach to providers as well as direct member engagement. Primary care providers are notified when patients are filling high-dose opioid prescriptions and are provided an opioid utilization report. The ICM team conducts monthly outreach to members attributed to non-PCMH practices who have filled high-dose opioid prescriptions. Members are offered MAT or other SUD treatment. The model also uses community health workers if community resource needs are identified. 		

Section II – Implementation Plan Administration

Please provide the contact information for the state's point of contact for the Implementation plan.

Name and Title: William Halsey, Director of Integrated Care, Division of Health Services, Department of Social Services Telephone Number: 860-424-5077 Email Address: <u>William.Halsey@ct.gov</u>

Section III – Implementation Plan Relevant Documents

Please provide any additional documentation or information that the state deems relevant to successful execution of the implementation plan.

Attachment A: Template for Substance Use Disorder Health Information Technology Plan

Attachment A Section I.

As a component of Milestone 5, Implementation of Strategies to Increase Utilization and Improve Functionality of PDMPs, in SMDL 17-003, states with approved Section 1115 Substance Use Disorder (SUD) demonstrations are generally required to submit a SUD Health Information Technology (IT) Plan as described in the Special Terms and Conditions (STCs) for these demonstrations within 90 days of demonstration approval. The SUD Health IT Plan will be a section within the state's SUD Implementation Plan Protocol and, as such, the state may not claim federal financial participation for services provided in Institute for Mental Disease until the SUD Health IT Plan has been approved by CMS.

In the event that the state believes it has already made sufficient progress with regards to the health IT programmatic goals described in the STCs (i.e., PDMP functionalities, PDMP query capabilities, supporting prescribing clinicians with

using and checking the PDMPs, and master patient index and identity management), it must provide an assurance to that effect via the assessment and plan below (see Table 1, "Current State").

SUD Demonstration Milestone 5.0, Specification 3: Implementation of Strategies to Increase Utilization and Improve Functionality of PDMP.

The specific milestones to be achieved by developing and implementing a SUD Health IT Plan include:

- Enhancing the health IT functionality to support PDMP interoperability.
- Enhancing and/or supporting clinicians in their usage of the State's PDMP.

The State should provide CMS with an analysis of the current status of its health IT infrastructure/"ecosystem" to assess its readiness to support PDMP interoperability. Once completed, the analysis will serve as the basis for the health IT functionalities to be addressed over the course of the demonstration — or the assurance described above.

The SUD Health IT Plan should detail the current and planned future state for each functionality/capability/support — and specific actions and a timeline to be completed over the course of the demonstration — to address needed enhancements. In addition to completing the summary table below, the State may provide additional information for each Health IT/PDMP milestone criteria to further describe its plan.

Table 1. State Health IT/PDMP Assessment and Plan

Milestone Criteria	Current State	Future State	Summary of Actions Needed
 5. Implementation of comprehensive treatment and prevention strategies to address Opioid Abuse and Opioid Use Disorder, that is: Enhance the State's health IT functionality to support its PDMP. Enhance and/or support clinicians in their usage of the State's PDMP. 	Provide an overview of current PDMP capabilities, health IT functionalities to support the PDMP and supports to enhance clinicians' use of the state's health IT functionality to achieve the goals of the PDMP.	Provide an overview of plans for enhancing the State's PDMP, related enhancements to its health IT functionalities and related enhancements to support clinicians' use of the health IT functionality to achieve the goals of the PDMP.	Specify a list of action items needed to be completed to meet the Health Information Technology (HIT)/PDMP milestones identified in the first column. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item
PDMP Functionalities	-	_	-
Enhanced interstate data sharing in order to better track patient specific prescription data	Connecticut's PDMP, the Connecticut Prescription Monitoring and Reporting System (CPMRS), participates in Prescription Monitoring Program Interconnect (PMPI). The system allows a user to search PDMPs in other states.	Connecticut will continue to grant access to PDMP users from other states via the PMPi platform. This will depend on each state's ability to share data. Connecticut will continue to explore expanding connectivity to states not currently exchanging with CPMRS, will participate in NESCSO SUPPORT Act planning process. Connecticut has begun	As data sharing is dependent on other states (including necessary changes to state law), there are no specific actions that can be listed here.

	 Currently there are 45 active and pending participants. Figure 1 illustrates that Connecticut has activated interstate data sharing with 40 states, in addition to Puerto Rico and Washington D.C., and includes all states bordering Connecticut and the northeast region. The CPMRS has not connected with all participants due to several factors, with the most common barrier being: A state is focusing on connecting with their border states first. A state is currently transitioning to a new PDMP system. A state has prioritized other PDMP projects over interstate connectivity. 	to use RxCheck hub to support interstate exchanges. Connecticut would like to continue to increase the number and value of the interstate data sharing agreements with other states. The proposed contract resources and existing administrative technician will work to improve the interstate data sharing relationships, as well as seek out additional state agreements to expand the value of the PDMP for Connecticut-covered providers. This activity will improve the comprehensiveness and accuracy of every PDMP query made by covered providers by ensuring that medication history located in other state PDMPs can be considered when consulting Connecticut's PDMP.	
Enhanced "ease of use" for prescribers and other State and federal stakeholders	Connecticut has been working diligently to encourage and facilitate integration of the CPMRS into EHRs. This integration puts the CPMRS data directly into the workflow of health care professionals,	Connecticut plans to continue to leverage opportunities described in SMDL 16-003 to help professionals and hospitals eligible for Medicaid EHR Incentive Payments connect to other Medicaid providers through the integration of CPMRS into EHRs and pharmacy dispensing systems. Hospitals	The Connecticut Department of Consumer Protection (DCP), the PDMP vendor (Appriss Health), and DSS, as the administrator of the EHR Incentive Program, will

bypassing multiple password	and pharmacies may request to have	continue to onboard new
requirements and the need to	CPMRS integrated into their EHRs and	EHR and pharmacy
exit their EHR to access the	pharmacy management systems.	dispensing vendors.
CPMRS from a separate web		
portal.	Effective January 1, 2021, dispensation	
	information for insulin drugs, glucagon	
As noted in the SUPPORT Act	drugs, diabetes devices, diabetic	
IAPD, CPMRS data have been	ketoacidosis devices, gabapentin, and	
integrated with some EHRs,	naloxone are required to be uploaded	
including three major health	into the CPMRS. All listed prescriptions	
systems. Connecticut is also	will be available on patient reports	
working on the integration of the	except for naloxone. Only CPMRS	
PDMP into the HIE, which is	admin will have access to naloxone	
seen as a more sustainable	data for the purpose of aggregate	
option.	population analytics that will help to	
	inform public policy.	
	The Connecticut Prescription Monitoring	
	Program (PMP) announced a statewide	
	initiative to integrate the CPMRS into	
	approved EHR/PMS using Appriss Health's PMP Gateway service in 2021. The	
	integration will eliminate the need for	
	providers to navigate to the CPMRS	
	website, log in, and enter their patient's	
	information. Instead, the EHR/PMS will	
	automatically initiate a patient query, which	
	will return the patient's controlled	
	substance prescription records directly	<u> </u>

		 within the clinical workflow inside the EHR/PMS. Access PMP data at the point-of-care Streamline searches 	
		Increase utilization of the CPMRS	
		 Access to PMP data and NarxCare analytics within the workflow 	
Enhanced connectivity	Leveraging the HIE	DCP has been working with Connecticut's	DCP, in collaboration with
between the State's	infrastructure would potentially	Office of Health Strategy (OHS) for the	OHS and DSS, will
PDMP and any	allow for the most efficient	purpose of integrating the CPMRS into the	continue to link the
statewide, regional or	pathway for practitioners and	HIE. The Health Information Exchange	CPMRS with the HIE
local HIE	dispensers to access a	(HIE) is working with our software vendor	consistent with the IAPD.
	complete patient profile that	to integrate the Connecticut Prescription	
	includes their controlled	Monitoring and Reporting System	
	substance history.	(CPMRS) data. The HIE is still in its	
		infancy in Connecticut and they are	
	PDMP Activities	working through the technical	
		specifications to ensure that the data	
	In 2018, Congress passed the	shared is appropriate and auditable to	
	SUPPORT Act, which includes	ensure compliance with regulations.	
	important health reforms to combat the opioid crisis by	The CPMRS can now be accessed	
	advancing treatment and	through approved electronic health	
	recovery initiatives, improving	records (EHR) and pharmacy	
	prevention, protecting	management systems (PMS) where	
	communities and more.	PDMP data and NarxCare analytics will	
	In December 2019, DSS	be delivered directly into practitioner	
	submitted a new IAPD to CMS,	workflow. The Connecticut Prescription	

Medicaid Management	Monitoring Program (PMP) announced a	
Information System Support	statewide initiative to integrate the	
<i>Act</i> , to request 100% federal	CPMRS into approved EHR/PMS using	
funds available under Section	Appriss Health's PMP Gateway service	
5042 of the SUPPORT Act. The	in 2021. For updated accessibility	
IAPD application was	statistics, see Table 1 and Table 2.	
	Statistics, see Table 1 and Table 2.	
subsequently approved in	The SUDDODT Ast and the LUT LADDs	
February of 2020. In July 2020,	The SUPPORT Act and the HIT IAPDs	
DSS submitted an updated HIT	include activities intended to expand the	
IAPD that included activities	capacity of the CPMRS by continuing to	
related to PDMP HIE	connect health systems and providers and	
connectivity.	by integrating CPMRS into EHRs. The	
	work proposed within the IAPDs will	
	continue the existing work of adding	
	connections and integrating into additional	
	EHRs and initiate some implementation	
	activities as well as planning for areas	
	where there are gaps between the current	
	PDMP and the definition of a "qualified"	
	PDMP, pursuant to the SUPPORT Act.	
	Connectivity and integration to the	
	statewide HIE ("Connie") is strategically	
	seen as a preferred solution for provider	
	workflow integration. For EHR integrations,	
	the HIE will connect to Appriss Health's	
	PDMP gateway product, to the RxCheck	
	hub or both. The HIE connection will	
	facilitate a bi-directional data feed between	
	the HIE and PDMP. The trigger for the	
[

		query will occur during the prescribing workflow and can be automated. The diagram after this chart (Figure 2) illustrates the basic connectivity architecture with the HIE available for	
		connections to the PDMP through the	
Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns ⁸	CPMRS data informs planning and decision making such as identification of geographical hot spots for prescribed opioids and other controlled substances, prescriber outreach and relationships between reported prescription drug use and overdose deaths. In 2016, the CPMRS introduced automated clinical notifications for prescribers and dispensers to assist them with timely information about patients they are treating. In 2018, the CPMRS added the "prescriber report," which provides prescribers with individual	Appriss Health hub. Connecticut will develop additional analytical tools to address limitations in the current system and correlate long-term opioid use directly to clinician prescribing patterns. Connecticut has recently purchased the "NarxCare Enterprise"™ platform via a federal grant. NarxCare provides a comprehensive tool to assess narcotic overdose and diversion risk. NarxCare aggregates and analyzes controlled substance prescription information from providers and pharmacies, and presents interactive, visual representations of that information as well as advanced analytic insights, complex risk scores and more features to aid physicians, pharmacists	Connecticut is considering purchasing another new analytical tool from Appriss Health to: • improve the ability to monitor all pharmacy and dispensing practitioners for uploading compliance. • identify those practitioners and prescribers who are not compliant with the lookup mandate or other aspects of the law. DCP and/or DSS will
	controlled substance prescribing	and care teams to increase patient safety	evaluate the feasibility of

⁸Shah 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. (See also "Use of PDMP" #2 below.)

Facilitate the State's ability to properly match	Integrated Eligibility System	OHS and Connie	DCP, OHS and DSS will work to identify
Current and Future PD			
	practitioners for uploading compliance.		
	pharmacy and dispensing		
	module from Appriss Health to improve the ability to monitor all		
	attempting to purchase a		
	Connecticut is currently		
	non-resident pharmacies.		
	dispensing practitioners and		
	compliance with uploading for		
	have the tools to determine		
	Connecticut's PDMP does not		
	Community Support Program (CSP) registrants in CPMRS.		
	mandatory registration of all		
	with the enforcement of the		
	users and allows reports to aid		
	range of analytical tools for all		
	platform that provides a better	implement this tool in the CPMRS.	
	to a new, more robust CPMRS	currently working with the vendor to	
	In 2016, the PDMP transitioned	overdose and diversion risk. DCP is	
		helps practitioners assess narcotic	prescribing characteristics
	their peers.		misuse based on initial
	prescribing compares against	sources to create more holistic risk	of long-term prescription
	data to assist them in understanding how their	and outcomes. The platform can also accommodate additional information	utilizing predictive analytic to forecast increased risk

patients receiving	Implemented in August 2017,	The State is developing a federated model	management across
•	the integrated eligibility system	of HIE (aka "network-of-networks"). This	systems for better
patients in the PDMP	uses a NextGate solution for	structure will allow both individual EHRs	integration.
(i.e., the State's Master	patient-matching across	and existing HIE initiatives to connect and	
Patient Index [MPI]	programs. The DSS Enterprise	share data through secure interfaces	As a benefit of the IAPD,
strategy with regard to	Master Person Index (EMPI) is	connecting public and private HIE nodes to	we are offering a simplified
PDMP query)	funded through a shared	the statewide HIE network using national	system to provide
	services APD and will be	standards for point-to-point exchange or	enhanced data sharing
	retained by DSS for continued	participating in a national network.	within the state known as
	use by the integrated eligibility	In this federated HIE data model, EHR	the gateway. We have
	system.	patient data will remain within the individual	onboarded a significant
		systems of record and be pulled or pushed	number of providers via
	EMPI	from HIE services as required. Queried	integration into the
		data will be organized and contextualized	electronic health record
	DSS implemented the NextGate	through HIE services to support identified	(EHR) and pharmacy
	EMPI solution in January 2016	use cases.	dispensing software that
	with a goal of creating a		leverage the data from
	consolidated view of	The roadmap has three major lanes:	those systems to provide
	patient/person information	(i) governance, (ii) enterprise data	searches and return PDMP
	across disparate source	governance, and (iii) HIE. See Figure 3.	data.
	systems as well as workflow and	Statewide HIE Roadmap	
	basic reporting tools for ongoing	The HIE will be implemented in multiple	The CPMRS can now be
	maintenance of the system.	stages to deliver functionality to the	accessed through
	Today, the EMPI is used by the	stakeholders/users in a timely and efficient	approved electronic
	State's eligibility and enrollment	manner, following an incremental delivery	health records (EHR) and
	system (DSS-ImpaCT) and the	methodology and procurement process.	pharmacy management
	State's HIE system, Access		systems (PMS) where
	Health CT. EMPI is hosted by	The initial focus is on core foundational	PDMP data and NarxCare
	the State's Department of	components: HIE services as shown in	analytics will be

Administrative Services, Bureau	Figure 3 Statewide HIE Roadmap. These	delivered directly into
of Enterprise Systems and	core services will focus on the installation	practitioner workflow.
Technology.	and configuration of HIE componentry,	The Connecticut
	including enhancement, transformation and	Prescription Monitoring
	alignment of data, management and	Program (PMP)
	auditing, technical assistance, and	announced a statewide
	deploying to existing EHRs via standard	initiative to integrate the
	protocols. Each stage will focus on the	CPMRS into approved
	release of solution components as required	EHR/PMS using Appriss
	to deliver the functionality captured in the	Health's PMP Gateway
	prioritized use cases. The HIE services will	service in 2021. For
	interface with the Core Data Analytic	updated accessibility
	Solution (CDAS) shared core system	statistics, see Table 1
	components, including the Informatica	and Table 2.
	Master Data Management (MDM) multi-	
	domain system Identity as a Service	
	(IDaaS)	
	The MDM component implemented	
	includes a master person index (MPI). The	
	HIE services will interface with the UConn	
	CDAS MDM solution for identity and	
	consent management.	
	Optimizing access to Medicaid patient data	
	and recognizing a statutory obligation for	
	hospitals to be connected within one year	
	of operations, the initial implementation of	
	use cases will focus on one or two FQHCs	
	and a large hospital. The HIE will utilize	

industry standard interfaces to obtain data
from the FQHCs and a hospital in the
format of Continuity of Care Documents
and/or Quality Reporting Document
Architecture Category I to the HIE.
The initial implementation will focus efforts
on building to match patients and providers
and establish care relationships. The result
is proven capability to patient matching that
will ensure the success of future
connections and value proposition to
stakeholders. Once stable service is
verified, the intention is to deploy to the
remaining FQHCs, hospitals and small
independent provider groups to include
additional EHRs, CDAS and lab
information. The HIT Project Management
Office (PMO) will develop and recommend
a sequence of connections as the HIE
scales based on readiness at care settings
and priorities that will be reviewed with the
HIT Advisory Council for evaluation.
The State will provide a single, combined
view of data regardless of the data
origination point through IDaaS. This will
capture a unified view of person, provider
and relationship data in a manner to deliver

a best instance of identity, as a service.
For example, the architectural approach
that we wish to achieve would allow the
interface of these identity services with
other master person index and provider
registry systems, such as, Medicaid EMPI,
and other related tools used to support
their specific needs.
Stakeholder outreach and feedback and
the movement to interface foundational
services via published web services and
application programming interface
architectures, identifies a clear objective to
provide an IDaaS for use by other
stakeholders. A key component of the
architecture is access controls to ensure
appropriate and permitted use of data
through identity management.
an ough laonaty management.
An additional shared service will perform
the transformation of data to align and
normalize the data for interoperability
across EHR systems. These services will
provide data parsing and standardization to
classify, de-duplicate and enrich clinical
data and enable improved patient care and
clinical informatics. Quality control and
assurance capability will be used for alerts

		and scorecards to enable providers to	
		better understand and improve the quality	
		of data in their EHRs.	
		Master prescription history database	
		Statewide databases like the CPMRS and	
		networks like Surescripts have established	
		feasible methods of maintaining and	
		accessing prescription medication fill data	
		and have largely addressed issues of	
		privacy, data security, data storage and	
		data access. The State is researching to	
		determine if, with appropriate resources	
		and legal empowerment, these databases	
		might form the basis of a centralized	
		master list of active prescription	
		medications and medication history.	
Use of PDMP – Support	ting Clinicians with Changing O	ffice Workflows / Business Processes	
Develop enhanced	Leveraging the HIE	PDMP has been working with OHS for the	Connecticut will continue to
provider	infrastructure would potentially	purpose of integrating the CPMRS into the	integrate the CPMRS into
workflow/business	allow for the most efficient	HIE once the infrastructure is built.	the HIE as the
processes to better	pathway for practitioners and	The new approved SUPPORT Act IAPD	infrastructure is built
support clinicians in	dispensers to access a	includes activities intended to expand the	consistent with the newly
accessing the PDMP	complete patient profile that	capacity of the CPMRS by connecting	approved IAPDs.
prior to prescribing an	includes their controlled	health systems and providers and	
opioid or other	substance history.	integrating CPMRS into EHRs. The work	The CPMRS is a highly
controlled substance to		proposed within this IAPD and the HIT	integrate tool in the EHR
address the issues		IAPD will continue the existing work of	and pharmacy dispensing
which follow		adding connections and integrating into	software today and looking

additional EHRs, begin some	to add the HIE. The
implementation activities, and begin the	software team at the EHR
planning for areas where there are gaps	and pharmacy dispensing
between the current PDMP and the	
	software get to determine
definition of a qualified PDMP pursuant to	where the information is
the SUPPORT Act. Planning for use cases	displayed based on their
dependent on PDMP participation and	internal development. In
utilization is also included and	2020, the CPMRS received
Connecticut's statewide HIE will be	over 19 million requests via
connected to the PDMP.	integrated search which
	was a new record for the
<i>Connie</i> is strategically seen as a preferred	state without connection to
solution for provider workflow integration.	the HIE. The technical
For EHR integrations, the HIE will connect	work of integration is being
to Appriss Health's PDMP Gateway	managed by the staff at the
product, to the RxCheck hub, or both. The	HIE and our software
HIE connection will facilitate a bi-directional	vendor. Our software
data feed between the HIE and PDMP.	vendor has an Active
The trigger for the query will occur during	Programming Interface
the prescribing workflow and can be	(API) developed but will
automated. The diagram (Figure 2) after	also build a custom
this chart illustrates the basic connectivity	interface if the EHR or
architecture with the HIE available for	pharmacy dispensing
connections to the PDMP, through the	software requires it.
Appriss Health hub. The Medicaid	·
enterprise can query the PDMP through an	The CPMRS can now be
HIE connection. In the future, if statutory	accessed through
and data sharing issues are resolved to	approved electronic
remove current restrictions, Medicaid could	health records (EHR) and

establish a direct connection to the PDMP	pharmacy management
if needed by a use case.	systems (PMS) where
Il fleeded by a use case.	PDMP data and NarxCare
Anno an ita ang ita ang ita ang ita ang ang ang ang ita a	
Among its various funding opportunities,	analytics will be
the SUPPORT Act provides resources to	delivered directly into
better integrate and utilize state PDMPs or	practitioner workflow.
PDMP in Connecticut (CPMRS). DSS,	The Connecticut
DCP and OHS recently submitted a	Prescription Monitoring
request to CMS to fund a planning and	Program (PMP)
design process to identify specific,	announced a statewide
tangible, value-added initiatives related to	initiative to integrate the
CPMRS.	CPMRS into approved
	EHR/PMS using Appriss
Current collaborations include a successful	Health's PMP Gateway
three-agency workgroup focused on the	service in 2021. For
SUPPORT Act. This group, composed of	updated accessibility
DSS, DCP, and OHS were successful in	statistics, see Table 1
receiving CMS approval for SUPPORT Act	and Table 2.
funding. The three agencies are now	
developing plans for PDMP improvements	
to make sure that the PDMP will meet the	
qualified standard for a qualified PDMP.	
Other initiatives that are in the joint DSS-	
OHS portfolio include e-consults and e-	
referrals.	
Through the SUPPORT Act IAPD and	
other SUPPORT Act-funded initiatives,	
opportunities related to the stated purpose	

		and goals of the Medication Reconciliation and Polypharmacy Committee are actively monitored.	
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	Connecticut will continue to implement Appriss Health's NarxCare program.	 Connecticut hopes to add to the CPMRS the NarxCare platform via a federal grant. NarxCare provides a comprehensive tool to assess narcotic overdose and diversion risk. NarxCare aggregates and analyzes controlled substance prescription information from providers and pharmacies, and presents interactive, visual representations of that information as well as advanced analytic insights, complex risk scores and more features to aid physicians, pharmacists and care teams to increase patient safety and outcomes. The platform can also accommodate additional information sources to create more holistic risk models, assessments and alerts. DCP is currently working with Appriss Health to implement this tool in the CPMRS. One large healthcare system and one national pharmacy chain have already purchased this enhanced analytic tool on their own. 	The PDMP administrator, along with the PDMP vendor (Appriss Health), are responsible for the development of processes and system testing for the inclusion of NarxCare. Integration into the CPMRS continues grow and as stated earlier we had over 19 million integrated searches in 2020. There are mandatory look-up requirements for prescribers of controlled substances in the law in Connecticut. The EHR vendor and operator as well as the pharmacy dispensing software operate are permitted flexibility regarding the timing of the information being presented.

			Currently, the state is
			providing NarxCare, which
			is an enhanced analytical
			tool to identify overdose
			risk, free as part of grants
			with other partners like the
			Department of Public
			Health, the Department of
			Mental Health and
			Addiction Services, the
			Center for Disease Control
			and Prevention, the
			Department of Justice, and
			the Substance Abuse and
			Mental Health Services
			Administration. The
			program is operational at
			this point.
Master Patient Index / Id	lentity Management		
Enhance the master	 The PDMP system already 	DCP and DSS will develop an approach for	DCP, OHS and DSS will
patient index (or master	uses an algorithm that	the CPMRS and HIE to identify	work to identify
data management	automatically links patient	management functions across both	management across
service, etc.) in support	records (coming from	systems with a goal to improve efforts to	systems for better
of SUD care delivery.	pharmacies) based on name,	integrate care and have better outcomes.	integration.
	date of birth, zip code and		
	street address.		
	 Appriss Health uses the 		
	prescription drug monitoring		

interface, AWARxE, which	
provides Project	
Management Professional	
staff the following capabilities	
to:	
 Authorize practitioners, 	
their delegates and	
pharmacists registering	
for CPMRS access	
— Manage CPMRS	
accounts	
 Maintain a list of data 	
submitters, from	
pharmacies and licensed	
practitioners, who	
dispense Schedule II, III,	
IV or V controlled	
substances	
 Approve data submissions 	
from pharmacies and	
licensed practitioners who	
dispense Schedule II, III,	
IV or V controlled	
substances under federal	
and state law	
 Conduct analysis of 	
pharmacies that have not	
reported or are delayed in	
reporting	
reporting	

	 Create dashboard announcements accessible to registered 		
	users — Consolidate patient		
	information for patients		
	reported to the database		
	with differences in name,		
	date of birth or gender		
	 Generate patient 		
	prescription history		
	reports — Generate dispensary		
	activity reports		
	 Generate alerts for 		
	practitioners and		
	pharmacists based on		
	thresholds for high doses,		
	high-risk drug		
	combinations, and		
	potentially risky patient behavior.		
Overall Objective for En	nhancing PDMP Functionality &	Interoperability	
Leverage the above	Prior to 2017, there was no	The PDMP administrator refers issues to	Connecticut will explore
functionalities/capabiliti	consistent way to track whether	Drug Control Agents, who enforce the	additional analytical tools
es/	or not CSP/CPMRS registrants	mandated lookup requirements.	to assist with enforcement
supports (in concert	who wrote a controlled	DSS receives reports from its medical and	to minimize the risk of
with any other state	substance prescription were	dental ASOs of Medicaid patients filling	inappropriate
health IT, technical	reviewing a patient's record	opioid prescriptions in amounts exceeding	overprescribing.

			1
assistance or workflow	when prescribing more than a	100 morphine milligram equivalents (MME)	
effort) to implement	three-day supply. In 2017,	per day for a minimum of 90 consecutive	The compliance module,
effective controls to	through a collaborative effort	days. That information is utilized for	which we hope to turn on
minimize the risk of	supported by a federal grant	outreach to providers.	by the end of the year,
inappropriate opioid	with DPH, DCP was able to hire		includes automated reports
overprescribing — and	a durational employee with		that will identify non-
to ensure that Medicaid	technical expertise in data		compliance with our law.
does not inappropriately	analytics to run additional		Currently, we can do these
pay for opioids	reports that aggregate the		manually and do so as
	number of prescribers who have		required during
	never reviewed any patient's		investigations. We
	controlled substance		recently turned on an
	prescription records. Appriss		enhance tool to identify
	Health has a new analytical tool		prescribers who were
	that will enable the PDMP to		utilizing the CMPRS via
	identify those who are not		integration without being
	compliant with the lookup		compliant with the
	mandate.		registration requirement
	The PDMP cannot generate		and credential. These
	automated, comprehensive		steps are dramatically
	reports to flag prescribers who		improving our data and will
	fail to follow the three-day		allow us to activate this
	supply mandated lookup.		module efficiently and
	Because of the lack of analytical		reduce false positives.
	tools, enforcement has been		
	based on individual complaints		
	to the Drug Control Division.		
	_		
	e-Prescribing Support		

The interChange system
includes e-Prescribing
functionality, which allows
providers to check eligibility and
medication history, access
program formulary information
and obtain potential drug
interactions for the Medicaid
program participants.
Surescripts is utilized as a
subcontractor to provide
connectivity between the
provider and the pharmacy and
between the provider and the
payer and to build the Medicaid
portal into the State's
e-Prescribing network.
Transaction volume for
e-Prescribing has increased
steadily since implementation in
2010 as more prescribers have
begun utilizing the functionality.
Approximately 777,500 eligibility
and 424,000 medication history
transactions are processed
monthly.

Attachment A Section II – Implementation HIT Administration

Please provide the contact information for the State's point of contact for the SUD Health IT Plan.

Name and Title: William Halsey, Director of Integrated Care, Division of Health Services, Department of Social Services

Telephone Number: 860-424-5077

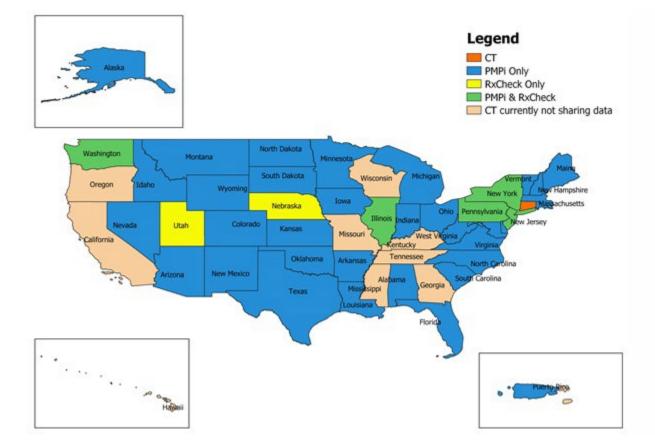
Email Address: William.halsey@ct.gov

Attachment A Section III – Relevant Documents

Please provide any additional documentation or information that the State deems relevant to successful execution of the implementation plan

Figure 1. Interstate PDMP Data Sharing

Authorized roles in the CPMRS currently have access to prescription data from 39 states, Washington DC, Puerto Rico, and the Military Health System. This includes all border states. Connecticut allow other states to connect via the PMP Interconnect (PMPi) or RxCheck, which are data sharing hubs that use end-to-end encryption to facilitate data sharing across state borders.



Source: https://portal.ct.gov/DCP/Prescription-Monitoring-Program/Prescription-Monitoring-Program, accessed on 10/25/2021.

Figure 2: PDMP Diagram with HIE

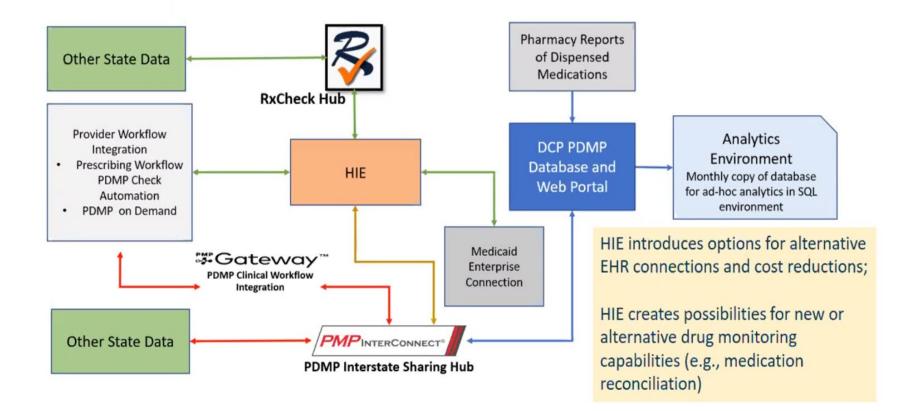


Figure 3: Statewide HIE Roadmap

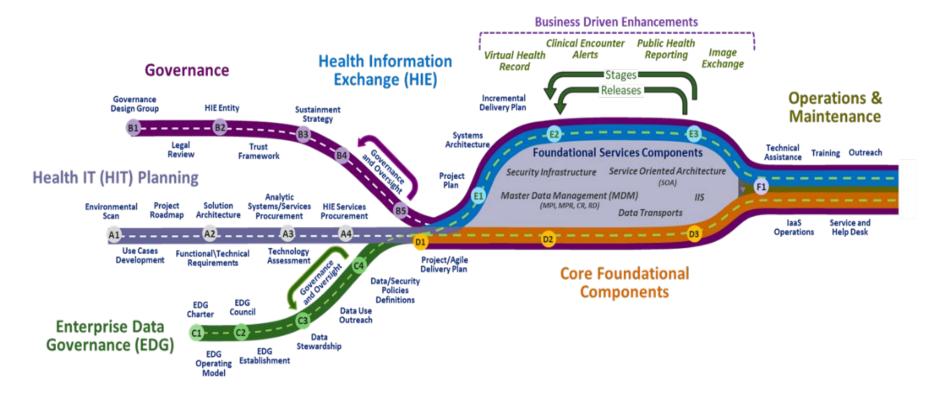


Table 1: CPMRS User Growth

	Prescribers	Prescriber Delegates	Pharmacists	Pharmacist's Delegate	Total
2016	24,068	362	2,255		26,685
2017	26,015	741	2,515		29,271
2018	28,791	1,157	2,730		32,678
2019	26,943	1,521	2,937	43	31,444
2020	29,351	1,767	3,026	68	34,212

Source: https://data.ct.gov/Health-and-Human-Services/Bar-Chart-CPMRS-Registered-Users/cx8y-d3r6

Table 2: CPMRS User Search Growth

	Law Enforcement	Pharmacist	Pharmacist's Delegate	Prescriber	Prescriber Delegate	Total
2015	5,574	465,256		484,736		955,566
2016	3,475	283,588		694,510		981,573
2017	3,924	675,926		1,130,511	142,033	1,952,394
2018	4,206	634,497		1,237,933	284,521	2,161,157
2019	3,808	611,141	3,027	1,392,390	300,580	2,310,946
2020	4,165	576,685	15,038	1,425,554	283,062	2,304,504
Source: <u>http</u>	os://data.ct.gov/H	Health-and-Hum	nan-Services/Bar	-Chart-CPMRS	-User-Searche	es-per-Year/i7mq-pe

Attachment D: SUD Monitoring Protocol

Medicaid Section 1115 Substance Use Disorder Demonstrations Monitoring Protocol Template

Note: PRA Disclosure Statement to be added here

1. Title page for the state's substance use disorder (SUD) demonstration or the SUD component of the broader demonstration

The state should complete this title page as part of its SUD monitoring protocol. Definitions for certain rows are provided below the table. The Performance Metrics Database and Analytics (PMDA) system will populate some rows of the table. The state should complete the rest of the table. The state can revise the demonstration goals and objectives if needed. PMDA will use this information to populate part of the title page of the state's monitoring reports.

State	Connecticut
Demonstration name	Connecticut Substance Use Disorder Demonstration
Approval period for section 1115 demonstration	Enter the current approval period for the section 1115 demonstration as listed in the current special terms and conditions (STC), including the start date and end date (MM/DD/YYYY – MM/DD/YYYY).Start Date: 04/14/2022End Date: 03/31/2027
SUD demonstration start date ^a	Enter the start date for the section 1115 SUD demonstration or SUD component if part of a broader demonstration (MM/DD/YYYY). 04/14/2022
Implementation date of SUD demonstration, if different from SUD demonstration start date ^b	Enter SUD demonstration implementation date (MM/DD/YYYY).
SUD (or if broader demonstration, then SUD-related) demonstration goals and objectives	 Enter summary of the SUD (or if broader demonstration, then SUD-related) demonstration goals and objectives. Under this demonstration, the State expects to achieve the following: Objective 1. Increase rates of identification, initiation, and engagement in treatment. Objective 2. Increase adherence to and retention in treatment. Objective 3. Reductions in overdose deaths, particularly those due to opioids. Objective 4. Reduce utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services. Objective 5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate. Objective 6. Improved access to care for physical health conditions among

^a **SUD demonstration start date:** For monitoring purposes, CMS defines the start date of the demonstration as the *effective date* listed in the state's STCs at time of SUD demonstration approval. For example, if the state's STCs at the time of SUD demonstration approval. For example, if the state's STCs at the time of SUD demonstration approval note that the SUD demonstration is effective January 1, 2020 – December 31, 2025, the state should consider January 1, 2020 to be the start date of the SUD demonstration. Note that the effective date is considered to be the first day the state may begin its SUD demonstration. In many cases, the effective date is distinct from the approval date of a demonstration; that is, in certain cases, CMS may approve a section 1115 demonstration with an effective date that is in the future. For example, CMS may approve an extension request on December 15, 2020, with an effective date of January 1, 2021 for the new demonstration period. In many cases, the effective date also differs from the date a state begins implementing its demonstration.

^b **Implementation date of SUD demonstration:** The date the state began claiming or will begin claiming federal financial participation for services provided to individuals in institutions for mental disease.

2. Acknowledgement of narrative reporting requirements

The state has reviewed the narrative questions in the <u>Monitoring Report Template</u> provided by CMS and understands the expectations for quarterly and annual monitoring reports. The state will provide the requested narrative information (with no modifications).

3. Acknowledgement of budget neutrality reporting requirements

☑ The state has reviewed the Budget Neutrality Workbook (which can be accessed via PMDA – see Monitoring Protocol Instructions for more details) and understands the expectations for quarterly and annual monitoring reports. The state will provide the requested budget neutrality information (with no modifications).

4. Retrospective reporting

The state is not expected to submit metrics data until after monitoring protocol approval, to ensure that data reflects the monitoring plans agreed upon by CMS and the state. Prior to monitoring protocol approval, the state should submit quarterly and annual monitoring reports with narrative updates on implementation progress and other information that may be applicable, according to the requirements in its STCs.

For a state that has monitoring protocols approved after one or more initial quarterly monitoring report submissions, it should report metrics data to CMS retrospectively for any prior quarters (Qs) of the section 1115 SUD demonstration that precede the monitoring protocol approval date. A state is expected to submit retrospective metrics data—provided there is adequate time for preparation of these data— in its second monitoring report submission that contains metrics. The retrospective monitoring report for a state with a first SUD demonstration year (DY) of less than 12 months, should include data for any baseline period Qs preceding the demonstration, as described in Part A of the state's monitoring protocols. (See Appendix B of the Monitoring Protocol Instructions for further instructions on determining baseline periods for first SUD DY's that are less than 12 months.) If a state needs additional time for preparation of these data, it should propose an alternative plan (i.e., specify the monitoring report that would capture the data) for reporting retrospectively on its section 1115 SUD demonstration.

In the monitoring report submission containing retrospective metrics data, the state should also provide a general assessment of metrics trends from the start of its demonstration through the end of the current reporting period. The state should report this information in Part B of its monitoring report submission (Section 3: Narrative information on implementation, by milestone and reporting topic). This general assessment is not intended to be a comprehensive description of every trend observed in the metrics data. Unlike other monitoring report submissions, for instance, the state is not required to describe all metric changes (+ or - greater than 2 percent). Rather, the assessment is an opportunity for a state to provide context on its retrospective metrics

data and to support CMS's review and interpretation of these data. For example, consider a state that submits data showing an increase in the number of medication-assisted treatment (MAT) providers (Metric #14) over the course of the retrospective reporting period. This state may decide to highlight this trend for CMS in Part B of its monitoring report (under Milestone 4) by briefly summarizing the trend and explaining that during this period, a grant supporting training for new MAT providers throughout its state was implemented.

For further information on how to compile and submit a retrospective monitoring report, the state should review Section B of the Monitoring Report Instructions document.

- ☑ The state will report retrospectively for any Qs prior to monitoring protocol approval as described above, in the state's second monitoring report submission that contains metrics after monitoring protocol approval.
- □ The state proposes an alternative plan to report retrospectively for any Qs prior to monitoring protocol approval: Insert narrative description of proposed alternative plan for retrospective reporting. Regardless of the proposed plan, retrospective reporting should include retrospective metrics data and a general assessment of metric trends for the period. The state should provide justification for its proposed alternative plan.

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Medicaid Section 115 SUD Demonstrations Pronocol (Part A) - Planned Subpopulations (Version 7.0) Suc Demostration Name Demostration Name

Table: Substance Use Disorder Demonstration Planned Subpopulations

	Lianned sub	FIANDER SUBPOPULATION REPORTING					Alignment with CMS-provided technical specifications manual	CILICAL SPECIFICATIONS MANUAL	
						Attest that planned subpopulation reporting	Subpopulations	Rele Attest that metrics	Relevant metrics
Subpopulation category	Subpopulations	Reporting priority	Reporting priority Relevant metrics	Subpopulation type	State will report (Y/N)	whin and category matches the description in State will the CNS-provided technical Subpopulation type report (N'N) specifications manual (N'N)	If the planned reporting or subposing the hybrid partical first hybrid particular the hybrid reporting or subposing the hybrid particle for state of the subposing the hybrid particle for the subposing the subposing the hybrid particle for the subposing the subposing the hybrid particle for the subposing the s	eporting for subpopulation If the p category matches CMS- matc provided technical which specifications mamual (V/N) category	reporting for subpopulation If the planned reporting of relevant netrics does not category matches CMS much (i.e., column $1 = {}^{n}N_{n}$), list the metrics for provided technical which start plans to report for each subpopulation specifications manual (V/N) category (Format netric number, comma sparated)
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Age group	Children <18, adults 18-64, and older adults 65 +	Required	Mepics #1-3, 6-12, 23, 24, 26, 27 CMS-provided	CMS-provided	Υ	N	Children/Young adults 12-21, Adults 21-65	V I. 2, 3	
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Age group	Children <18, adults 18-64, and older adults 65+	Required	Metrics#1-3, 6-12, 23, 24, 26, 27 CMS-provided	CMS-provided	Y	Ă		2	
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Pregnancy status	Pregnant, Not pregnant	Required	Metrics#1-3, 6-12	CMS-provided	Y	Y			
Criminal justice status	Criminally involved, Not criminally involved	Required	Metrics#1-3, 6-12	CMS-provided	×	Y fi	Providers use the H9 and HZ modifiers on residential claims for any DOC/Judicial involved members		
OUD population	Opioid diagnosis	Recommended	Metrics #2-12, 23, 24, 26, 27, 36	CMS-provided	Y	Y		,	
[Insert row(s) for any state-specific subpopulation(s)]	ubpopulation(s)]								

olumn F = "N"), enter explanation in corresponding row in column H. a If the state is not reporting a required

¹ If the safe is reporting on the Dani-clights stars, Preparecy starts, Crimin Justice starts, and OUD population subpopulation categories, the start should use column II to outlie its subpopulation identification approach as explained in Version 4.0 of the Maticald Section 1115 Substance Use Disorder Damostrations Mathematican Proceedings and Control Control

ategories, the state should (1) select N in column G and (2) provide an e. cetegory in column H.

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 $^\circ$ If the state is planning to phase in the reporting of any of the subpthe report (SUDDY and Q) in which it will begin reporting the sub-

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· Use Disorder

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I able 1. Substance Us	Dates of first SUD demonstration year (SUD DY1)	Start date (MM/DD/YYY)	End date (MM/DD/YYYY) Dates of first quarter of the baseline	period for CMS-constructed metrics Reporting period (SUD DY and Q) (Format DY#O#: e.g., DY101)	Start date (MM/DD/YYY)"	End date (MM/DD/YYYY)	Broader section 115 domentarian reporting period corresponding with the first SLD reporting quarter, if applicable. If there is no broader domonstration, fill in the first SLD reporting period. (Format DY 200: c.g. DN3Q1)	First SUD monitoring report due date (per STCs) (MM/DD/YYY)	First SUD monitoring report in which the state plans to report annual metrics that are established quality measures (EQMs)	Baseline period for EQMs (Format CY#; e.g., CY2019)	SUD DY and Q associated with monitoring report (Format DY#Q#; e.g., DY1Q1)	SUD DY and Q start date (MM/DD/YYYY)	SUD DY and Q end date (MM/DD/YYYY)	Dates of last SUD reporting quarter:	Start date (MM/DD/YYY)	End date (MM/DD/YYYY)	

Schedule tino Rei **Table 2. Substance Use Disorder**

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Attachment E: Evaluation Design



Government Human Services Consulting

Substance Use Disorder 1115 Waiver

Evaluation Design

State of Connecticut May 10, 2023

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Section 1 General Background Information

History and Overview

Modernizing the State of Connecticut's (Connecticut's or State's) Medicaid system of delivering Substance Use Disorder (SUD) treatment services has been an ongoing and sequential process beginning with the contracting for a Behavioral Health (BH) administrative services organization (ASO) in 2006 to better manage the continuum of BH services. In keeping with the goal of modernization, Connecticut Department of Social Services (DSS), in collaboration with its sister State agencies, the Connecticut Department of Mental Health and Addiction Services (DMHAS) and the Connecticut Department of Children and Families (DCF), has implemented a comprehensive SUD benefit package of services provided by a statewide network of SUD treatment service providers that will be financed by Medicaid for Medicaid beneficiaries. Except as otherwise specified, references to Medicaid throughout this Evaluation Design also include the Children's Health Insurance Program (CHIP).

The 1115 SUD Waiver Demonstration (Demonstration) will address Connecticut's opioid crisis and support the State's effort to implement an enhanced comprehensive and lasting response to this epidemic as well as similar challenges with use of substances other than opioids. Connecticut is experiencing one of the most significant public health crises in its history. The striking escalation of opioid use and misuse over the last five years is impacting individuals, families, and communities throughout the State.

From calendar year 2012 through 2018, the rate of unintentional drug-related overdose deaths in Connecticut grew from 12.2 per 100,000 to 29.9 per 100,000.¹ Connecticut's overdose deaths continue to climb with no sign of relenting. In calendar years 2019 and 2020, fatal drug overdose deaths in Connecticut rose 16.7% and 14.3% respectively from the previous year. The majority (82%) of overdose deaths in 2019 were related to fentanyl or fentanyl analogs.²

Recent Context for Connecticut's Medicaid Program

In 2006, DCF, which oversees BH for children in the State and DSS, in conjunction with a legislatively mandated oversight council, formed the Connecticut Behavioral Health Partnership (CT BHP), authorized pursuant to State statute (section 17a-22h of the Connecticut General Statutes), with ValueOptions³ serving as the ASO.

In 2010, DMHAS, which oversees BH for adults in the State, joined the CT BHP (and the authorizing statute was amended accordingly) and, collectively, a request for proposal for an ASO vendor for the expanded CT BHP was issued. ValueOptions bid on, and was awarded, the contract to be the ASO for the expanded CT BHP. The new contract went live on April 1, 2011,

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¹ Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999–2018 on CDC WONDER Online Database, released in 2020.Data are from the Multiple Cause of Death Files, 1999-2018, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Available at: <u>http://wonder.cdc.gov/ucd-icd10.html on May 13, 2020</u>.

² Connecticut Office of the Chief Medical Examiner, per CDC-SUDORS grant guidelines (April 19, 2021) as published in the CT Department of Public Health Drug Overdose Monthly Report, March 2021.

³ As a result of the 2014 merger between ValueOptions, Inc. and Beacon Health Strategies, LLC, ValueOptions, Inc. officially changed its name to Beacon Health Options on December 9, 2015.

when more than 200,000 additional Medicaid members, primarily adults, but also a small number of youth, were added. That change brought the total membership included under the CT BHP to more than 600,000 members at that time.

While the goals of the original CT BHP described above remained in place, ValueOptions as the ASO was described in the new contract as being "the primary vehicle for organizing and integrating clinical management processes across the payer streams, supporting access to community-based services, assuring the delivery of quality services and preventing unnecessary institutional care." Additionally, ValueOptions was expected to enhance communication and collaboration within the BH delivery system, assess network adequacy on an ongoing basis, improve the overall delivery system and provide integrated services supporting health and recovery by working with the Departments (DSS, DCF, and DMHAS) to recruit and retain both traditional and non-traditional providers.

Effective January 1, 2012, DSS transitioned from three managed care organizations (MCOs) managing the physical health care of a large portion of the State's Medicaid population to a managed fee-for-service (FFS) structure with a single ASO for physical health, similar to the model in place for BH with ValueOptions. ValueOptions partnered with the MCO that ultimately won the bid for this contract, Community Health Network of Connecticut (CHNCT). While this contract did not increase membership, it did result in increased responsibility for ValueOptions to coordinate care provided to Medicaid members. The new contract, which went live in 2012, embedded ValueOptions clinical care managers in the CHNCT office and leveraged McKesson technology to identify the most at-risk members to ultimately impact health outcomes.

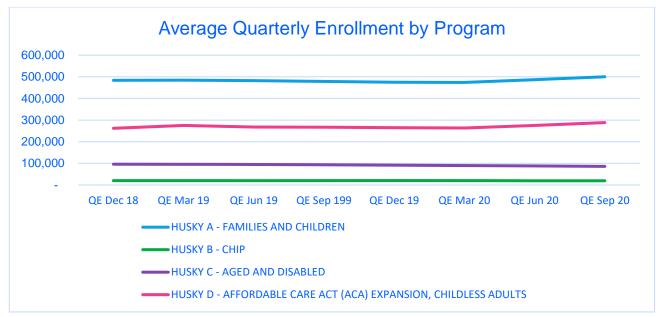
As of September 2020, Connecticut Medicaid and CHIP had approximately 895,000 enrollees, including almost 20,000 CHIP enrollees (HUSKY B) and approximately 289,000 Medicaid adult expansion enrollees (HUSKY D) who receive the Alternative Benefit Plan (ABP) covered services as required under federal law. HUSKY A enrollees include approximately 500,000 low-income Medicaid members parents/caregiver relatives and children. HUSKY C enrollees include over 86,000 older adults and people with disabilities.

The HUSKY D benefits under the ABP were aligned with the underlying Medicaid State Plan benefits. Although Connecticut Medicaid did not reimburse for residential SUD services, there was a State-funded benefit for HUSKY D Medicaid beneficiaries using a former edition of the American Society of Addiction Medicine (ASAM) Criteria for utilization management (UM).

Today, the CT BHP is composed of DSS, DMHAS, and DCF. CT BHP contracts with Beacon Health Options, the BH ASO, to authorize and coordinate Medicaid BH services (mental health and SUD services) for HUSKY Health members in Connecticut. Covered benefits and services administered by the CT BHP are available to members who are enrolled in HUSKY A, HUSKY B, HUSKY C, and HUSKY D. (Separate from its HUSKY Health/Medicaid responsibilities, the BH ASO also provides administrative support to a small set of services for the non-Medicaid DCF limited benefit group.) See below for a chart reflecting the relative size of each HUSKY population.

Under the Demonstration, a full continuum of SUD care for HUSKY A, HUSKY B, HUSKY C, and HUSKY D will be financed by Medicaid subject under a new Medicaid Rehabilitative State Plan. In addition, the Judicial Branch Court Support Services Division (JB-CSSD) and the Department of Corrections (DOC) have joined with the CT BHP sister agencies to ensure that Medicaid eligible members receive SUD treatment when they are on probation, parole, inpatient, or otherwise eligible for services.





Substance Use Disorder Treatment in Connecticut

The following services were the covered Medicaid SUD behavioral benefits and services prior to the Demonstration:

- Screening, Brief Intervention and Referral to Treatment (SBIRT) Services
- Outpatient Services
- Methadone Maintenance
- Medication for Addiction Treatment (MAT)
- Intensive Outpatient Services (IOP)
- Partial Hospitalization Program (PHP)
- Ambulatory Withdrawal Management
- Inpatient Hospital Substance Use Withdrawal Management
- Residential Treatment Center for Children through DCF

⁴ Source: DSS January 8, 2021 presentation to MAPOC, Financial Trends in the Connecticut HUSKY Health Program Transparency, Sustainability and COVID Impacts. Available at:

https://www.cga.ct.gov/ph/med/related/20190106 Council%20Meetings%20&%20Presentations/20210108/HUSKY%20Financial%20Trends%20January%202021 %20.pdf

- Targeted Case Management (TCM) for Ages 19 and under
- TCM for Adults with Serious Mental Illness and Co-Occurring SUD.

Connecticut requested the Demonstration to enable Federal Financial Participation (FFP) under Medicaid and CHIP for SUD residential treatment and other health care services provided in accordance with the latest edition of ASAM criteria for people residing in Institutions for Mental Disease (IMDs). The Demonstration builds upon the State's successful implementation of the CT BHP and leverages this strong foundation to ensure Connecticut's Medicaid beneficiaries have access to the entire continuum of SUD services as defined by ASAM Levels of Care (LOCs).

There are no residential services for adolescent girls in Connecticut. All residential services must be provided out of State, which reduces the ability of the facility to provide family therapy. The State would like to recruit providers within the State's border to provide these services to improve care for adolescent girls. In order to meet demonstration requirements accessibility to ASAM residential services for all Medicaid eligible populations, the Demonstration contains a specific focus on treatment for adolescent girls.

Demonstration Approval

On April 14, 2022, Connecticut received approval for its application for a section 1115(a) demonstration titled "Connecticut Substance Use Disorder Demonstration" (Project Number 11-W-00372/1 and 21-W-00069/1) effective April 14, 2022 through March 31, 2027.

Description of the Demonstration

The objective of this Demonstration is to provide access to a full array of SUD treatment services for Connecticut Medicaid enrollees and improve the delivery system for these services to provide more coordinated and comprehensive SUD treatment for these individuals.

This Demonstration seeks to improve outcomes for Medicaid members diagnosed with SUD by providing critical access to SUD treatment services, including inpatient and residential SUD treatment in IMDs, as part of a full continuum of treatment services that follow ASAM LOCs. Under a new SUD State Plan Amendment (SPA), which will be associated with this Demonstration, Connecticut will implement a comprehensive, integrated SUD benefit that includes residential treatment settings. However, existing IMD limitations in FFS create barriers to ensuring members are able to access SUD treatment at a LOC appropriate to their needs using the ASAM criteria. Connecticut seeks Demonstration authority to remove Federal Medicaid restrictions on IMDs as SUD treatment settings in FFS. The new Medicaid SUD treatment continuum will enhance critical access to the full ASAM SUD treatment continuum. Mercer Government Human Services Consulting (Mercer) anticipate that this demonstration will accomplish the following goals, which make up our demonstration hypothesis. This waiver Demonstration will:

- 1. Increase rates of identification, initiation, and engagement in treatment for Opioid Use Disorder (OUD) and other SUDs.
- 2. Increase adherence to and retention in treatment for OUD and other SUDs.
- 3. Reduce overdose deaths, particularly those due to opioids.

- 4. Reduce utilization of emergency departments (EDs) and inpatient hospital settings for OUD and other SUD treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.
- 5. Lead to fewer readmissions to the same or higher LOC where readmissions is preventable or medically inappropriate for OUD and other SUDs.
- Improve access to care for physical health conditions among beneficiaries with OUD or other SUDs.

The Demonstration Implementation Plan addresses system reforms and activities needed to achieve the Milestones:

- 1. Access to critical LOCs for OUD and other SUDs
- 2. Widespread use of evidence-based, SUD-specific patient placement criteria
- 3. Use of nationally recognized, evidence-based, SUD program standards to set residential treatment provider qualifications
- 4. Sufficient provider capacity at each LOC, including MAT
- Implementation of comprehensive treatment and prevention strategies to address opioid misuse and Connecticut Substance Use Disorder Section 1115(a) Medicaid Demonstration OUD
- 6. Improved care coordination and transitions between LOCs

Milestone 1: Access to Critical LOCs for SUDs

Connecticut's pre-Demonstration SUD Medicaid treatment system included coverage of the following:

- Outpatient
- Intensive Outpatient
- Partial Hospitalization
- MAT (medications, as well as counseling and other services, with sufficient provider capacity to meet the needs of Medicaid beneficiaries in the State)
- Intensive LOCs in inpatient hospital settings
- Medically-supervised withdrawal management in limited settings

Under the Demonstration, the State will submit a SPA to provide a more complete continuum of care using ASAM criteria and standards including intensive LOCs in residential settings and withdrawal management.

Milestone 2: Use of ASAM Placement Criteria

Connecticut contracts with two entities for review of SUD admissions and placements using prior authorization and UM standards in the FFS Medicaid, block grant, and State-funded SUD

delivery systems. The State requires both the DSS-contracted Medicaid BH ASO for UM (currently Beacon Health Options) and DMHAS' contractor for quality management (QM) (currently Advanced Behavioral Health, Inc.) that is funded with State general funds and federal Substance Abuse and Mental Health Services Administration (SAMHSA) block grant dollars to utilize ASAM principles to ensure provider quality. Pre-Demonstration, the BH ASO utilized the ASAM placement criteria third edition and the DMHAS UM contractor utilized the ASAM placement criteria second edition. Prior to the Demonstration, Connecticut had not trained nor required treatment providers to create individualized treatment plans for individuals using multi-dimensional assessments based on the six dimensions of care as outlined in ASAM.

Under the Demonstration, SUD treatment services provided in the Medicaid FFS delivery system will comply with the current ASAM criteria for all prior authorization and utilization review decisions resulting in continuity across the Medicaid delivery systems. Connecticut will train all providers to utilize multi-dimensional assessments based on the six dimensions of care as outlined in ASAM to create individualized treatment plans. DSS, or its designee, will ensure appropriate UM is in place for SUD services for all LOCs, including prior authorization for SUD residential treatment services for individuals enrolled in the FFS delivery system. DSS will ensure Medicaid members have access to interventions at the SUD LOC appropriate for each person's diagnosis and individual circumstances. DSS will update any provider agreements necessary to emphasize the required use of the most current edition of ASAM placement criteria for providers of SUD treatment services. The State also intends to implement provider training on this requirement for ASAM placement criteria and its application to all SUD treatment services.

Milestone 3: Use of ASAM Program Standards for Residential Provider Qualifications

Connecticut Medicaid did not previously cover adult SUD residential services. Under the Demonstration, Connecticut will submit a SPA to cover residential treatment delivered by providers whose qualifications are consistent with the most current version of ASAM. Currently, requirements for State-funded and federal SAMHSA block grant-funded residential SUD treatment, residential withdrawal management, and inpatient SUD treatment services require general compliance with ASAM second edition standards.

Under the Demonstration and SPA, Medicaid policy manuals will be modified to reflect the current ASAM criteria for residential programs, including requirements for specific services, hours of clinical care, and credentials of staff for residential treatment. The amended policies will include a requirement that residential treatment providers offer MAT either onsite or by facilitating access offsite with a MAT provider. Connecticut will also implement a process for initial certification and ongoing monitoring of residential treatment providers to ensure compliance with the ASAM requirements under the Demonstration.

Milestone 4: Provider Capacity of SUD Treatment including MAT

Connecticut currently contracts for 948 adult SUD residential treatment beds across 19 providers and 12 adolescent beds in one provider, using non-Medicaid funds. All but three of these certified SUD residential, withdrawal management, and inpatient SUD treatment service providers have 17 or more beds and meet the definition of an IMD.

The State will develop an assessment of the availability of the ambulatory providers enrolled in Medicaid and whether they are accepting new patients for each of the SUD ambulatory ASAM LOCs. This assessment will indicate whether facilities are currently accepting Medicaid members.

DSS will work with its partner agencies in the State to ensure the SUD provider network is adequate and distributed geographically to meet the demands for these services. If services are unavailable within a specific geographic region, DSS will recruit qualified providers within the region or seek expansion from existing providers, including those that may be outside the defined geographical boundaries in need.

Milestone 5: Implementation of Opioid Use Disorder (OUD) Comprehensive Treatment and Prevention Strategies — Opioid Prescribing Guidelines and Other Interventions to Prevent Opioid Misuse

To address the opioid and prescription medication crisis, the Connecticut Department of Public Health (DPH) has implemented prescribing guidelines to prevent opioid over-use through updates to Connecticut policy and law affecting the prescribing of controlled substances and opioid medications.⁵ The relevant State agencies have also collaborated with legislators and various professional groups to enhance the Connecticut Prescription Monitoring and Reporting System (CPMRS), sometimes known as the Prescription Drug Monitoring Program (PDMP).

Effective October 1, 2019, Connecticut amended the Medicaid State Plan to reflect new Drug Utilization Review provisions required in Federal law (Section 1004 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act [SUPPORT Act; P.L. 115-271]). These provisions are designed to reduce opioid-related overprescribing and misuse. The required provisions include: 136 separate opioid prescription claim reviews at the point of sale as well as retrospective reviews, monitoring, and management of antipsychotic medication in children, and identification of processes to detect fraud and abuse.

Connecticut's Expanded Coverage of, and Access to, Naloxone for Overdose Reversal

Connecticut has taken steps over the past decade to make naloxone more widely available. Legislation was first introduced in 2011 in the Connecticut General Assembly and subsequent legislative sessions have included new pieces of legislation that have made naloxone more accessible over the years. A "Good Samaritan" law passed in 2011 that protects people who call 911 seeking emergency medical services for an overdose from arrest for possession of drugs/paraphernalia. State legislation enacted in 2012, which allowed prescribers (e.g., physicians, surgeons, physicians' assistants, advanced practice registered nurses, dentists and podiatrists) to prescribe, dispense or administer naloxone to any person to prevent or treat a drug overdose, protects the prescriber from civil liability and criminal prosecution. The protection from civil liability and criminal prosecution was extended to the person administering the naloxone in response to an overdose in 2014. Legislation enacted in 2015 allows

⁵ Rodrick Marriott, PharmD, Director, Drug Control Division, Connecticut Department of Consumer Protection, Connecticut Laws Impacting Prescribing and Practice, 2019. Available at: <u>https://portal.ct.gov/-/media/DCP/drug_control/PMP/Educational-Materials/Prescribing-Laws-2019-CM.pdf</u>

pharmacists, who have been trained and certified, to prescribe and dispense naloxone directly to customers requesting it. Most recently, Public Act (PA) 18-166 allows prescribers to develop agreements with organizations wishing to train and distribute naloxone. This legislation established new reporting requirements, established a framework for expanding distribution and availability of naloxone, enacted limitations on prescribing controlled substances, and commissioned a feasibility study for opioid intervention courts. All these changes have made naloxone more readily available.

In addition, as outlined in the State's Implementation Plan, Connecticut has established other initiatives addressing OUD, including expanding availability of naloxone using federal grant funds, such as the federal State Opioid Response grant. A total of 12,000 naloxone kits were made available for distribution in State Fiscal Year (SFY) 2019 through DMHAS, DOC, DPH, the Connecticut Hospital Association and the Regional Behavioral Health Action Organizations.

Increasing Utilization and Improving Functionality of PDMPs

Connecticut first mandated prescriber use of the CPMRS, the State's PDMP, in 2015, with additional provisions added in 2016. CPMRS is a tool to track the dispensing of controlled prescription drugs to patients. CPMRS is designed to monitor this information for suspected misuse or diversion (i.e., channeling drugs into illegal use), and can give a prescriber or pharmacist critical information regarding a patient's controlled substance prescription history. This information has helped prescribers and pharmacists identify high-risk patients who would benefit from early interventions.

Since implementation, the use of CPMRS has grown. In 2018, CPMRS reported 1.9 million annual requests from law enforcement, pharmacists, and prescribers. This is nearly double the annual law enforcement, pharmacist, and prescriber requests from four years earlier when there were approximately one million requests.

Connecticut plans to continue to leverage opportunities described in State Medicaid Director Letter (SMDL) 16-003 to help professionals and hospitals eligible for the Medicaid Promoting Interoperability Program, formerly known as the Medicaid Electronic Health Record (EHR) Incentive Program, connect to other Medicaid providers through the integration of CPMRS into EHRs and pharmacy management systems.

Milestone 6: Improved Care Coordination and Transitions between LOCs

Connecticut has multiple interventions for coordinating the care of individuals with SUD and transitioning between LOCs including, but not limited to, facility credentialing, discharge, referral and transition requirements, and care management initiatives at DSS, DCF, and DMHAS.

Under the Demonstration, Connecticut will examine all of the service definitions and existing care management models and strengthen the transition management component for SUD populations between LOCs. DSS, DCF, and DMHAS will create a clear delineation of responsibility for improved coordination and transitions between LOCs to ensure individuals receive appropriate follow-up care following residential treatment.

In addition, to ensure improved care coordination and transitions between LOCs under the Demonstration, Connecticut will also monitor access and health care outcome measures by demographic information, including race and ethnicity. In addition, Connecticut intends to

implement coverage of enhanced individualized care coordination for individuals with SUD that is designed to identify, prevent, and address health inequities and challenges related to social determinants of health.

Population Impacted

This Demonstration will not change the current delivery system structure. All Medicaid services will continue to be delivered through a FFS delivery system. However, as the State will make various improvements to the SUD service system statewide, including aligning with ASAM third edition criteria, analyzing care management initiatives that are available and improving coordination of care, and improving transitions of care. Overall, while continuing to use a FFS delivery system structure, the Demonstration will streamline, clarify, and improve the content of each LOC and improve transitions in the care management system.

Medicaid eligibility requirements will not differ from the approved Medicaid State Plan and all Medicaid members with an assessed SUD treatment need will be impacted by the Demonstration.

Demonstration Evaluation

This Evaluation Design intends to produce a comprehensive and independent evaluation of the original Connecticut 1115 SUD Waiver Demonstration, as described above, that complies fully with Standard Terms and Conditions (STCs) 34 through 45. The Demonstration will evaluate whether the Connecticut Medicaid SUD treatment system is more effective through a provision of a complete coordinated continuum of care using ASAM placement criteria and standards, including SUD residential treatment services. The delivery system reforms are particularly important to address the needs of the Medicaid expansion population, which has historically been underserved.

Connecticut's independent evaluation will measure and monitor the outcomes of the SUD Demonstration. The evaluation will focus on the key goals and milestones of the Demonstration. The researchers will assess the impact of providing the full continuum of SUD treatment services, particularly residential treatment, on hospital ED utilization, inpatient hospital utilization, and readmission rates. Both a midpoint assessment and an interim evaluation at the end of the five-year waiver period will be completed. The evaluation will be designed to demonstrate achievement of the Demonstration's goals, objectives, and metrics. As required by the Centers for Medicare & Medicaid Services (CMS), the Evaluation Design will include the following elements:

- General background information
- Evaluation questions and hypotheses
- Methodology
- Methodological limitations
- Attachments

Section 2 Evaluation Questions and Hypotheses

Evaluation questions and hypotheses to be addressed were derived from and organized based on the Driver Diagrams below. The overall Connecticut Goals of the project are to: 1) Increase enrollee access to and use of appropriate SUD treatment services based on ASAM criteria, 2) Improve quality of care and population health outcomes for Medicaid enrollees with SUD, 3) Improve care coordination and care transitions for Medicaid enrollees with SUD, and 4) Maintain or reduce Medicaid cost of individuals with SUD.

To accomplish these Connecticut Goals, the Demonstration includes several key activities, organized by **primary drivers** of change as they occur in the driver diagrams below:

- Improved access to the most beneficial LOC via a full continuum of available SUD services
- · Improved rates of initiation, engagement, and retention in treatment
- Reduced utilization of EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate
- Reduce readmissions to the same or higher LOC where the readmission is preventable or medically inappropriate
- Improved access to care coordination among beneficiaries, including improved discharge planning and transitions
- · Maintained or reduced costs, where possible

The specific evaluation questions to be addressed were selected based on the following criteria:

- 1. Potential for improvement, consistent with the key milestones of the Demonstration listed above.
- 2. Potential for measurement, including (where possible and relevant) baseline measures that can help to isolate the effects of Demonstration initiatives and activities over time.
- 3. Potential to coordinate with ongoing performance evaluation and monitoring efforts.

Questions were selected to address the Demonstration's major program goals, to be accomplished by Demonstration activities associated with each of the primary drivers. Specific hypotheses regarding the Demonstration's impact are posed for each of these evaluation questions. These are linked to the primary drivers in the diagrams and tables beginning in Section 2 "Driver Diagrams, Research Questions, and Hypotheses," directly following the next section "Targets for Improvement".

Targets for Improvement

The table below outlines the targets for improvement of the SUD waiver, organized by Primary Drivers of change.

Primary Drivers	Targets
Improved access to the most beneficial LOC via a full continuum of available SUD services	Increased use of evidence-based treatment criteria.Ensure sufficient provider capacity.
Increase rates of identification, initiation, engagement, and retention in treatment	 Increased access to critical LOCs for OUD and other SUDs. Improved access for youth through early intervention and SUD treatment in ambulatory ASAM LOC.
Reduced utilization of EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate	 Increased use of Evidence-based SUD Specific Patient Placement Criteria. Increased provider capacity at each LOC, including MAT for SUD/OUD.
Reduced readmissions to the same or higher LOC where the readmission is preventable or medically inappropriate	 Increased use of Evidence-based SUD Specific Patient Placement Criteria. Increased use of comprehensive treatment and prevention strategies to address opioid misuse and OUD.
Improved access to care coordination among beneficiaries, including improved discharge planning and transitions	 Improved care coordination and transitions between LOCs for physical care. Improved discharge planning and continuity of care between providers.
Maintain or reduce Medicaid costs for individuals with SUD, where possible	 The Demonstration will remain budget neutral to the Federal government. Residential services and any other new SUD treatment services including care coordination developed under this Demonstration.

Driver Diagrams, Research Questions, and Hypotheses

The four Connecticut Goals represent the ultimate intentions of the waiver. The primary drivers are strategic improvements necessary to achieve the Connecticut Goals. The secondary drivers describe the interventions (milestones) targeted for improvement in order to achieve the strategic improvements.

These primary and secondary drivers of change are based on the March 2017 CMS letter to State Medical Directors, which outlined the interest of CMS to work with the states "to provide a full continuum of care for people struggling with addiction," and in hearing state-proposed "solutions that focus on improving quality, accessibility, and outcomes in the most cost-effective manner." The letter offered states the flexibility to design 1115 Demonstrations aimed at making significant improvements over the course of a five-year period on the following six goals and six milestones specific to addiction to opioids or other substances.⁶

Goals:

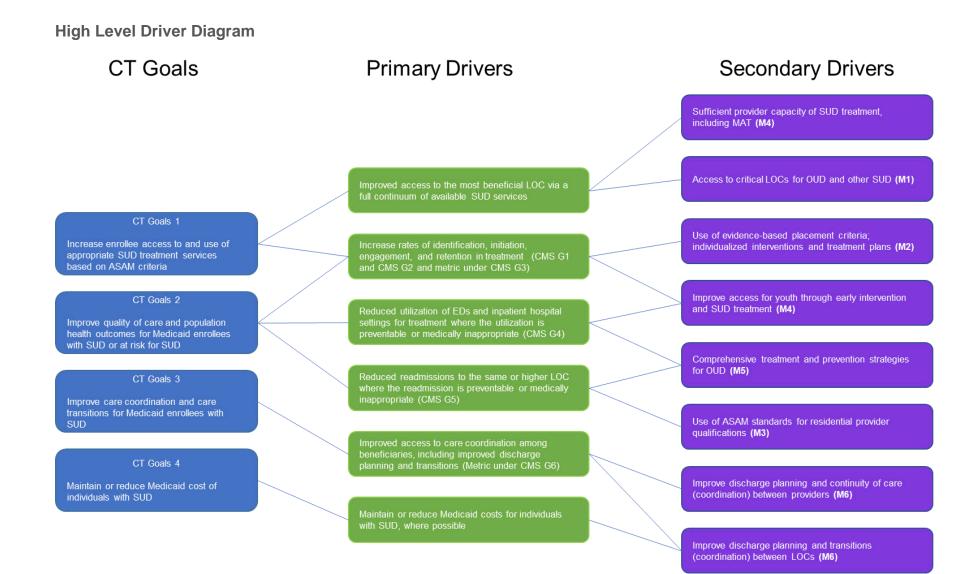
- 1. Increased rates of identification, initiation, and engagement in treatment. (Primary Driver 2)
- 2. Increased adherence to and retention in treatment. (Primary Driver 2)
- 3. Reductions in overdose deaths, particularly those due to opioids. (Metric under Primary Driver 2)
- 4. Reduced utilization of EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services. (Primary Driver 3)
- 5. Fewer readmissions to the same or higher LOC where the readmission is preventable or medically inappropriate. (Primary Driver 4)
- 6. Improved access to care for physical health conditions among beneficiaries. (Metric under Primary Driver 5)

Milestones:

- 1. Access to critical LOCs for OUD and other SUDs.
- 2. Widespread use of evidence-based, SUD-specific patient placement criteria.
- 3. Use of nationally recognized, evidence-based SUD program standards to set residential treatment provider qualifications.
- 4. Sufficient provider capacity at each LOC.
- 5. Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD.
- 6. Improved care coordination and transitions between LOCs.

⁶ State Medicaid Director Letter #17-0003 is available at: https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd17003.pdf.

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Measuring Effects on the Four Connecticut Goals

For the outcome evaluation, select performance measures will be used to demonstrate observed changes in outcomes, using an interrupted time-series (ITS) design where sufficient pre-demonstration data is available, or with pre-post comparisons or comparisons to national benchmarks where sufficient pre-demonstration data is not available. Additional performance measures will be collected to monitor progress on meeting the milestones and project goals. These performance measures are grouped and described under the related primary drivers.

The research design table in Section 3, outlines the research questions and hypotheses of the evaluation, organized by each primary driver.

Section 3 Methodology

Evaluation Design

The evaluation of the Connecticut SUD 1115 Waiver Demonstration will utilize a mixed-methods Evaluation Design with three main goals:

- 1. Describe the progress made on specific Demonstration-supported activities (process/implementation evaluation).
- 2. Demonstrate change/accomplishments in each of the Demonstration milestones (short-term outcomes).
- 3. Demonstrate progress in meeting the overall project goals/Connecticut Goals.

A combination of qualitative and quantitative approaches will be used throughout the evaluation. Qualitative methods will include key informant interviews with DSS, DCF, DMHAS, JB-CSSD, DOC and provider staff, ASOs, and other identified stakeholders regarding Demonstration activities, as well as document reviews of contracts, policy guides, and manuals. Quantitative methods will include descriptive statistics and time series analyses showing change over time in both counts and rates for specific metrics and ITS analysis to assess the degree to which the timing of waiver interventions affect changes across specific outcome measures.

Qualitative analysis will include document review and interviews with key informants. It will identify and describe the SUD service delivery system and changes occurring during the Demonstration for Medicaid enrollees. Each of the milestones will be discussed and documented. This will allow identification of key elements Connecticut intends to modify through the Demonstration and measure the effects of those changes. Using a combination of case study methods, including document review, telephone interviews, and face-to-face meetings, a descriptive analysis of the key Connecticut Demonstration features will be conducted.

The evaluation will analyze how the State is carrying out its implementation plan and track any changes it makes to its initial design as implementation proceeds. Both planned changes that are part of the Demonstration design (e.g., expansion of ASAM) and operational and policy modifications the State makes based on changing circumstances and the creation of a new SPA will be identified. Finally, it is possible that, in some instances, changes in the policy environment in the State will trigger alterations to the original Demonstration implementation plan.

During ongoing communication with the State, detailed information on how Connecticut has implemented each milestone, including how it has structured the submission of a SPA supporting ASAM expansion, identified providers at each ASAM level, implemented PDMP and other Health Information Technology (HIT) changes, and structured care coordination between LOCs for beneficiaries enrolled in the Demonstration, will be collected. The evaluation will analyze the scope of each of these milestones as implemented, the extent to which they conduct these functions Mercer directly or through contract, and internal structures established to promote implementation of the milestones.

Key informant interviews and document reviews will occur at four critical junctures: initially, prior to the mid-point assessment, prior to the interim evaluation report being written, and prior to the final summative evaluation report being finalized.

The key informant interviews will be conducted with staff members in the following departments who are directly responsible for SUD 1115 implementation and operations: DSS, DMHAS, DCF, JB-CSSD, DOC, ASOs, and service providers.

To maximize efficiency in the evaluation, most outcome measures align with performance measures being reported to CMS for each of the six milestones. As the independent evaluator/contractor, Mercer will calculate the quantitative performance measures, according to metrics specifications, and based on data provided by DSS, along with other State agencies, as needed. Mercer is currently receiving monthly transfers of Connecticut's Medicaid Management Information System (MMIS) data, through a Health Insurance Portability and Accountability Act (HIPAA)-compliant secure portal. Mercer is also arranging to receive pre-demonstration detailed claims data on inpatient, residential, and ambulatory SUD services delivered prior to the Demonstration start date. Mercer will calculate all performance measures using the period of time specified in the CMS technical manual (e.g., monthly, quarterly, or annually).

The Demonstration is open to all adult and adolescent (Medicaid and CHIP) non-expansion and expansion members, so a concurrent comparison group of Connecticut Medicaid members is not available. Outcomes will be assessed, where possible, using an ITS quasi-experimental design. The ITS analysis projects metrics derived from a pre-demonstration time period into the post-demonstration implementation time period as a comparison for actual post-demonstration implementation metrics. In cases where there are not enough data points for reliable projects (e.g., annual measures) we will use a basic time series analysis, or pre-post analyses, to describe changes over time.

Target and Comparison Populations

Because there is not an available comparison population, the "comparison population groups" in this design will be a projection of each measure, based on historical data, of what the group would look like in the absence of the Demonstration.

The Target population includes non-expansion and expansion adult and adolescent Medicaid beneficiaries with a SUD diagnosis. Based on Demonstration goals and activities, we do not anticipate that the Demonstration will have *intentional* differential impacts on specific subgroups, except for adolescents, and adolescent girls, as noted in the evaluation table below. However, to account for known long-term disparities in access to care, engagement, and outcomes, we will use some demographic categories as covariates in our analyses. Additionally, some covariates based on OUD diagnosis will be used in examining changes in specific SUD utilization metrics. Other specified subpopulations (e.g., dual eligible, pregnant women, and the criminal justice population) will likely have insufficient data to provide reliable analysis. All members

who are eligible for and/or receive services will be included in all descriptive time series and ITS analysis, so no sampling strategy is needed.

Evaluation Period

The evaluation period is April 1, 2022 through March 31, 2027. The draft SUD Mid-point assessment is due 60 days after March 31, 2025. The Draft Interim Evaluation is due March 31, 2026 or with the extension application. Draft interim results derived from a portion of this evaluation period, April 1, 2022 through June 30, 2023 (with three months run out of claims data) will be reported in the Draft Interim Evaluation Report due to CMS on June 30, 2024. The Draft Summative Evaluation Report analysis will allow for a three-month run out of claims data. Results across this time period will be included in the Draft Summative Evaluation Report due to CMS by June 30, 2027.

Evaluation Measures and Data Sources

The Evaluation Design and evaluation measures are based on sources that provide valid and reliable data that will be readily available throughout the demonstration and final evaluation. To determine if data to be used for the evaluation are complete and accurate, the independent evaluator will review the quality and completeness of data sources (including but not limited to claims for pharmacy, professional, and facility services as well as eligibility data). Example analyses the independent evaluator will use to determine reliability and accuracy of claims data include, but are not limited to: frequency reports, valid values, missing values, date and numerical distributions, and duplicates (part of adjustment logic).

As often as possible, measures in the evaluation have been selected from nationally recognized measure stewards for which there are strict data collection processes and audited results.

The following tables summarize: the primary drivers and hypotheses, process (implementation) and outcome measures for the evaluation, measure steward (if applicable), numerator and denominator definitions where appropriate, types of data (quantitative or qualitative), and data sources.

Mercer will calculate all performance measures for the Demonstration period using claims data from DSS, except for overdose deaths, which is calculated using vital statistics data maintained by DPH.

CONNECTICUT GOAL 1: Increase enrollee access to and use of appropriate SUD treatment services based on ASAM criteria.

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method					
	Primary Driver: Improved access to care via a full continuum of available SUD services. Hypothesis 1: The Demonstration will increase the availability of critical LOCs for Medicaid enrollees.											
Research Question 1.1: Has access to critical LOCs improved in Medicaid?	Submission of SPA to include residential care and to update SUD service standards to align with ASAM standards for each LOC.	N/A	Cumulative for interim reporting period, and for summative reporting period.		None	Key Informant Interviews (DSS, DMHAS, DCF/ JB-CSSD/DOC staff, Medicaid, and DMHAS/DCF ASO representatives; Document Review (ASO policies and procedures, provider addendums, provider review tools)	Thematic analysis of interviews and final SPA.					
	Stakeholder reports of successful implementation and adequate access to each ASAM critical LOC.	N/A	Cumulative for interim reporting period, and for summative reporting period.		None	Key Informant Interviews (DSS, DMHAS/DCF/ JB-CSSD, DOC staff, Medicaid, and DMHAS/DCF ASO representatives;	Thematic analysis of interviews and final SPA. We area also exploring beneficiary focus groups,					

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Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method
						Document Review (ASO policies and procedures, provider addendums, review tools, SPA)	leveraged through existing participatory and advocacy organizations.

Primary Driver: Improved access to care via a full continuum of available SUD services.

Hypothesis 2: The Demonstration will increase the use of residential, MAT, withdrawal management, early intervention, and ambulatory care available by Medicaid enrollees.

Research Question 2.1 Since the development of the 1115 SUD waiver, are more individuals receiving services at critical LOCs when compared to the numbers	Number/percent of beneficiaries who receive prevention or early intervention services (CMS #7).	CMS	Monthly	Number of unique members in the denominator with a service claim for early intervention services (e.g., procedure codes associated with SBIRT).	Members with a SUD diagnosis (CMS #3) for percentage	Claims	ITS; controlling for demographic subgroups
prior to the waiver?	Number/percent of beneficiaries who use outpatient	CMS	Monthly	Number of unique members in the	Members with a SUD diagnosis (CMS #3) for percentage	Claims	ITS; controlling for demographic subgroups

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method
	services (CMS #8).			denominator with a claim for outpatient services for SUD (e.g., outpatient recovery or motivational enhancement therapies, step-down care, and monitoring for stable patients).			
	Number/percent of beneficiaries who use intensive outpatient and partial hospitalization services (CMS #9).	CMS	Monthly	Number of unique members in the denominator with a claim for intensive outpatient and/or partial hospitalization services for SUD (e.g., specialized outpatient SUD	Members with a SUD diagnosis (CMS #3) for percentage	Claims	ITS; controlling for demographic subgroups

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method
				therapy and other clinical services).			
	Number/percent of beneficiaries who use residential and/or inpatient services for SUD (CMS #10).	CMS	Monthly	Number of unique members in the denominator with a service for residential and/or inpatient services for SUD.	Members with a SUD diagnosis (CMS #3) for percentage	Claims	ITS; controlling for demographic subgroups
	Number of beneficiaries who have a claim for MAT for SUD during the measurement period (CMS #12).	CMS	Monthly	Number of unique members in the denominator with a service for MAT services.	Members with a SUD diagnosis (CMS #3) for percentage	Claims	ITS; controlling for demographic subgroups
	Number/percent of beneficiaries who use withdrawal management	CMS	Monthly	Number of unique members in the denominator	Members with a SUD diagnosis (CMS #3) for percentage	Claims Include DMHAS data in numerator for baseline years	ITS; controlling for demographic subgroups

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Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method
	services (CMS #11).			with a service or pharmacy claim for withdrawal management services.			
	Number and length of IMD stays for SUD (CMS #36).	CMS	Yearly	Total number of days in an IMD for inpatient/ residential discharges for SUD.	Total number of discharges from an IMD for beneficiaries with an inpatient or residential treatment stay for SUD.	Claims Include DMHAS data in numerator for baseline years	Descriptive Time Series; pre-post one-way ANCOVA statistic comparing baseline average to post-demonstration average, controlling for demographic subgroups
	mproved access to e Demonstration					services acement criteria by	all providers.
Research Question 3.1: Has the use of evidence-based SUD-specific patient placement criteria (ASAM criteria) been	Number/percent of providers certified at each LOC.	Evaluator, with input from the agency collecting the data	Yearly	Number of providers in the denominator licensed at each LOC.	Total number of SUD providers (CMS #13) for percentage	DMHAS and DCF certification records	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion (for each LOC)

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method
implemented across all LOCs for all patient populations? (Process Question)	Description of activities to monitor provider use of ASAM criteria for patient placement for providers who are certified at higher LOCs, as well as non-certified providers at ASAM .5 and 1 LOCs.	N/A	Cumulative for interim reporting period, and for summative reporting period.		None	Key Informant interviews from Medicaid ASO and DMHAS/DCF ASO staff; aggregate reports from onsite provider monitoring records	Thematic analysis of interviews and documents Medicaid ASO reports on the number of ASAM LOC requested by the provider and either denied or changed by the Medicaid ASO for providers at all LOCs DMHAS/DCF ASO Numeric reports on provider compliance with use of ASAM Placement criteria
	Description of training and technical assistance activities to align providers with new ASAM standards.	N/A	Cumulative for interim reporting period, and for summative reporting period.		None	Key Informant interviews and document review from ASOs and State agency partners	Thematic analysis of interviews and documents Numeric reports on the number of provider staff trained in ASAM

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method				
Primary Driver: Improved access to care via a full continuum of available SUD services. Hypothesis 4: The Demonstration will increase provider capacity for SUD treatment at critical LOCs for individuals in the State.											
Research Question 4.1: Has the availability of providers in Medicaid accepting new patients, including MAT providers, improved under the Demonstration?	Number/percent of Medicaid- accepting providers licensed at each LOC.	Evaluator, with input from the agency collecting the data	Yearly	Number of Medicaid providers in the denominator licensed at each LOC.	Total number of SUD providers (CMS #13) for percentage	Medicaid ASO and DMHAS provider capacity tracking records	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion (for each LOC)				
	Number/percent of beneficiaries receiving any SUD treatment service (CMS #6).	CMS	Monthly	Number of unique members in the denominator receiving at least one SUD treatment service or pharmacy claim during the measurement period.	Number of unique members enrolled in the measurement period (for percentage) Subpopulations: OUD, Age, Dual, Pregnant, and Criminal Justice	Claims	ITS; controlling for demographic subgroups Compare "Received Any Substance Use Treatment in the Past Year" as benchmark if DMHAS data is not available/useable for ITS				
	The number of providers who were enrolled in	CMS	Yearly	Number of providers.	None	Key Informant interviews and document review	Time series				

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Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method
	Medicaid and qualified to deliver SUD services during the measurement period (CMS #13).					from ASOs and State agency partners	
	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period and who meet the standards to provide buprenorphine or methadone as part of MAT (CMS #14).	CMS	Yearly	Number of providers.	None	Key Informant interviews and document review from ASOs and State agency partners	Time series

Primary Driver: Improved access to care via a full continuum of available SUD services.

Hypothesis 5: The Demonstration will improve access and develop capacity for adolescent girls needing SUD residential treatment.

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method
Research Question 5.1: Has access to SUD residential treatment improved for adolescent girls?	Number/percent of adolescent girls enrolled in Medicaid who use residential and/or inpatient services for SUD (CMS #10 — specific subgroup).	CMS	Monthly	Number of unique members in the denominator with a service for residential and/or inpatient services for SUD.	Adolescent (12–17) girls with a SUD diagnosis (CMS #3) for percentage.	Claims Qualitative Interview Have any residential providers been certified to serve adolescent girls	ITS

Primary Driver: Improved access to care via a full continuum of available SUD services.

Hypothesis 6: More adolescent SUD treatment services will be provided at the ambulatory ASAM LOCs.

Research Question 6.1 Will more adolescents be treated for SUD using early identification and ambulatory ASAM LOCs including early access to treatment?	Number/percent of adolescent beneficiaries who receive prevention or early intervention services (CMS #7).	CMS	Monthly	Number of unique members in the denominator with a service claim for early intervention services (e.g., procedure codes associated with SBIRT).	Adolescent (ages 12–17) members with a SUD diagnosis (CMS #3) for percentage	Claims	ITS
	Number/percent of adolescent	CMS	Monthly	Number of unique	Adolescent (ages 12–17)	Claims	ITS

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method	
	beneficiaries who use outpatient services (CMS #8).			members in the denominator with a claim for outpatient services for SUD (e.g., outpatient recovery or motivational enhancement therapies, step-down care, and monitoring for stable patients).	members with a SUD diagnosis (CMS #3) for percentage			
Primary Driver: Increase rates of identification, initiation, engagement, and retention in treatment. Hypothesis 7: The Demonstration will improve rates of identification, initiation, and engagement in treatment.								
Research Question 7.1:	Initiation of Alcohol and	National Committee	Yearly	Number of unique	Number of unique	Claims	Descriptive time series; pre-post chi	

Question 7.1: Has the widespread use of ASAM patient placement criteria resulted in increased	Alcohol and Other Drug (AOD) Abuse or Dependence Treatment (IET-AD) (CMS #15).	Committee for Quality Assurance (NCQA) National Quality Forum	,	unique members in the denominator who initiate treatment through an inpatient AOD	unique members with a new episode of AOD abuse or dependence	series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion
rates of				admission,		

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Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method
identification, initiation, and engagement in treatment for members with SUD diagnoses?		(NQF) #0004		outpatient visit, intensive outpatient visit or partial hospitalization, telehealth, or medication treatment within 14 days of the diagnosis.			Compare to CMS Medicaid Adult Core Set national median as benchmark if pre-demonstration data is not available/ useable
	Engagement of AOD Abuse or Dependence Treatment (IET-AD) (CMS #15).	NCQA NQF #0004	Yearly	Number of unique members in the denominator who were engaged in ongoing AOD treatment within 34 days of the initiation visit.	Number of unique members with a new episode of AOD abuse or dependence and initiated treatment	Claims	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion Compare to CMS Medicaid Adult Core Set national median as benchmark if pre-demonstration data is not available/ useable

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method		
Primary Driver: Improved access to the most beneficial LOC via a full continuum of available SUD services. Hypothesis 8: The Demonstration will improve access and develop capacity for adolescent girls needing SUD residential treatment.									
Research Question 8.1: Did more adolescent girls receive residential SUD treatment as a result of the Demonstration?	Number/percent of adolescent female beneficiaries who use residential and/or inpatient services for SUD (CMS #10).	CMS	Monthly	Number of unique members in the denominator with a service for residential and/or inpatient services for SUD.	Adolescent female members with a SUD diagnosis (CMS #3) for percentage	Claims Qualitative Interview Have any residential providers been certified to serve adolescent girls	ITS; controlling for demographic subgroups		

CONNECTICUT GOAL 2: Improve quality of care and population health outcomes for Medicaid enrollees with SUD.

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method	
Primary Driver: Reduced utilization of EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate Hypothesis 9: The 1115 SUD Demonstration will decrease the rate of ED and hospital use among Medicaid enrollees with SUD.								
Research Question 9.1: What is the impact of the Demonstration on ED	ED Utilization for SUD per 1,000 Medicaid Beneficiaries (CMS #23).	CMS	Monthly	Number of ED visits for SUD.	All Medicaid members	Claims	ITS; controlling for demographic subgroups	

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method
utilization by Medicaid enrollees with SUD?							
Research Question 9.2: Did inpatient stays decrease after implementation of UM?	Inpatient Stays for SUD per 1,000 Medicaid Beneficiaries (CMS #24).	CMS	Monthly	Number of inpatient stays for SUD.	All Medicaid members	Claims Include DMHAS data in numerator for baseline years	ITS; controlling for demographic subgroups

Primary Driver: Reduced utilization of EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate

Hypothesis 10: The 1115 SUD Demonstration will lead to lower hospitalization readmission rates for enrollees with SUD.

Research question 10.1: Did readmissions to the same or higher LOC, where readmission is preventable or medically inappropriate for OUD and other SUD, decrease?	Readmissions Among Beneficiaries with SUD (CMS #25).	CMS	Yearly	Acute hospital admissions from the denominator with at least one acute readmission for any diagnosis within 30 days of discharge.	Acute hospital admissions for members with SUD diagnosis	Claims	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion
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Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method				
•	Primary Driver: Increase rates of identification, initiation, engagement, and retention in treatment . Hypothesis 11: Enrollees with SUD will have fewer opioid-related overdose deaths.										
Research question 11.1: Did comprehensive treatment and prevention strategies correspond to a reduction in overdose deaths and activities that support overdose death reduction?	Overdose Deaths (rate) (CMS#27).	Evaluator, with input from the agency collecting the data	Yearly	Number of Medicaid members with overdose as cause of death.	All Medicaid members	State data on cause of death	Descriptive time series (data ID's Medicaid members? Possible ITS); pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion Also compare to National Center for Health Statistics national drug overdose death rate as benchmark				

CONNECTICUT GOAL 3: Improve care coordination and care transitions for Medicaid enrollees with SUD.

Research		Measure					
question	Measure	Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method

Primary Driver: Improved access to care coordination among beneficiaries, including improved discharge planning and transitions

Hypothesis 12: The 1115 SUD Demonstration will increase the rate of Medicaid enrollees with SUD-related conditions who are also receiving primary/ambulatory care.

Research Question 12.1: What is the impact of the Demonstration on the integration of physical and BH care among Medicaid enrollees with SUD and co-morbid conditions?	Access to Preventive/ Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD (AAP) (Adjusted Healthcare Effectiveness Data and Information Set [HEDIS] measure) (CMS #32).	NCQA	Yearly	Number of unique members with SUD with an ambulatory or preventative care visit.	Number of unique members with a SUD diagnosis (CMS #4)	Claims	Descriptive time series; pre-post chi square test of significance comparing baseline proportion to post-demonstration period proportion
Research Question 12.2 Has the Demonstration impacted access to care for individuals	Follow-Up After ED Visit for AOD Abuse or Dependence (FUA-AD) (CMS #17-1).	NCQA	Yearly	Number of ED visits for members in the denominator who had a follow-up visit	Number of ED visits for members with a principal diagnosis of AOD abuse or dependence.	Claims	Descriptive time series; pre-post one-way ANCOVA comparing baseline average to post-demonstration average, controlling

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method
with SUD by linking beneficiaries with community- based services and supports following ED				for AOD abuse or dependence within: 30 days 7 days			for demographic subgroups Also compare to CMS Medicaid Adult Core Set national median as benchmark
visits and reducing readmission rates for hospital stays?	Follow-Up After ED Visit for Mental Illness (FUM-AD) (CMS #17-2). Follow-Up After Hospital Admission for Mental Illness	NCQA	Yearly	Number of ED visits for members with a principal diagnosis of mental illness or intentional self-harm and who had a follow-up visit for mental illness within: 30 days 7 days	Number of ED visits for members with a principal diagnosis of mental illness or intentional self-harm	Claims	Descriptive time series; pre-post one-way ANCOVA comparing baseline average to post-demonstration average, controlling for demographic subgroups Also compare to CMS Medicaid Adult Core Set national median as benchmark

Primary Driver: Increase rates of identification, initiation, engagement, and retention in treatment. **Hypothesis 13: Medicaid IMD providers will demonstrate consistency in program design and discharge planning policies.**

Research question 13.1: Did IMD providers improve program design and discharge planning policies? (Process Question)	Description of training and technical assistance activities to align providers with new ASAM standards.	N/A	Cumulative for interim reporting period, and for summative reporting period.		None	Key Informant interviews and document review with SUD providers	Thematic analysis of interviews and documents
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CONNECTICUT GOAL 4: Maintain or reduce Medicaid cost of individuals with SUD.

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method		
Primary Driver: Maintain or reduce Medicaid costs for individuals with SUD, where possible									
Hypothesis 14: The Demonstration will be budget neutral to the Federal government. Hypothesis 15: Total Medicaid SUD spending during the measurement period will remain constant after adjustment for the new residential services and any other new SUD treatment services including care coordination developed under this Demonstration.									
Research Question 14.1: Will Medicaid maintain or decrease	SUD Spending (CMS #28).	CMS		The sum of all Medicaid spending on SUD treatment services.	None	Claims Use provider paid amounts	Descriptive time series		

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method
overall costs after accounting for the newly added residential and withdrawal management	SUD Spending within IMDs (CMS #29).	CMS	Yearly	The sum of all Medicaid spending on inpatient/ residential treatment for SUD provided within IMDs.	None	Claims Use provider paid amounts	Descriptive time series
services?	Per Capita SUD Spending (CMS #30).	CMS	Yearly	The sum of all Medicaid spending on SUD treatment services (CMS #28).	Members with a SUD diagnosis (CMS #4)	Claims Use provider paid amounts	Descriptive time series; pre-post one-way ANCOVA statistic comparing baseline average to post-demonstration average, controlling for demographic subgroups
	Per Capital SUD Spending within IMDs (CMS #31).	CMS	Yearly	The sum of all Medicaid spending on inpatient/ residential treatment for SUD provided within IMDs (CMS #29).	Number of members with a claim for inpatient/ residential treatment for SUD in an IMD	Claims Use provider paid amounts	Descriptive time series; pre-post one-way ANCOVA statistic comparing baseline average to post-demonstration average, controlling for demographic subgroups

Research question	Measure	Measure Steward	Time Period	Numerator	Denominator ^a	Data Sources	Analytic Method
	Total Cost PMPM	CMS SUD Evaluation Design Guidance, Appendix C	·	The sum of all Medicaid spending (Inpatient, Outpatient, Pharmacy, Long Term Care, Capitation payments, Administrative Costs, Federal Costs) for members with a SUD diagnosis	Member months per quarter for members with a SUD diagnosis	Claims Use provider paid amounts CMS 64 for Federal Costs Data source for administrative costs:	ITS; controlling for demographic subgroups

Analytic Methods

Multiple analytic techniques will be used, depending on the type of data for the measure and the use of the measure in the Evaluation Design (e.g., process measure versus outcome measures). Descriptive, content analysis will be used to present data related to process evaluation measures gathered from document reviews, key informant interviews, etc., as discussed previously. Qualitative analysis software (R Qualitative, ATLAS, or similar) will be used to organize documentation, including key informant interview transcripts. Analysis will identify common themes across interviews and documents. In some cases, checklists may be used to analyze documentation (e.g., licensure) for compliance with standards. These data will be summarized in order to describe the activities undertaken for each project milestone, including highlighting specific successes and challenges.

Descriptive statistics including frequency distributions and time series (presentation of rates over time) will be used for quantitative process measures in order to describe the output of specific waiver activities. These analysis techniques will also be used for some short-term outcome measures in cases where the role of the measure is to describe changes in the population, but not to show specific effects of the waiver Demonstration. Where pre-demonstration and post-demonstration rates are comparable, pre-post distributional test will be made to quantify statistical differences in process measures before and after the demonstration.

An ITS will be used to describe the effects of waiver implementation in metrics that are measured on a monthly or quarterly basis. Specific outcome measure(s) will be collected for multiple time periods both before and after start of intervention. Segmented regression analysis will be used to measure statistically the changes in level and slope in the post-intervention period (after the waiver) compared to the pre-intervention period (before the waiver). The ITS design will be dependent on being able to use similar historical data on specific outcome measures collected from DSS based on SUD services provided prior to the Demonstration. The ITS design uses historical data to forecast the "counterfactual" of the evaluation, that is to say, what would happen if the Demonstration did not occur. We propose using basic time series linear modeling to forecast these "counterfactual" rates for three years following the Demonstration implementation.⁷ The more historical data available, the better these predictions will be. ITS models are commonly used in situations where a contemporary comparison group is not available.⁸ The State has considered options for a contemporary comparison group. Since the Demonstration will target all adult and adolescent non-expansion and expansion Medicaid members in need of SUD services, the only viable groups for comparison within the State would be those covered with private insurance, which would include a very different demographic population.

For this Demonstration, establishing the counterfactual is somewhat nuanced. The driver diagram and evaluation hypotheses assume that Demonstration activities will have overall positive impacts on outcome measures. The figure below illustrates an

⁷ E Kontopantelis (2015). Regression based quasi-experimental approach when randomisation is not an option: interrupted time series analysis. British Medical Journal (BMJ). Available at: <u>https://www.bmj.com/content/350/bmj.h2750</u>.

⁸ Ibid.

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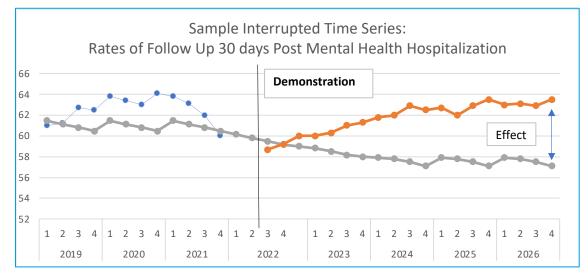
ITS design that uses basic regression forecasting to establish the counterfactual — this is represented by the grey line in the graphic. The counterfactual is based on historical data (the blue line). It uses time series averaging (trend smoothing) and linear regression to create a predicted trend line (shown below as the grey line). The orange line in the graph is the (sample) actual observed data. Segmented regression analysis will be used to measure statistically the changes in level and slope in the post-intervention period compared to the predicted trend (see "effect" in the graph below).

 $\mathbf{Y}_{t} = \beta_{0} + \beta_{1}\mathbf{T} + \beta_{2}\mathbf{X}_{t} + \beta_{3}\mathbf{T}\mathbf{X}_{t}$

Where β_0 represents the baseline observation, β_1 is the change in the measure associated with a time unit (quarter or year) increase (representing the underlying pre-intervention trend), β_2 is the level change following the intervention and β_3 is the slope change following the intervention (using the interaction between time and intervention: TX_t).⁹

This can be represented graphically as follows.





Pre-demonstration data from January 1, 2018 to March 30, 2022 will be calculated using the monthly, quarterly, or annual period of time as specified in the CMS technical specifications for each metric. Trends in these data for each measure will be used to predict the counterfactual (what would have happened without the Demonstration). Outcomes measures will be calculated beginning April 1, 2022 through the end of the waiver Demonstration project (March 31, 2027). A discussion of including confounding variables (e.g., COVID-19, other SUD efforts) is included in the next section.

⁹ Bernal JL, Cummins S, Gasparrini A. "Interrupted time series regression for the evaluation of public health interventions: a tutorial" (2017 Feb.). International Journal of Epidemiology 46(1): 348-355. Mercer

Quantitative outcome measures with yearly measurement periods that are expressed as averages or proportions will be analyzed with pre-post tests. While two or three pre-demonstration measurement periods for yearly metrics may not be enough information to establish a trend for the ITS analysis, pre-post analyses may reveal differences in outcomes before and after the Demonstration. One-way analysis of covariance, or t-tests will be used to compare pre-demonstration averages with post-demonstration averages, and chi-square tests will be used to compare proportions.

Qualitative analysis will utilize data collected from three main sources: 1) key informant interviews with State staff working on implementation efforts, ASO representatives, and providers, 2) key process documentation (e.g., policy and procedure manuals, guidance documents), and 3) provider addendums. Informant sampling will be largely based on convenience/snowball sampling where key stakeholders provide initial lists of potential interviewees, based on their perspective on Demonstration implementation activities. Meeting minutes listing attendees will also be reviewed to identify potential interviewees. ASO staff and provider staff will also be included. Because this likely will be a large number of people, the independent evaluator will work with the State to determine whether to conduct focus groups with these populations, or to engage in a strategic stratified sampling process. The latter will ensure representation across the industry, and from providers stratified by geography/location, size, and services provided. Document reviews will include meeting minutes, policy and procedure documents, provider contracts, and others identified during the qualitative analysis process. Themes will be identified by multiple coders who review documents, identify initial themes, then collaborate in the creation of a central list of primary and secondary themes.

Key informant interviews and document reviews will occur at four critical junctures: initially, prior to the mid-point assessment, prior to the interim evaluation report being written, and prior to the final summative evaluation report being finalized. Specifically, the initial qualitative analysis will occur October 2024–December 2024. The second qualitative analysis will occur October 2025–December 2025. The third qualitative analysis will occur April 2027–June 2027 if the waiver is not renewed.

Section 4 Methodological Limitations

There are two primary limitations to the evaluation methodology presented here. The first involves issues of data quality and data sources that either: 1) are not sufficient to conduct the analysis proposed here (e.g., not enough historical data for needed prior time periods), or 2) contain errors. An additional limitation is related to the design itself because this evaluation plan relies heavily on descriptive, time series analysis, and qualitative data, this evaluation will describe what happened after the Demonstration was implemented, but it will be difficult to isolate why changes occurred. In other words, it will be difficult to directly attribute changes after waiver implementation to the activities undertaken as part of the waiver. Each of these limitations is discussed in greater detail within this section.

Some of the metrics being computed by Mercer will be calculated for the historic period using non-Medicaid data for residential services. Both Mercer and the Department are working closely to request and test extracts of pre-demonstration data. While it is unclear at this time the degree to which it will be possible to generate historical data needed to forecast the slope of the "counterfactual" trend line (what would have happened without the Demonstration), Mercer has access to this historical data and utilized it in the past. This historical data is an important component of the ITS design, but also supports the descriptive time series analysis. In particular, there will be a limitation in estimating the slope of what the trend line would be without the Demonstration if the data is not sufficient to model what would have happened without implementation.

While the ITS design is the strongest available research method, in the absence of a randomized trial or matched control group, there are some threats to the validity of results in the design.¹⁰ The primary threat is that of history, or other changes over time happening during the waiver period. This ITS design is only valid to the extent that the Demonstration program was the only thing that changed during the evaluation period. Other changes to policies or programs could affect the outcomes being measured under the Demonstration. Mercer will attempt to control this threat by considering other policy and program changes happening concurrent to the waiver period interventions. At a minimum, we will use qualitative methods, in the form of key informant interviews, to identify other initiatives or events may have occurred during the Demonstration that might influence Demonstration effects. Mercer will conduct a gualitative assessment of these likely impacts and will use time series analysis to show how trends may have changed at these critical time periods. In order to isolate the effects of these efforts, Mercer will also conduct additional iterations of the ITS. Using identified critical time points as additional variables, we will test whether other major efforts had a statistically significant impact in the post-demonstration waiver trend. The analysis will note the

¹⁰ Penfold RB, Zhang F. "Use of interrupted time series analysis in evaluating heath care quality improvements." Academic Pediatrics, 2013 Nov-Dec, 13(6Suppl): S38-44.

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dates of other changes and analyze the degree to which the slope of the trend line changes after implementation of other interventions are made.

The impact of COVID-19 most likely affected the pre-demonstration period, and Mercer anticipates a statically significant impact on most metrics. Therefore, in the initial forecasting within the ITS model, the independent evaluator will include a COVID-19 covariant for the start of the pandemic in the forecast model. Essentially, the ITS for this evaluation will create two counterfactual scenarios using historical data. Mercer will create a "without" COVID-19 forecast using historical data only prior to March of 2020 as one potential counterfactual to compare against actual trends. If we can establish sufficient data points between March 2020 and the waiver start date of April 2022, we can estimate the COVID-19 impact on the forecast. Mercer will also create a forecast with data through the pre-demonstration period (up to January 2021) that includes data during the times COVID-19 was prevalent in the State. As long as COVID-19 remains prevalent during the Demonstration period, we anticipate that using the "with COVID-19" model as the counterfactual will be more accurate. Additional covariate time periods can be added to the model if there are significant shifts in either COVID-19 prevalence numbers or policy shifts (e.g., new stay at home orders) in the State. Mercer will also qualitatively explore how COVID-19 impacted the implementation of the waiver, based on data from key informant interviews.

A related threat to the validity of this evaluation is external (history such as the pandemic). Because we have not identified a comparison group (a group of Medicaid members who would be eligible for the waiver interventions but who will not receive them and/or for whom data will not be collected), it will be difficult to attribute causality. It will be less certain whether the changes observed in outcomes are due entirely to the waiver interventions, rather than some external, outside cause (including other program and policy changes described earlier). However, the ITS design controls for this threat to some degree, by linking what would have likely happened (e.g., forecasting the trajectory of counts and rates over time) without any program changes and comparing this forecast to actual changes over time. To strengthen this design as much as possible, as many data points will be collected as possible across multiple years preceding waiver changes. This will allow for adjustment of seasonal or other, cyclical variations in the data. Additionally, the design will examine multiple change points and identifying key areas of major program and policy adjustments, so that with each major milestone accomplishment, corresponding changes to metrics can be observed

The ITS analysis will also include a sensitivity analysis to determine the degree to which specific ITS assumptions impact the analysis. Specifically, the degree to which the assumption that trends in time are linear versus non-linear will be addressed. Additionally, this model assumes that changes will occur directly after the intervention. However, it is possible that for some outcomes, there will be a lag between the start of the waiver and observed outcomes.

Mercer will also attempt to limit this threat to validity by triangulating our data. Claims data trends across multiple time periods will be compared to trends happening at other points in time (other large policy or program shifts that might influence the slope of the trend in addition to the demonstration). Also, key informant interviews will be used to inform the quantitative findings and explain the degree to which individuals are seeing

demonstration impacts. Mercer will also attempt to seek out national and other State data for benchmarking, that will allow us to determine whether Connecticut is performing in a similar fashion to other demonstration states, non-demonstration states, or national benchmarks overall.

According to the literature on ITS analysis, estimating the level and slope parameters requires a minimum of eight observations before and after implementation in order to have sufficient power to estimate the regression coefficients.¹¹ Evaluators will need to work closely with the DSS, DMHAS, and their respective data teams to gather as many data points as possible and discuss limitations within the evaluation findings if enough points cannot be collected.

It should also be noted that ITS cannot be used to make inferences about any one individual's outcomes as a result of the waiver. Conclusions can be drawn about changes to population rates, in aggregate, but not speak to the likelihood of any individual Medicaid member having positive outcomes as a result of the waiver.

Qualitative data, while useful in confirming quantitative data and providing rich detail, can be compromised by individual biases or perceptions. Key informant interviews, for example, represent a needed perspective around context for Demonstration activities and outcomes. However, individuals may be limited in their insight or understanding of specific programmatic components, meaning that the data reflects perceptions, rather than objective program realities. The evaluation will work to address these limitations by collecting data from a variety of different perspectives to help validate individuals' reports. In addition, standardized data collection protocols will be used in interviews and interviewers will be trained to avoid "leading" the interviewee or inappropriately biasing the interview. It will also utilize multiple "coders" to analyze data and will create a structured analysis framework, based on research questions that analysts will use to organize the data and to check interpretations across analysts. Finally, results will be reviewed with stakeholders to confirm findings.

¹¹ Ibid. Mercer

Section 5 Attachments

As part of the STCs, as set forth by CMS, the Demonstration project is required to arrange with an independent party to conduct an evaluation of the SUD Demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. Mercer, through a request for proposal (RFP) process, contracts to provide technical assistance to DSS, including this independent evaluation work.

Mercer was selected as the waiver evaluator. Mercer will develop the Evaluation Design, calculate the results of the study, evaluate the results for conclusions, and write the Interim and Summative Evaluation Reports.

Mercer has over 25 years of experience assisting state governments with the design, implementation, and evaluation of publicly sponsored health care programs. Mercer currently has over 25 states under contract and has worked with over 35 different states in total. They have assisted states like Arizona, Connecticut, Missouri, and New Jersey in performing independent evaluations of their Medicaid programs; many of which include 1115 Demonstration waiver evaluation experience. Given their extensive experience, the Mercer team is well equipped to work effectively as the external evaluator for the Demonstration project. The table below includes contact information for the lead coordinators from Mercer for the evaluation:

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Charles Lassiter	Engagement Leader	charles.lassiter@mercer.com
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Tonya Aultman-Bettridge, PhD	Evaluator	taultman-bettridge@triwestgroup.net
Laurie Klanchar, RN, MSN	Clinician	laurie.klanchar@mercer.com
Brenda Jackson, MPP	Specialty Consulting Sector	brenda.jackson@mercer.com

Appendix A Conflict of Interest Statement

Connecticut (DSS) has taken steps to ensure that Mercer is free of any conflict of interest and will remain free from any such conflicts during the contract term. DSS considers it a conflict if Mercer currently 1) provides services to ASOs or health care provider doing business in Connecticut under the Health First Connecticut program; or 2) provides direct services to individuals in DSS or DMHAS-administered programs included within the scope of the technical assistance contract. If DSS discovers a conflict during the contract term, DSS may terminate the contract pursuant to the provisions in the contract.

Mercer's Government specialty practice does not have any conflicts of interest, such as providing services to any MSOs or health care providers doing business in Connecticut under the Connecticut program or to providing direct services to individual recipients. One of the byproducts of being a nationally operated group dedicated to the public sector is the ability to identify and avoid potential conflicts of interest with our firm's multitude of clients. To accomplish this, market space lines have been agreed to by our senior leadership. Mercer's Government group is the designated primary operating group in the Medicaid space.

Before signing a contract to work in the Medicaid market, either at the state-level or otherwise, we require any Mercer entity to discuss the potential work with Mercer's Government group. If there is a potential conflict (i.e., work for a Medicaid health plan or provider), the engagement is not accepted. If there is a potential for a perceived conflict of interest, Mercer's Government group will ask our state client if they approve of this engagement, and we develop appropriate safeguards such as keeping separate teams, restricting access to files, and establish process firewalls to avoid the perception of any conflict of interest. If our client does not approve, the engagement will not be accepted. Mercer has collectively turned down a multitude of potential assignments over the years to avoid a conflict of interest.

Given that Mercer is acting as both technical assistance provider and independent evaluator for this project, DSS and Mercer have implemented measures to ensure there is no perceived conflicts of interest. This contract was awarded following a competitive bidding process that complied with all Connecticut State laws, the Mercer evaluation team (TriWest) is functionally and physically separate from the technical assistance team, and the contract does not include any performance incentives that would contribute to a perception of conflicted interests between technical assistance services and the independence of the evaluation process. As an additional firewall, the evaluation statistical analyses will be conducted by a subcontractor that has not had any interaction with the technical assistance team, using data that has been reviewed and accepted by CMS (through monitoring protocol submissions).

In regards to Mercer's proposed subcontractors, all have assured Mercer there will be no conflicts and that they will take any steps required by Mercer or DSS to mitigate

any perceived conflict of interest. To the extent that we need to implement a conflict mitigation plan with any of our valued subcontractors, we will do so.

Mercer, through our contract with DSS, has assured that it presently has no interest and will not acquire any interest, direct or indirect, which would conflict in any manner or degree with the performance of its services. Mercer has further assured that in the performance of this contract, it will not knowingly employ any person having such interest. Mercer additionally certified that no member of Mercer's Board or any of its officers or directors has such an adverse interest.

Appendix B Evaluation Budget

	DY 1	DY2	DY3	DY4	DY5	Final Evaluation	Total Evaluation Cost	
	2021	2022	2023	2024 2025		6/30/2027	Total Evaluation Cost	
State of Connecticut								
DSS	\$100,000*	\$50,000**	\$50,000	\$50,000	\$50,000	\$50,000	\$350,000	

*Estimates based on 1) Demonstration Year 1 (DY1) data infrastructure and data sharing protocol build between Departments and vendor; and 2) staff review of DY1 deliverables.

**Estimates for DY2–DY5 based on State of Connecticut review of annual, ongoing deliverables.

Evaluation Budget — Independent Evaluator/Contractor — Mercer Hours								
	Senior Consultant	Junior Consultant	Consultant	Project Management	Total Hours			
Evaluation Activities								
Develop and draft Evaluation Design	288	72		30	390			
Revise drafted Evaluation Design	28	7			35			
Draft Interim Evaluation report	72	18		26	116			
Finalize Interim Evaluation report	40	10			50			
Draft Summative Evaluation report	92	23		26	141			
Finalize Summative Evaluation report	40	10			50			

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Evaluation Budget — Independent Evaluator/Contractor — Mercer Hours									
	Senior Consultant	Junior Consultant	Consultant	Project Management	Total Hours				
Data Activities									
Load, validate, and scrub raw data — Evaluation measures for Annual reports.		250	250	10	510				
Load, validate, and scrub raw data — Evaluation measures for Interim and Final Evaluation report	148	148	35		331				
File mapping to standardize file format — Evaluation measures for Annual reports.	100	195	100	10	405				
File mapping to standardize file format — Evaluation measures for Interim and Final Evaluation report		128	128	10	266				
Initial programming/validation of code for measure development — Evaluation measures (37)	88	10	88		186				
Run and validate programming/coding for each measure, generate the measures — Evaluation measures for annual reports. (10 measures; 40 hours/year; 10 PM)		100	100	10	210				
Statistical measures for the evaluation: Interim and Final report (300 hours/report)	100	250	250	10	610				
Final Total:					3,300				

Evaluation Budget — Independent Evaluator/Contractor — Mercer Costs									
	FY1 – DY1	FY2 – DY1, 2	FY3 – DY2, 3	FY4 – DY3, 4	FY5 – DY4, 5	FY6 – DY5	FY7 – DY6	FY8	Total Cost
Evaluation Activities									
Develop and draft Evaluation Design	\$115,140								\$ 115,140
Revise drafted Evaluation Design		\$10,465							\$ 10,465
Draft Interim Evaluation report					\$33,410				\$ 33,410
Finalize Interim Evaluation report						\$14,950			\$ 14,950
Draft Summative Evaluation report							\$40,885		\$ 40,885
Finalize Summative Evaluation report								\$14,950	\$ 14,950
Data Activities									
Load, validate, and scrub raw data — Evaluation measures for Annual reports.		\$27,750	\$27,750	\$27,750	\$27,750	\$27,750			\$ 138,750
Load, validate, and scrub raw data — Evaluation measures for Interim and Final Evaluation report (190 hours initial		\$52,975		\$30,263			\$30,263		\$ 113,50 ⁷

Evaluation Budget — Independent Evaluator/Contractor — Mercer Costs									
	FY1 – DY1	FY2 – DY1, 2	FY3 – DY2, 3	FY4 – DY3, 4	FY5 – DY4, 5	FY6 – DY5	FY7 – DY6	FY8	Total Cost
File mapping to standardize file format — Evaluation measures for Annual reports.		\$44,163	\$17,650	\$17,650	\$17,650	\$17,650			\$ 114,763
File mapping to standardize file format — Evaluation measures for Interim and Final Evaluation report				\$34,694		\$34,694			\$ 69,388
Initial programming/validation of code for measure development — Evaluation measures (37)		\$172,744							\$ 172,744
Run and validate programming/coding for each measure, generate the measures — Evaluation measures for Annual reports.		\$12,600	\$12,600	\$12,600	\$12,600	\$12,600			\$ 63,000

Evaluation Budget — Independent Evaluator/Contractor — Mercer Costs									
	FY1 – DY1	FY2 – DY1, 2	FY3 – DY2, 3	FY4 – DY3, 4	FY5 – DY4, 5	FY6 – DY5	FY7 – DY6	FY8	Total Cost
Statistical measures for the evaluation: Interim and Final report				\$78,250		\$78,250			\$ 156,500
Final Total:									\$ 1,058,446

Appendix C Potential Timeline and Major Deliverables

The table below highlights key evaluation milestones and activities for the waiver and the dates for completion.

Deliverable	STC Reference	Date
Submit evaluation design plan to CMS	36	October 11, 2022
Final evaluation design due 60 days after comments received from CMS	36	60 days after comments received from CMS
Mid-point assessment due	29	No later than 60 days after March 31, 2025
Draft Interim Report due	40	March 31, 2026
Final Interim Report due 60 days after CMS comments received	40(d)	60 days after comments received from CMS
Draft Summative Evaluation Report due 18 months following demonstration	41	Within 18 months after March 31, 2027 if the waiver is not renewed
Final Summative Evaluation Report due 60 days after CMS comments received	41(a)	60 days after comments received from CMS



Mercer Health & Benefits LLC

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