

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



September 30, 2022

Teresa Miller
Secretary
Pennsylvania Department of Human Services
625 Forster Street, Room 333
Harrisburg, PA 17120

Dear Secretary Miller:

The Centers for Medicare & Medicaid Services (CMS) is approving Pennsylvania's request to extend the demonstration project entitled, "Medicaid Coverage for Former Foster Care Youth from a Different State and Substance Use Disorder (SUD) Demonstration" (Project Number: 11-W-00308/3), in accordance with section 1115(a) of the Social Security Act (the Act). This approval is effective October 1, 2022 through September 30, 2027. Approval of this demonstration extension request will enable the state to continue to receive federal financial participation (FFP) for state plan services provided to otherwise-eligible Medicaid beneficiaries who are primarily receiving treatment and withdrawal services for SUD while residing in institutions for mental diseases (IMD). Additionally, the demonstration enables Pennsylvania to continue to provide Medicaid coverage to out-of-state former foster care youth under age 26 who were in foster care under the responsibility of another state or tribe in such other state when the individual reached the age of 18 years old (or such higher age as the state has elected for termination of federal foster care assistance under title IV-E of the Social Security Act (the Act)), were enrolled in Medicaid at that time, and are now applying for Medicaid in Pennsylvania.

CMS's approval of the section 1115(a) demonstration is subject to the limitations specified in the attached waiver and expenditure authorities, special terms and conditions (STC), and any supplemental attachments defining the nature, character, and extent of federal involvement in this demonstration project. The state may deviate from Medicaid and CHIP state plan requirements only to the extent those requirements have been specifically listed as waived or not applicable under the demonstration.

The goals of this demonstration are to increase and strengthen coverage of former foster care youth and improve health outcomes for this vulnerable population as well as provide access to high quality, evidence-based SUD treatment services covering critical levels of care including outpatient, intensive outpatient, medication assisted treatment (MAT), residential, inpatient, and medically supervised withdrawal management.

Specifically, the demonstration is expected to maintain the continuum of services to treat addiction to opioids and other substances, including services provided to Medicaid enrollees with SUD who are short-term residents in residential and inpatient treatment facilities that meet the definition of an IMD and who receive services via managed care.

In addition, the extension will continue Medicaid coverage for out-of-state former foster care youth under age 26 who were in foster care under the responsibility of another state or tribe in such other state when the former foster youth reached age 18 years old. Section 1001(a)(2) of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (referred to hereafter as the SUPPORT Act) amends Medicaid coverage requirements for the state plan former foster care children eligibility group only for individuals who turn age 18 on or after January 1, 2023, effective January 1, 2023. This statutory change will require states, when determining eligibility under the state plan, to recognize the former foster care status of individuals who aged out of foster care from another state than where they currently live and are applying for Medicaid. However, Pennsylvania will need to maintain section 1115 demonstration authority to provide coverage to former foster care youth from other states who reached age 18 prior to January 1, 2023.

Consideration of Public Comments

To increase the transparency of demonstration projects, sections 1115(d)(1) and (2) of the Social Security Act (the Act) direct the Secretary of HHS to issue regulations providing for two periods of public comment on a state's application for a section 1115 demonstration that would result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing. The first comment period occurs at the state level before submission of the section 1115 application, and the second comment period occurs at the federal level after the application is received by the Secretary. Section 1115(d)(2)(A) and (C) of the Act further specifies that comment periods should be "sufficient to ensure a meaningful level of public input," but the statute imposed no additional requirement on the states or the Secretary to provide individualized responses to address those comments, as might otherwise be required under a general rulemaking. Accordingly, the implementing regulations issued in 2012 at 42 C.F.R. § 431.416(d)(2) provide that CMS will review and consider all comments received by the deadline, but will not provide individualized written responses to public comments.

During the federal comment period, which took place from April 12, 2022 through May 12, 2022, CMS received two comments. One commenter expressed support for the demonstration extension and praised the state for the development of programs that support the vulnerable populations that the demonstration covers (former foster care youth and persons with SUD).

The other commenter opposed the demonstration extension for various reasons, including making an argument that the IMD exclusion cannot be waived. Section 1115(a)(2) of the Act grants the Secretary the authority, in the context of a demonstration project under 1115(a), to provide federal matching of state expenditures that would not otherwise be federally matchable under the terms of section 1903. Specifically, with respect to state expenditures under a section 1115 "demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of [Medicaid]," expenditures that would "not otherwise" be matchable

under 1903 may “be regarded as expenditures under the State plan or plans approved under such title, or for administration of such State plan or plans . . . as may be appropriate.” This “expenditure authority” has been exercised by the Secretary for decades to conduct demonstration projects that provide coverage to individuals or services that could not otherwise be covered under a Medicaid state plan. This has allowed the Secretary to expand eligibility for benefits to individuals who would not otherwise be eligible, and for services that would not otherwise be covered. This interpretation has been upheld in court as a valid exercise of the Secretary’s demonstration authority under section 1115. For example, federal courts have upheld demonstration projects that covered individuals under section 1115(a)(2) who would not otherwise be eligible for coverage, and imposed cost-sharing obligations on these individuals that would not be permissible under the Medicaid statute.¹

The commenter also expressed concerns that authorizing FFP for services provided in IMDs could risk diverting resources away from community-based services and would undermine community integration efforts for beneficiaries with SUD. Nothing in this demonstration requires that services be provided to any individual in any particular setting, nor does it limit the availability of community-based settings. In fact, findings from the state’s interim evaluation of the SUD component of this demonstration show broad success at both increasing access to early intervention, MAT, and other outpatient services and decreasing reliance on residential treatment.

The commenter expressed the view that Pennsylvania has not presented a valid hypothesis that would justify approval. Pennsylvania has presented valid hypotheses that align with the SUD demonstration guidance in SMD #17-003.² As required under all section 1115 demonstrations, Pennsylvania will be required to submit an evaluation design for the renewal period that conforms with CMS SUD 1115 demonstration evaluation guidance, to include specific hypotheses that will be tested.

The commenter also shared concerns about how long the SUD demonstrations are approved. As explained in the SUD SMDL, CMS has determined that these demonstrations promote the objectives of Medicaid and states, like Pennsylvania, should have the opportunity to extend the demonstrations. Pennsylvania has been testing several hypotheses, including whether the demonstration increases access to SUD services, improves follow-up care after discharge from emergency departments and decreases readmissions.³ As noted above, Pennsylvania must submit an evaluation design within 180 days of the extension approval for CMS review and approval.

Finally, the commenter also raised concerns about the length of stay in IMDs. The STCs, Implementation Plan, and Monitoring Protocol require the state to report on length of stays to ensure short-term residential treatment stays.

After carefully reviewing the demonstration extension proposal and the public comments submitted during the federal comment period, CMS has concluded that the demonstration is

¹ *Spry v. Thompson*, 487 F.3d 1272 (9th Cir. 2007); *Wood v. Betlach*, No. CV-12-08098, 2013 WL 3871414 (D. Ariz. July 26, 2013).

² Available at: <https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd17003.pdf>

³ Pennsylvania SUD Interim Evaluation Report.

likely to assist in promoting the objectives of Medicaid as it is expected to improve access to medical assistance services, including high quality OUD/SUD care.

Other Information

Consistent with CMS requirements for section 1115 demonstrations, and as outlined in the STCs, the state is required to conduct systematic monitoring and robust evaluation of the demonstration. Throughout the life-cycle of the demonstration approval period, monitoring will help track the state's progress towards its demonstration milestones and goals. The state will continue monitoring the SUD components of the demonstration through Quarterly and Annual Monitoring Reports that will include quantitative and qualitative data. Additionally, the state will develop an Evaluation Design for this demonstration approval period by incorporating well-crafted hypotheses, research questions, and analyses that support understanding the demonstration's impact on beneficiary coverage, access to and quality of care, and health outcomes. The state will contract with an independent evaluator to conduct the demonstration's Interim and Summative Evaluations, in alignment with the approved Evaluation Design, to assess whether the demonstration initiatives are effective in producing the desired outcomes for beneficiaries and the state's Medicaid program overall. Likewise, the state will also have an independent assessor conduct an independent Mid-Point Assessment of the demonstration's progress toward its SUD goals, outlining any necessary mitigation strategies. The state and CMS will work collaboratively such that the state's demonstration monitoring and evaluation efforts accommodate data collection and analyses stratified by key subpopulations of interest—to the extent feasible—to inform a fuller understanding of existing disparities in access, utilization, quality, and health outcomes, as well as how the demonstration might support bridging any such inequities.

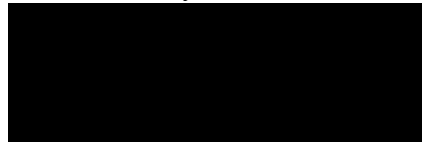
CMS's approval of this demonstration project is contingent upon compliance with the enclosed expenditure authority and the STCs defining the nature, character, and extent of anticipated federal involvement in the demonstration. The award is subject to our receiving your written acknowledgement of the award and acceptance of these STCs within 30 days of the date of this letter.

The project officer for this demonstration is Mr. Felix Milburn. He is available to answer questions concerning your section 1115 demonstration. Mr. Milburn's contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop S2-25-26
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Email: Felix.Milburn@cms.hhs.gov

We appreciate your state’s commitment to providing health coverage to the people in Pennsylvania, and we look forward to our continued partnership on the Pennsylvania Medicaid Coverage for Former Foster Care Youth from a Different State and SUD section 1115(a) demonstration. If you have any questions regarding this approval, please contact Ms. Judith Cash, Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (410) 786-9686.

Sincerely,



Deputy Administrator and Director

Enclosure

cc: Dan Belnap, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES

SECTION 1115 DEMONSTRATION WAIVER AUTHORITY

DEMONSTRATION NUMBER: 11-W-00308/3

DEMONSTRATION TITLE: Medicaid Coverage for Former Foster Care Youth from a Different State and SUD Demonstration

DEMONSTRATION AWARDEE: Pennsylvania Department of Human Services

Under the authority of section 1115(a)(1) of the Social Security Act (the Act) the following waivers are granted to enable implementation of the “Medicaid Coverage for Former Foster Care Youth from a Different State” section 1115(a) demonstration. These waivers are effective beginning October 1, 2022 and are limited to the extent necessary to achieve the objectives below. These waivers may only be implemented consistent with the approved Special Terms and Conditions (STCs) set forth in the accompanying document.

All requirements of the Medicaid program expressed in law, regulation and policy statement, not expressly waived in this list or identified as not applicable in the accompanying expenditure authority and/or the approved STCs, shall apply to this demonstration project for the period beginning October 1, 2022 through September 30, 2027. This waiver authority does not apply to the SUD component of the demonstration.

Title XIX Waiver Authority

1. Provision of Medical Assistance

Section 1902(a)(8) and 1902(a)(10)

To the extent necessary to permit the Commonwealth of Pennsylvania to limit the provision of medical assistance (and treatment as eligible) for individuals described in the eligibility group under section 1902(a)(10)(A)(ii)(XX) of the Act and the Medicaid State Plan to only former foster care youth who are under 26 years of age, were in foster care under the responsibility of another state or tribe on the date of attaining 18 years of age (or such higher age as the state has elected), and who were enrolled in Medicaid on that date.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SECTION 1115 DEMONSTRATION EXPENDITURE AUTHORITY

NUMBER: 11-W-00308/3

TITLE: Medicaid Coverage for Former Foster Care Youth from a Different State and SUD Demonstration

AWARDEE: Pennsylvania Department of Human Services

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Pennsylvania (the state) for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from October 1, 2022, through September 30, 2027, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

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

1. **Residential and Inpatient Treatment Services for Individuals with Substance Use Disorder (SUD).** Expenditures for Medicaid state plan services furnished to otherwise eligible individuals enrolled in managed care who are primarily receiving treatment and/or withdrawal management services for SUD who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD) as described in STC 5.6.

CENTERS FOR MEDICARE & MEDICAID SERVICES

SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00308/3

TITLE: Medicaid Coverage for Former Foster Care Youth from a Different State and Substance Use Disorder Demonstration

AWARDEE: Pennsylvania Department of Human Services

1. PREFACE

The following are the Special Terms and Conditions (STCs) for the Pennsylvania Former Foster Care Youth from a Different State and Substance Use Disorder (SUD) section 1115(a) Medicaid demonstration (hereinafter referred to as “demonstration”). The parties to this agreement are the Pennsylvania Department of Human Services (“Pennsylvania” or “the state”) and the Centers for Medicare & Medicaid Services (CMS). The STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and Pennsylvania’s obligations to CMS during the life of the demonstration. The STCs are effective October 1, 2022 through September 30, 2027 (the approval period) unless otherwise specified.

The amended STCs have been arranged into the following subject areas:

1. Preface
2. Program Description and Objectives
3. General Program Requirements
4. Eligibility, Benefits, and Budget Neutrality for the FFCY Component of the Demonstration
5. Pennsylvania Substance Use Disorder (SUD) Component of the Demonstration
6. Cost Sharing
7. Delivery Systems
8. Monitoring and Reporting Requirements
9. General Financial Requirements
10. Monitoring Budget Neutrality for the Demonstration
11. Evaluation of the Demonstration
12. Schedule of Deliverables

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

Attachment A: Template for Annual Operational Reports
Attachment B: Developing the Evaluation Design for SUD
Attachment C: Preparing the Interim and Summative Evaluation Reports
Attachment D: Evaluation Design (reserved)

2. PROGRAM DESCRIPTION AND OBJECTIVES

This section 1115(a) demonstration enables Pennsylvania to provide Medicaid coverage to out-of-state former foster care youth under age 26 who were in foster care under the responsibility of another state or tribe in such other state when they turned 18 (or such higher age as the state has elected for termination of federal foster care assistance under title IV-E of the Social Security Act (the Act)), were enrolled in Medicaid at that time, and are now applying for Medicaid in Pennsylvania. In addition to the FFCY program, the demonstration enables the Commonwealth of Pennsylvania to provide high quality, clinically appropriate SUD treatment services for short-term residents in residential and inpatient treatment settings that qualify as an institution for Mental Diseases (IMD).

The objectives of the Former Foster Care Youth (FFCY) demonstration component are to increase and strengthen overall coverage of former foster care youth and improve health outcomes for this population.

2018 Substance Use Disorder (SUD) Amendment

Through the SUD/opioid use disorder (OUD) amendment effective July 1, 2018, Pennsylvania received authority to provide high quality, clinically appropriate SUD treatment services for short-term residents in residential and inpatient treatment settings that qualify as Institutions for Mental Diseases (IMD). This component is continued during this approval period to maintain critical access to opioid use disorder (OUD) and other SUD services and continue delivery system improvements for these services to provide more coordinated and comprehensive OUD/SUD treatment for Medicaid beneficiaries. The demonstration will continue to build on the state's existing efforts to improve models of care focused on supporting individuals in the community and home, outside of institutions and strengthen a continuum of SUD services based on the American Society of Addiction Medicine (ASAM) criteria or other nationally recognized assessment and placement tools that reflect evidence based clinical treatment guidelines.

The state will continue to test whether this SUD expenditure authority is likely to assist in promoting the objectives of Medicaid by achieving the following results:

1. Increased rates of identification, initiation, and engagement in treatment;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced 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;
5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; and
6. Improved access to care for physical health conditions among beneficiaries.

3. GENERAL PROGRAM REQUIREMENTS

- 3.1. **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).
- 3.2. **Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program expressed in federal law, regulation, and policy statement not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.
- 3.3. **Changes in Medicaid Law, Regulation, and Policy.** The state must, within the timeframes specified in the applicable federal law, regulation, or written policy, come into compliance with changes in law, regulation, or policy affecting the Medicaid program 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 3.7. CMS will notify the state 30 calendar days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.
- 3.4. **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 3.7 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.
- 3.5. **State Plan Amendments.** The state will not be required to submit title XIX state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population covered through the Medicaid 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 state plan governs.

- 3.6. **Changes Subject to the Amendment Process.** Demonstration changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS through an approved amendment to the Medicaid state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 3.7 below, except as provided in STCs 3.3.
- 3.7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit 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 3.12. 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 though the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the “with waiver” expenditure total as result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
 - d. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the Evaluation Design and annual progress reports will be modified to incorporate the amendment provisions, as
- 3.8. **Extension of the Demonstration.** If the state intends to request an extension of the demonstration it must submit an application to CMS from the Governor of the state in accordance with the requirements of 42 CFR §431.412(c). States that do not intend to request

an extension of the demonstration beyond the period authorized in these STCs must submit a phase-out plan consistent with the requirements of STC 3.9.

- 3.9. **Demonstration Phase Out.** The state may only suspend or terminate this demonstration, in whole or in part, consistent with the following requirements:
- a. **Notification of Suspension or Termination.** The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with the requirements of STC 3.12, 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. **Transition and Phase-out Plan Requirements.** The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct redeterminations of Medicaid eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.
 - c. **Transition and Phase-out Plan Approval.** The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.
 - d. **Transition and Phase-out Procedures.** The state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e). The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206 through 431.214. 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.

- e. **Exemption from Public Notice Procedures 42 CFR §431.416(g).** CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
- f. **Enrollment Limitation during Demonstration Phase-out.** If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.
- g. **Federal Financial Participation (FFP).** If the project is terminated or any relevant waivers 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.

3.10. **Withdrawal of Waiver or Expenditure Authority.** CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX. 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.

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

3.12. **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 submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates. The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or contained in the

state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 3.7 or extension, are proposed by the state.

- 3.13. **Federal Financial Participation (FFP).** No federal matching 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.
- 3.14. **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.
- 3.15. **Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid program – including public benefit or service programs, procedures for obtaining Medicaid benefits or services, possible changes in or alternatives to Medicaid programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. 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).

4. ELIGIBILITY, BENEFITS, AND BUDGET NEUTRALITY FOR THE FFCY COMPONENT OF THE DEMONSTRATION

- 4.1. **Eligibility for the FFCY Component.** Individuals eligible for the FFCY demonstration component are limited to “out-of-state former foster care youth” who are defined as youth under age 26 who were in foster care under the responsibility of a state other than Pennsylvania or a tribe in such other state when they turned age 18 (or such higher age as the state has elected for termination of federal foster care assistance under title IV-E of the Act), were enrolled in Medicaid at that time, are now applying for Medicaid in Pennsylvania, and are not otherwise eligible for Medicaid.
- 4.2. **Benefits and Cost-sharing provided under the FFCY Component.** Out-of-state former foster care youth ages 18, 19 or 20 will receive the same Medicaid State Plan benefits as set forth in the State Plan for all other beneficiaries under 21 years of age (i.e., Children). Out-of-state former foster care youth ages 21 to 26 will receive the same Medicaid State Plan benefits as set forth in the State Plan for beneficiaries 21 years of age and older (i.e., Adults). Out-of-state former foster care youth aged 18 to 26 will be subject to the same cost-sharing requirements and exclusions as set forth in the State Plan for the eligibility group under which the individual is enrolled in accordance with their age (i.e., Children or Adults).

- 4.3. **FFCY State Plan Amendment.** Section 1002 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (“the SUPPORT Act”) (Pub. L. 115-271) makes certain changes to Medicaid eligibility for former foster care youth, including a requirement to cover former foster care youth from other states. For individuals who turn age 18 and age out of foster care on or after January 1, 2023, the mandatory group for former foster care children under section 1902(a)(10)(A)(i)(IX) of the Act will cover otherwise eligible former foster care youth from any state.
- 4.4. **Budget Neutrality for FFCY.** CMS has determined that the FFCY component of the demonstration is budget neutral based on CMS’ assessment that the waiver authorities granted for the FFCY demonstration component are unlikely to result in any increase in federal Medicaid expenditures, and that no expenditure authorities are associated with the FFCY component of the demonstration. The FFCY demonstration component will not include a budget neutrality expenditure limit, and no further test of budget neutrality will be required for the FFCY component. Accordingly, the state will not be allowed to obtain budget neutrality “savings” from the FFCY demonstration component. All expenditures associated with the FFCY population (with the exception of SUD IMD expenditures) will be reported on the CMS-64 base form(s) for Medicaid State Plan populations in accordance with section 2500 of the State Medicaid Manual.

CMS reserves the right to request a budget neutrality analysis for the FFCY demonstration component from the state if the state seeks a change to the demonstration pursuant to STCs 3.6 and 3.7 that may impact costs associated with the FFCY demonstration component.

5. PENNSYLVANIA SUBSTANCE USE DISORDER (SUD) COMPONENT OF THE DEMONSTRATION

- 5.1. **Eligibility Groups Affected by the Demonstration.** All affected groups derive their eligibility through the Medicaid state plan, and are subject to all applicable Medicaid laws and regulations in accordance with the Medicaid state plan.
- 5.2. **Opioid Use Disorder/Substance Use Disorder Program.** The demonstration benefit package for Pennsylvania Medicaid recipients includes OUD/SUD services provided in residential and inpatient treatment settings that qualify as an IMD as specified below, which are not otherwise matchable expenditures under section 1903 of the Act. The state is eligible to receive FFP for Pennsylvania Medicaid recipients residing in IMDs under the terms of this demonstration for coverage of medical assistance, including OUD/SUD benefits that would otherwise be matchable if the beneficiary were not residing in an IMD. Pennsylvania will aim for a statewide average length of stay of 30 days in residential treatment settings, to be monitored pursuant to the SUD Monitoring Protocol as outlined in Attachment F below, to ensure short-term residential treatment stays. Under this demonstration component, beneficiaries will have access to high-quality, evidence-based OUD and other SUD treatment services ranging from medically supervised withdrawal management to ongoing chronic care for these conditions in cost-effective settings while also improving care coordination and care for comorbid physical and mental health conditions.

The coverage of OUD/SUD inpatient, residential treatment and withdrawal management services in IMDs expands Pennsylvania’s current OUD/SUD benefit package available to all Pennsylvania Medicaid recipients as outlined in the table below. Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

Pennsylvania SUD Benefits Coverage with Expenditure Authority		
SUD Benefit	Medicaid Authority	Expenditure Authority
Outpatient Services	State plan (Individual services covered)	
Intensive Outpatient Services	State plan (Individual services covered)	
Partial Hospitalization	1915(b)	
Medication-Assisted Treatment (MAT)	State plan	Services provided to individuals in IMDs
Residential Treatment	1915(b)	Services provided to individuals in IMDs
Medically Supervised Withdrawal Management	1915(b)	Services provided to individuals in IMDs
Inpatient	State plan (Individual services covered)	Services provided to individuals in IMDs
Recovery Supports Services	1915(b)	Services provided to individuals in IMDs

Pennsylvania attests that the services indicated in Table 1, above, as being covered under the Pennsylvania Medicaid state plan and 1915(b) authority are currently covered in the Pennsylvania Medicaid state plan and 1915(b) authority.

- 5.3. **SUD Implementation Plan.** The state’s SUD Implementation Plan, initially approved for the period from July 1, 2018 through September 30, 2022, remains in effect for the approval period from October 1, 2022 through September 30, 2027, and is affixed to the STCs as Attachment E. Any future modifications to the approved Implementation Plan will require CMS approval. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral. The approved SUD Implementation Plan describes 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 of this SUD demonstration project:

- a. **Access to Critical Levels of Care for OUD and other SUDs:** Service delivery for new benefits, including residential treatment and withdrawal management, within 12-24 months of OUD/SUD program demonstration approval;
- b. **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 comparable assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of OUD/SUD program demonstration approval;
- c. **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 SUD program demonstration approval;
- d. **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 Preferred Provider Substance Use Disorder Treatment Standards of the Vermont Department of Health's Division of Alcohol and Drug Abuse Programs. The state will 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 comparable, 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 OUD/SUD program demonstration approval;
- e. **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 SUD program demonstration approval;
- f. **Standards of Care:** Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of SUD program demonstration approval;
- g. **Sufficient Provider Capacity at each Level of Care including Medication-assisted Treatment for OUD:** An assessment of the availability of providers in the key levels of care throughout the state, or in the regions of the state participating under this

demonstration, including those that offer MAT, within 12 months of SUD program demonstration approval;

- h. **Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and 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;
- i. **SUD Health IT Plan:** Implementation of the milestones and metrics as detailed in STC 5.3; and
- j. **Improved Care Coordination and Transitions between Levels of Care:** Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of SUD program demonstration approval.

5.4. **SUD Mid-Point Assessment.** The state will contract with an independent entity to conduct a mid-point assessment by September 30, 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 addition, if applicable, the state should use the prior approval period experiences as context, and conduct the Mid-Point Assessment in light of the data from any such prior approval period(s). In the design, planning and conduction of the mid-point assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: SUD treatment providers, beneficiaries, and other key partners.

The state must require that the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than sixty (60) days after September 30, 2025. The state must brief CMS on the report. The state must submit a revised Mid-Point Assessment Report within 60 calendar days after receipt of CMS's comments, if any.

For milestones and measure targets at medium to high risk of not being achieved, the state will submit to CMS modifications to the SUD Implementation Plan and SUD Monitoring Protocol for ameliorating these risks subject to CMS approval. Elements of the Mid-Point Assessment include:

- a. An examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plans and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol,
- b. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date,

- c. A determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets,
- d. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state’s SUD Implementation Plan or to pertinent factors that the state can influence that will support improvement, and
- e. An assessment of whether the state is on track to meet the budget neutrality requirements.

5.5. **SUD Health Information Technology (Health IT).** The state has provided CMS with an assurance that it has a sufficient health IT infrastructure/“ecosystem” at every appropriate level (i.e. state, delivery system, and individual provider) to achieve the goals of the demonstration—or it will submit to CMS a plan to develop the infrastructure/capabilities. This “SUD Health IT Plan,” or assurance is included as a section of the state’s approved “Implementation Plan” (see STC 5.3), which remains in effect for the approval period from October 1, 2022 through September 30, 2027, and is affixed to the STCs as Attachment E. The SUD Health IT Plan will 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 SUD health IT ecosystem improvement.

- a. The SUD Health IT section of the Implementation Plan will include implementation milestones and dates for achieving them.
- b. The SUD Health IT Plan must be aligned with the state’s broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state’s Behavioral Health (BH) “Health IT” Plan.
- c. The SUD Health IT Plan will describe the state’s goals, each DY, to enhance the state’s prescription drug monitoring program’s (PDMP).¹
- d. The SUD Health IT Plan will address how the state’s PDMP will enhance ease of use for prescribers and other state and federal stakeholders.² This will also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan will 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

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

² *Ibid.*

- prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.
- e. The SUD 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 SUD 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.
 - f. The SUD Health IT Plan will describe how the activities described in (a) through (e) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.³
 - g. In developing the Health IT Plan, states should use the following resources:
 - i. States may use resources at Health IT.Gov (<https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/>) in “Section 4: Opioid Epidemic and Health IT.”
 - ii. States may also use the CMS 1115 Health IT resources available on “Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability” at <https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html>. States should review the “1115 Health IT Toolkit” for health IT considerations in conducting an assessment and developing their Health IT Plans, found at <https://www.healthit.gov/topic/advancing-interoperability-medicaid>.
 - iii. 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 plans and, more generally, to meet the goals of the demonstration
 - h. The state will include in its SUD Monitoring Protocol (see Attachment F an approach to monitoring its SUD Health IT Plan which will include performance metrics provided by CMS or State defined metrics to be approved in advance by CMS.
 - i. The state will monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in an addendum to its Annual Reports (see STC 8.8).

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

- j. 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.
- k. Where there are opportunities at the state and provider levels (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state should use the federally recognized standards, barring another compelling state interest.
- l. Where there are opportunities at the state and provider levels 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.

5.6. **Residential Treatment Services.** Treatment services delivered to residents of an institutional care setting, including facilities that meet the definition of an institution for mental diseases (IMD), are provided to Pennsylvania Medicaid recipients with a SUD diagnosis when determined to be medically necessary by the Behavioral Health Managed Care Organization (BH-MCO) utilization review staff and in accordance with an individualized service plan.

- a. Residential treatment services are provided in an Pennsylvania Department of Drug and Alcohol Programs (DDAP)-licensed facility that has been enrolled as a Medicaid provider and assessed by DDAP as delivering care consistent with ASAM or other nationally recognized, SUD-specific program standards for residential treatment facilities.
- b. Residential treatment services can be provided in settings of any size.
- c. The implementation date for residential treatment services is July 1, 2018.
- d. Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

Covered services include:

- a. Clinically-directed therapeutic treatment to facilitate recovery skills, relapse prevention, and emotional coping strategies.
- b. Addiction pharmacotherapy and drug screening;
- c. Motivational enhancement and engagement strategies;
- d. Counseling and clinical monitoring;

- e. Withdrawal management and related treatment designed to alleviate acute emotional, behavioral, cognitive, or biomedical distress resulting from, or occurring with, an individual's use of alcohol and other drugs;
- f. Regular monitoring of the individual's medication adherence;
- g. Recovery support services;
- h. Counseling services involving the beneficiary's family and significant others to advance the beneficiary's treatment goals, when (1) the counseling with the family member and significant others is for the direct benefit of the beneficiary, (2) the counseling is not aimed at addressing treatment needs of the beneficiary's family or significant others, and (3) the beneficiary is present except when it is clinically appropriate for the beneficiary to be absent in order to advance the beneficiary's treatment goals; and,
- i. Education on benefits of medication assisted treatment and referral to treatment as necessary.

6. COST SHARING

- 6.1. **Cost Sharing.** Cost sharing imposed upon individuals under the demonstration is consistent with provisions of the approved state plan.

7. DELIVERY SYSTEMS

- 7.1. Enrollees enrolled in this demonstration will receive services through the state's managed care delivery system.

8. MONITORING AND REPORTING REQUIREMENTS

- 8.1. **Monitoring Calls.** CMS will convene periodic conference calls with the state.
 - a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to), any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, budget neutrality, the status of investment submissions, 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.
- 8.2. **Post-Award Forum.** Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state shall afford the public with

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

- 8.3. **Submission of Post-Approval Deliverables.** The state shall submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.
- 8.4. **Compliance with Federal Systems Innovation.** As federal systems continue to evolve and incorporate 1115 waiver reporting and analytics functions, the state shall 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, Transformed Medicaid Statistical Information System (T-MSIS), and other data elements that have been agreed to for reporting and analytics are provided by the state; and
 - c. Submit all deliverables to the appropriate system as directed by CMS.
- 8.5. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in the amount of \$5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as “deliverable(s)”) are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

The following process will be used: 1) thirty (30) days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) thirty (30) days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

- a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
- b. For each deliverable, the state may submit 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 described below can

be provided. CMS may agree to a corrective action as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.

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

8.6. Deferral of Federal Financial Participation (FFP) from IMD claiming for Insufficient Progress Towards 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 Protocol 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.

8.7. SUD Monitoring Protocol. The state must submit an updated Monitoring Protocol for the SUD programs authorized by this demonstration within one hundred fifty (150) calendar days after approval of the demonstration. The Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. The state must submit a revised Monitoring Protocol within sixty (60) calendar days after receipt of CMS's comments. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs, as Attachment F. 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 5.3 and reporting relevant information to the state's Health IT plan described in STC 5.3(i);

- 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 12 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.

8.8. **Quarterly and Annual Monitoring Reports.** The state must submit three (3) Quarterly Monitoring Reports and one (1) compiled 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) days following the end of each demonstration quarter. The compiled Annual Monitoring Report (including the fourth quarter information) is due no later than ninety (90) days following the end of the DY. The state must submit a revised Monitoring Report within sixty (60) calendar days after receipt of CMS's 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 Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

- a. **Operational Updates.** 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 operational and other challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. 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. **Performance Metrics.** Per applicable CMS guidance and technical assistance, the performance metrics will provide data to support tracking the state's progress towards meeting the demonstration's annual goals and overall targets as will be identified in the approved SUD Monitoring Protocol, and will cover key policies under this demonstration.

Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and

access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, and 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. **Budget Neutrality and Financial Reporting Requirements.** Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on the CMS-64.
- d. **Evaluation Activities and Interim Findings.** Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.
- e. **SUD Health IT.** The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 5.5(d).

8.9. **Corrective Action Plan Related to Demonstration 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. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS will withdraw an authority, as described in STC 3.10, when metrics indicate substantial, sustained directional change, inconsistent with state targets and goals, as applicable, and the state has not implemented corrective action. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

9. GENERAL FINANCIAL REQUIREMENTS

9.1. **Allowable Expenditures.** This demonstration project is approved for expenditures applicable to services rendered during the demonstration approval period designated by CMS. CMS will

provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.⁴

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

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

- 9.4. **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 for purposes of Title XIX must be made in an amount not to exceed the non-federal share of title XIX payments and any payment derived from a proper IGT is not contingent upon receipt of the IGT.
 - 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.
 - f. The State Medicaid Director or his/her designee certifies that all state and/or local funds used as the state's share of the allowable expenditures reported on the CMS-64

for this demonstration were in accordance with all applicable federal requirements and did not lead to the duplication of any other federal funds.

9.5. 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 managed care organization, prepaid inpatient health plan (PIHP), and prepaid ambulatory health plan (PAHP) payments comply with all requirements on payments in 42 CFR §438, including 438.6(b)(2), 438.6(c), 438.6(d), 438.60 and/or 438.74.

9.6. Requirements for health care related taxes and provider donations. As a condition of demonstration approval, the state attests to the following, as applicable:

- a. 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.

9.7. State Monitoring of Non-Federal Share. No later than 60 days after demonstration approval, the state must provide a report to CMS regarding payments under the demonstration specifying that payments under the demonstration are funded all or in part by a locality tax, if the state operates any locality taxes that constitute any non-federal share for the demonstration. This requirement also applies, effective upon initiation of a locality tax, if the state initiates a new locality tax for non-federal share of the demonstration. This report must include:

- a. Any agreement written or otherwise regarding the arrangement among the providers with counties, the state or other entities for each locality tax;
- b. Number of hospitals in each locality of the taxing entities for each locality tax;
- c. Whether or not all hospitals will be paying the assessment for each locality tax;

- d. The assessment rate that the hospitals will be paying for each locality tax;
- e. Whether any hospitals that pay the assessment will not be receiving payments funded by the assessment;
- f. Number of hospitals that receive at least the total assessment back in the form of Medicaid payments for each locality tax;
- g. The monitoring plan for the taxing arrangement to ensure that the tax comply with section 1903(w)(4) of the Social Security Act and 42 CFR 433.68(f); and
- h. Information on whether the state will be reporting the assessment on the CMS form 64.11A as required under Section 1903(w) of the Act.
- i. This deliverable is subject to the deferral as described in STC 8.5.

9.8. **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 10:

- a. Administrative costs, including those associated with the administration of the demonstration;
- b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
- c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third-party liability.

9.9. **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.

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

Master MEG Chart					
MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description
SUD IMD TANF: Substance Use Disorder, Institution for Mental Disease, Temporary Assistance for Needy Families	Hypo 1	X		X	Expenditures for individuals who are inpatients in an IMD under terms of the demonstration for any day during the month.
SUD IMD SSI Duals – NFCE: Substance Use Disorder, Institution for Mental Disease, Supplemental Security Duals, who are Nursing Facility Care Eligible	Hypo 1	X		X	Expenditures for individuals who are nursing facility eligible and inpatients in an IMD under terms of the demonstration for any day during the month.
SUD IMD SSI Duals – NFI: Substance Use Disorder, Institution for Mental Disease, Supplemental Security Income Duals, who are Nursing Facility Ineligible.	Hypo 1	X		X	Expenditures for an individuals who are not nursing facility eligible but are inpatients in an IMD under terms of the demonstration for any day during the month.
SUD IMD SSI Non-Duals: Substance Use Disorder, Institution for Mental Disease, Supplemental Security Income for Non-Duals	Hypo 1	X		X	Expenditures for individuals who are inpatients in IMDs under terms of the demonstration for any day during the month.
SUD IMD HCE: Substance Use Disorder, Institution for Mental Disease,	Hypo 1	X		X	Expenditures for individuals who are inpatients in IMDs under terms of the

Master MEG Chart					
MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description
HealthChoice Expansion					demonstration for any day during the month.

- 9.11. **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-00194/1). 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 payment associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.
- a. **Cost Settlements.** The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b, in lieu of lines 9 or 10c. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.
 - b. **Premiums and Cost Sharing Collected by the State.** The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by DY on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.
 - c. **Pharmacy Rebates.** Because pharmacy rebates are included in the base expenditures used to determine the budget neutrality expenditure limit, the state must report the portion of pharmacy rebates applicable to the demonstration on the appropriate forms CMS-64.9 WAIVER and 64.9P waiver for the demonstration, and not on any other CMS-64.9 form (to avoid double counting). The state must have a methodology for assigning a portion of pharmacy rebates to the demonstration in a way that reasonably reflects the actual rebate-eligible pharmacy utilization of the demonstration

- population, and which identifies pharmacy rebate amounts with DYs. Use of the methodology is subject to the approval in advance by the CMS Regional Office, and changes to the methodology must also be approved in advance by the Regional Office. Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.
- d. **Administrative Costs.** The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the Master MEG Chart table, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.
 - e. **Member Months.** As part of the Quarterly and Annual Monitoring Reports described in section 8.8, the state must report the actual number of “eligible member months” for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. The term “eligible member months” refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.
 - f. **Budget Neutrality Specifications Manual.** The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state’s Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 or 64.10 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
SUD IMD TANF	Report expenditures for costs of medical assistance that could be covered for TANF individuals, were it not for the IMD prohibition under the state plan, provided to otherwise eligible individuals during a month in an IMD.	n/a	Follow CMS 64.9 Base Category of Service Definitions	Date of service	MAP	Y	07/01/18	09/30/27
SUD IMD SSI Duals	Report expenditures for costs of medical assistance	n/a	Follow CMS 64.9 Base Category of Service Definitions	Date of service	MAP	Y	07/01/18	09/30/22

MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 or 64.10 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
	that could be covered for SSI dual eligible individuals, were it not for the IMD prohibition under the state plan, provided to otherwise eligible individuals during a month in an IMD.							
SUD IMD SSI Duals NFCE	Report expenditures for costs of medical assistance that could be covered for SSI dual eligible	n/a	Follow CMS 64.9 Base Category of Service Definitions	Date of service	MAP	Y	10/01/22	09/30/27

MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 or 64.10 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
	individuals who are nursing facility care eligible, were it not for the IMD prohibition under the state plan, provided to otherwise eligible individuals during a month in an IMD.							
SUD IMD SSI Duals – NFI	Report expenditures for costs of medical assistance that could be covered for SSI dual eligible	n/a	Follow CMS 64.9 Base Category of Service Definitions	Date of service	MAP	Y	10/01/22	09/30/27

MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 or 64.10 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
	individuals who are not nursing facility care eligible, were it not for the IMD prohibition under the state plan, provided to otherwise eligible individuals during a month in an IMD.							
SUD IMD SSI Non-Duals	Report expenditures for costs of medical assistance that could be covered for SSI individuals	n/a	Follow CMS 64.9 Base Category of Service Definitions	Date of service	MAP	Y	07/01/18/	09/30/27

MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 or 64.10 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
	who are not dual eligibles, were it not for the IMD prohibition under the state plan, provided to otherwise eligible individuals during a month in an IMD.							
SUD IMD HCE	Report expenditures for costs of medical assistance that could be covered for Health Choices Expansion (Adult	n/a	Follow CMS 64.9 Base Category of Service Definitions	Date of service	MAP	Y	07/01/18	09/30/27

MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 or 64.10 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
	Group) eligibles, were it not for the IMD prohibition under the state plan, provided to otherwise eligible individuals during a month in an IMD.							

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

Demonstration Years		
Demonstration Year 6	October 1, 2022 to September 30, 2023	12 months
Demonstration Year 7	October 1, 2023 to September 30, 2024	12 months
Demonstration Year 8	October 1, 2024 to September 30, 2025	12 months
Demonstration Year 9	October 1, 2025 to September 30, 2026	12 months
Demonstration Year 10	October 1, 2026 to September 30, 2027	12 months

9.13. **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 10. CMS will provide technical assistance, upon request.

9.14. **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.

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

- a. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments, CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.
- b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget

neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.

- 9.16. **Budget Neutrality Adjustments.** To the extent that there are any changes to the federal Section 1115 demonstration budget neutrality approach during the demonstration period, the state has the opportunity to submit an adjustment aligning with these changes, along with detailed data to justify this, for CMS review without submitting an amendment pursuant to STC 3.7. All changes in budget neutrality would apply retroactively to the date of the federal policy changes.
- 9.17. **Budget Neutrality Adjustments for Increased Provider Rates.** The state may submit an adjustment to its budget neutrality for CMS review, upon receiving an appropriation for provider rate increases, without submitting an amendment pursuant to STC 3.7. All changes to budget neutrality would apply on the state's effective date for the increase.

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.

10. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

- 10.1. **Limiting 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 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.
- 10.2. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis. If the 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.

- 10.3. **Calculation of the Budget Neutrality Limits and How They Are Applied.** To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.
- 10.4. **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.
- 10.5. **Hypothetical Budget Neutrality.** When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be “hypothetical;” that is, the expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS’s current view that states should not have to “pay for,” with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state’s WW hypothetical spending exceeds the supplemental test’s expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending through savings elsewhere in the demonstration or to refund the FFP to CMS.
- 10.6. **Hypothetical Budget Neutrality Test 1: SUD Expenditures.** 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.

Hypothetical Budget Neutrality Test 1									
MEG	PC or Agg	WOW Only, WW Only, or Both	Base Year	Trend Rate	DY 6 PMPM	DY 7 PMPM	DY 8 PMPM	DY 9 PMPM	DY 10 PMPM
SUD IMD TANF	PC	Both	SFY 2020	5.6%	\$611.81	\$646.07	\$682.25	\$720.46	\$760.80
SUD IMD SSI Duals-NFCE	PC	Both	SFY 2020	5.6%	\$6,405.94	\$6,764.67	\$7,143.49	\$7,543.53	\$7,965.97
SUD IMD SSI Duals-NFI	PC	Both	SFY 2020	5.6%	\$244.77	\$258.48	\$272.95	\$288.24	\$304.38
SUD IMD SSI Non-Duals	PC	Both	SFY 2020	5.6%	\$2,379.66	\$2,512.92	\$2,653.64	\$2,802.25	\$2,959.17
SUD IMD HCE	PC	Both	SFY 2020	5.6%	\$871.65	\$920.46	\$972.01	\$1,026.44	\$1,083.92

10.7. **Composite Federal Share Ratios.** 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 the MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration’s approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

10.8. **Exceeding Budget Neutrality.** CMS will enforce budget neutrality agreement over the life of the demonstration, which extends from July 1, 2022 to December 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 eliminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

10.9. **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 (CAP) 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.

Budget Neutrality Test Mid-Course Correction Calculation		
Demonstration Year	Cumulative Target Definition	Percentage
DY6	Cumulative budget neutrality limit plus:	1.5 percent
DY6 through DY7	Cumulative budget neutrality limit plus:	1.0 percent
DY6 through DY8	Cumulative budget neutrality limit plus:	0.5 percent
DY6 through DY9	Cumulative budget neutrality limit plus:	0.0 percent
DY6 through DY10	Cumulative budget neutrality limit plus:	0.0 percent

11. EVALUATION OF THE DEMONSTRATION

- 11.1. **Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state shall cooperate fully and timely with CMS and its contractors’ in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state shall include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they shall make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 8.5.
- 11.2. **Independent Evaluator.** Upon approval of the demonstration, the state must use an independent party to conduct an evaluation of the demonstration (except for the Former Foster Care Youth component) to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The independent party must sign an agreement to conduct the demonstration evaluation in an independent manner in accord 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.
- 11.3. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design no later than 180 calendar days after the approval of the demonstration. The draft Evaluation Design must be developed in accordance with Attachment B (Developing the Evaluation Design for SUD) of these STCs, CMS’s evaluation design guidance for SUD

and SMI/SED, and any other applicable CMS evaluation guidance and technical assistance for the demonstration's other policy components. The Evaluation Design must also be developed in alignment with 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 8.8. For any amendment to the demonstration, the state will be required to update the approved Evaluation Design to accommodate the amendment component. The amended Evaluation Design must be submitted to CMS for review no later than 180 calendar days after CMS's approval of the demonstration amendment. Depending on the scope and timing of the amendment, in consultation with CMS, the state may provide the details on necessary modifications to the approved Evaluation Design via the monitoring reports. The amendment Evaluation Design must also be reflected in the state's Interim (as applicable) and Summative Evaluation Reports, described below.

- 11.4. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) days after receipt of CMS's comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design to the state's website within thirty (30) days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the Monitoring Reports. Once CMS approves the Evaluation Design, if the state wishes to make changes, the state must submit a revised Evaluation Design to CMS for approval if the changes are substantial in scope; otherwise, in consultation with CMS, the state may include updates to the Evaluation Design in monitoring reports.
- 11.5. **Evaluation Questions and Hypotheses.** Consistent with Attachments B and C (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Reports) of these STCs, the evaluation deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS evaluation guidance and technical assistance, 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. For example, hypotheses for the SUD component of the demonstration must support an assessment of the demonstration's success in achieving the core goals of the program through addressing, among other outcomes, initiation and compliance with treatment, utilization of health services in appropriate care settings, and reductions in key outcomes such as deaths due to overdose. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF). Furthermore, the evaluation must accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, and/or geography)—to the extent feasible—to inform a fuller understanding of existing disparities in access and health

outcomes, and how the demonstration's various policies might support bridging any such inequities.

- 11.6. **Evaluation Budget.** A budget for the evaluation 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 evaluation such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.
- 11.7. **Interim Evaluation Report.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for extension of the demonstration, 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 or any components within the demonstration that expire prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
 - c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted, or one year prior to the end of the demonstration, whichever is sooner. If the state is not requesting an extension for a demonstration, an Interim Evaluation Report is due one year prior to the end of the demonstration.
 - d. The state must submit the final Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report. Once approved by CMS, the state must post the final Interim Evaluation Report to the state's Medicaid website within 30 calendar days.
 - e. The Interim Evaluation Report must comply with Attachment C (Preparing the Interim and Summative Evaluation Reports) of these STCs.
- 11.8. **Summative Evaluation Report.** The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The draft Summative Evaluation Report must be developed in accordance with Attachment C (Preparing the Interim and Summative Evaluation Reports) of these STCs, and in alignment with the approved Evaluation Design.
- a. Unless otherwise agreed upon in writing by CMS, the state must submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.

- b. Once approved by CMS, the state must post the final Summative Evaluation Report to the state’s Medicaid website within 30 calendar days.

- 11.9. **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. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.
- 11.10. **State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the interim evaluation, and/or the summative evaluation.
- 11.11. **Public Access.** The state shall post the final documents (e.g., Implementation Plan, Monitoring Protocol, Monitoring Reports, Close Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state’s Medicaid website within 30 days of approval by CMS.
- 11.12. **Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment 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.

12. SCHEDULE OF DELIVERABLES

Date	Deliverable	STC
30 days after demonstration approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
150 days after approval date	SUD Monitoring Protocol	STC 8.7
180 days after approval date	Draft Evaluation Design	STC 11.3
60 days after receipt of CMS comments	Revised Draft Evaluation Design	STC 11.4

30 days after CMS Approval	Approved Evaluation Design published to state's website	STC 11.4
60 days from September 30, 2025	Mid-Point Assessment submitted to CMS	STC 5.4
One year prior to the end of the demonstration, or with renewal application	Draft Interim Evaluation Report	STC 11.7
60 days after receipt of CMS comments	Final Interim Evaluation Report	STC 11.7
18 months after the end of the demonstration	Draft Summative Evaluation Report	STC 11.8
60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	STC 11.8
30 calendar days of CMS approval	Approved Final Summative Evaluation Report published to state's website	STC 11.8
Monthly Deliverables	Monitoring Calls	STC 8.1
Quarterly Deliverables Due 60 days after end of each quarter, except 4th quarter	Quarterly Monitoring Reports	STC 8.8
	Quarterly Expenditure Reports	STC 9.2
Annual Deliverables - Due 90 days after end of each 4th quarter	Annual Reports	STC 8.8

Attachment A:

ANNUAL REPORT TEMPLATE FOR THE FORMER FOSTER CARE YOUTH COMPONENT

State: _____

Demonstration Year and Period: _____

Approved start and end date of the Demonstration _____

A. Introduction

Please describe the goal(s) and objectives of the demonstration and status of key operational milestones.

B. Eligibility and Enrollment Information, including member month reporting

Topic	Measure [Reported for each month included in the annual report]	Narrative
Total Enrollment	Total number unduplicated enrolled [as of the last day of the month]	Describe the percent increase or decrease (or no change) from these quarters compared to the previous quarters. If this is the first annual report of your demonstration, describe whether or not the number of enrollees aligns with your expectations.
New Enrollment	Total number of new enrollees [as of the last day of the month]	Describe the percent increase or decrease (or no change) from these quarters compared to the previous quarters. If this is the first annual report of your demonstration, describe whether or not the number of new enrollees aligns with your expectations. Please also describe any outreach methods the state is currently using or plans to use in the future to identify and enroll this population.
Re-Enrollment	Total number of beneficiaries who disenrolled and later reenrolled [as of the last day of the month]	Describe the percent increase or decrease (or no change) from these quarters compared to the previous quarters. If this is the first annual report of your demonstration, describe whether or not the number of reenrollees aligns with your expectations.

Topic	Measure [Reported for each month included in the annual report]	Narrative
Disenrollment	Total number of beneficiaries who disenrolled [as of the last day of the month]	Please describe the trend (percent increase or decrease, or no change) for these quarters compared to the previous quarters. If this is the first annual report of your demonstration, please describe whether or not the number of disenrollees aligns with your expectations. Please also describe major reasons for to disenrollment (if known) and any actions taken to mitigate inappropriate disenrollment.

C. Utilization Monitoring

The state will summarize utilization through a review of claims/encounter data for the demonstration population. This includes the following:

Topic	Measure [Reported for each month included in the annual report]
Utilization Monitoring	Total number of beneficiaries with any claim
	Total number of beneficiaries with primary care appointments
	Total number of beneficiaries with behavioral health appointments
	Total number of beneficiaries with emergency department visits
	Total number of beneficiaries with inpatient visits

D. Grievances and Appeals

Describe any grievances and appeals filed during the quarters by the demonstration population by type, highlighting any patterns that are concerning. Describe actions being taken to address any significant issues evidenced by patterns of appeals.

E. Operational/Policy/Systems/Fiscal Developments/Issues and Action Plans

Identify and describe any other significant program developments/issues/problems that have occurred in the current quarters or are anticipated to occur in the near future that affect the operation or evaluation of the demonstration, including but not limited to program development, access to care, quality of care, approval and contracting with Managed Care

Entities, managed care contract compliance, fiscal issues, systems issues, and pertinent legislative or litigation activity.

Please provide a description of each issue as well as any immediate and long-term action plans to address any problems identified. Include a discussion of the status of action plans implemented in previous periods until resolved.

F. Demonstration Evaluation Activities and Interim Findings

Please provide a summary of the progress of evaluation activities, including key milestones accomplished. Include:

- Status of progress against timelines outlined in the approved Evaluation Design.
- Any challenges encountered and how they are being addressed.
- Status of any evaluation staff recruitment or any RFPs or contracts for evaluation contractual services (if applicable).
- Description of any interim findings or reports, as they become available.

ATTACHMENT B

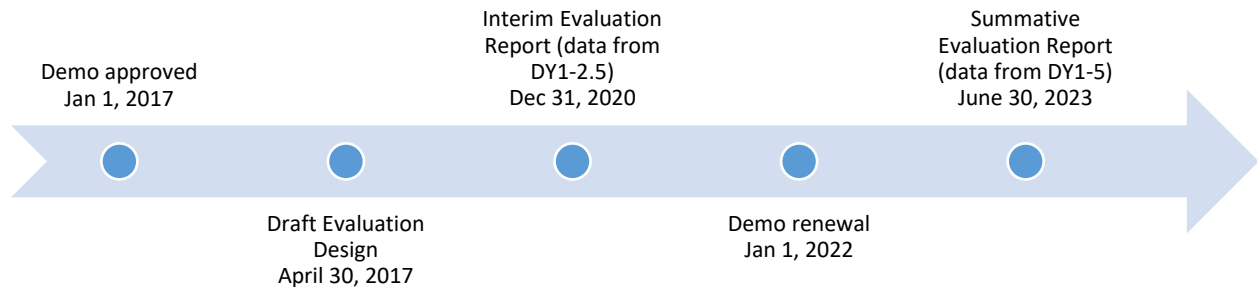
Developing the Evaluation Design

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 is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration).

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: <https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf>.

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’s Core Set of Health Care Quality Measures for Children in

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

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

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

D. Methodological Limitations – This section provides 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.

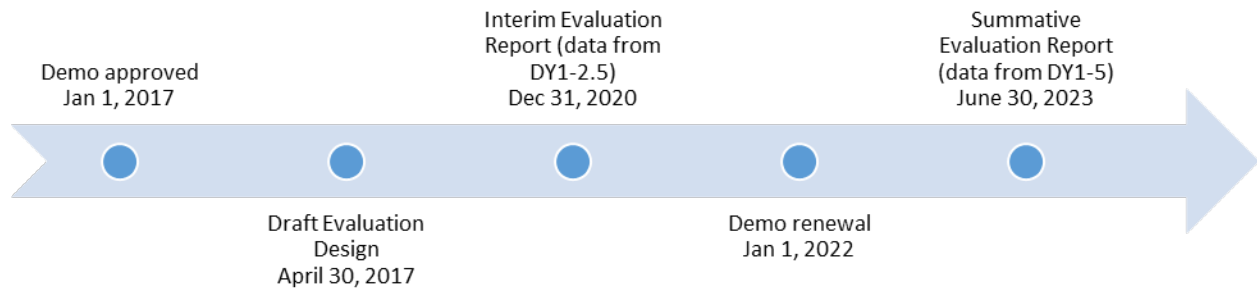
Attachment C: Preparing the Interim and Summative Evaluation Reports

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 is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration).

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 deliverables 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 submitting an application for renewal, the Interim Evaluation Report should be posted on the state's website with the application for public comment. Additionally, the Interim Evaluation Report must be included in its entirety with the application submitted to CMS.

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: <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 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 D:
Evaluation Design
(reserved)

Attachment E

Substance Use Disorder (SUD) Implementation Plan Protocol Originally Approved on June 28, 2018

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

1. Please also see [“Available SUD Services” table](#) in “Section IV: Comprehensive Evidence-Based Benefit Design”.
2. The links to all applicable licensing regulations for the levels of care covered under each milestone criterion are provided at the end of this milestone.
3. Information on “Required Services and Support Systems” and “Recommended Services and Support Systems” discussed in this milestone is derived from Pennsylvania Client Placement Criteria (PCPC), the link to which is provided at the end of this milestone.
4. Specific staffing requirements for each level of care also come from PCPC.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Coverage of outpatient services	<p>Covered by the state plan (see “<i>Clinic Services</i>” – “<i>Drug and Alcohol and Methadone Maintenance Clinic Services</i>” on Attachment 3.1A/3.1B, Page 4b of the state plan).</p> <p>Applicable licensing regulations: Title 28 § 704, 705, 709, 711.</p> <p>Required Services and Support Systems include:</p> <ul style="list-style-type: none"> • Biopsychosocial Assessment • Specialized professional medical consultation, and tests such as a physical examination, psychiatric evaluation, HIV and TB testing, and other laboratory work, as needed 	<p>Pennsylvania has completed the cross walk of the ASAM criteria with our current system of care, including types of service, hours of clinical care and credentials of staff. Additionally, to assist the field in correctly applying</p>	<p>None needed. Service already provided.</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<ul style="list-style-type: none"> • Individualized treatment planning, with reviews at least every 60 days • Psychotherapy, including individual, group, and family (per clinical evaluation) • Aftercare planning and follow-up • Transportation to treatment services, <p>Recommended Services and Support Systems include the following:</p> <ul style="list-style-type: none"> • Occupational and vocational counseling (non-Medicaid funds) • Case management [under 1915(b) in-lieu of authority] • Social services that allow the staff to assist with attendance monitoring, child care, and the provision of shelter and other basic needs (non-Medicaid funds) • Structured positive social activities available within non-program hours, including evenings and weekends (non-Medicaid funds) • Access to more intensive LOC as clinically indicated (Medicaid and non-Medicaid) • Collaboration between the treatment team and various agencies for the coordinated provision of services (non-Medicaid) <p>Required Staff: The required Staff at an outpatient care facility include a director and counselor(s), and a clinical supervisor for every eight full-time counselors or counselor</p>	<p>ASAM, DDAP has developed an application guidance for PA's current substance use system. While PA will begin to utilize The ASAM Criteria's for admission determination of level of care on July 1, 2018, other details of aligning PA's SUD system of care (services, hours of service, staff credentials, etc.) with the ASAM Criteria will be an ongoing process beyond July 2018 and is expected to be completed within 24</p>	

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>assistants, or both. The State of PA recognizes that, based on the agency size and profile, a single person may hold one or more of the above positions. Additional staff may include a clinical supervisor or lead counselor, social services counselor, a psychiatrist, a psychologist, a medical consultant, and any other health and human services staff or consultants (i.e. SUD counselors or other certified SUD clinicians) who may more effectively serve the facility's population.</p>	<p>months of the demonstration approval.</p>	
<p>Coverage of intensive outpatient services</p>	<p>Covered by the state plan (see "<i>Clinic Services</i>" – "<i>Drug and Alcohol and Methadone Maintenance Clinic Services</i>" on Attachment 3.1A/3.1B, Page 4b of the state plan).</p> <p>Applicable licensing regulations: Title 28 § 704, 705, 709, 711.</p> <p>Required Services and Support Systems include:</p> <ul style="list-style-type: none"> • Biopsychosocial Assessment • Specialized professional medical consultation, and tests such as a physical examination, psychiatric evaluation, HIV and TB testing, and other laboratory work, as needed • Individualized treatment planning, with reviews at least every 60 days (recommended: every 30 days) • Psychotherapy, including individual, group, and family (per clinical evaluation) 	<p>Already provided</p>	<p>None needed. Service already provided</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<ul style="list-style-type: none"> • Aftercare planning and follow-up • Development of discharge plan and plan for referral into continuum of care • Transportation to treatment services <p>Recommended Services and Support Systems include:</p> <ul style="list-style-type: none"> • Psychoeducational seminars (non-Medicaid) • Structured positive social activities available within non-program hours, including evenings and weekends (non-Medicaid) • Access to more intensive LOC, as clinically indicated(Medicaid and non-Medicaid) • Emergency telephone line available when program is not in session (non-Medicaid) • Collaboration between the treatment team and various agencies for the coordinated provision of services (non-Medicaid)Occupational and vocational counseling (non-Medicaid) • Case management (under in-lieu-of authority), and social services that allow the staff to assist with attendance monitoring, child care, and the provision of stable shelter and other basic care needs (non-Medicaid). <p>Required Staff: The required Staff at an intensive outpatient care facility include a director and counselor(s), and a clinical</p>		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>supervisor for every eight full-time counselors or counselor assistants, or both. The State of PA recognizes that, based on the agency size and profile, a single person may hold one or more of the above positions. Additional staff may include a clinical supervisor or lead counselor, social services counselor, a psychiatrist, a psychologist, a medical consultant, and any other health and human services staff or consultants (i.e. SUD counselors or other certified SUD clinicians) who may more effectively serve the facility's population.</p>		
<p>Coverage of medication assisted treatment (medications as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state)</p>	<p>Counseling and methadone maintenance covered by the state plan under "<i>Clinic Services</i>" – "<i>Drug and Alcohol and Methadone Maintenance Clinic Services</i>" on Attachment 3.1A/3.1B, Page 4b of the state plan.</p> <p>Methadone maintenance clinics are licensed by DDAP under Pennsylvania regulations, Title 28 § 715, <i>Standards for Approval of Narcotic Treatment Program</i>, which includes requirements for medication management and counseling. This chapter is available at: https://www.pacode.com/secure/data/028/chapter715/chap715toc.html</p> <p>Other medications (buprenorphine, vivitrol) covered under "<i>Prescribed Drugs</i>" - see</p>	<p>Already provided</p>	<p>None needed. Service already provided</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>Attachment 3.1A/3.1B, Page 5a of the state plan.</p> <p>Please also see Medication Assisted Treatment in <i>Section IV: Comprehensive Evidence-Based Benefit Design</i> of this application as well as the Medicaid formulary available at https://papdl.com/sites/default/files/ghs-files/Penn%20PDL%2007252017%20v2017_1.g.pdf (see Opiate Dependence Treatments on page 35 of this Formulary list)</p>		
<p>Coverage of intensive levels of care in residential and inpatient settings</p>	<p>Medically Managed Inpatient Residential - (corresponding to ASAM Level 4) covered by the state plan under <i>“Inpatient Services”</i> - see Attachment 3.1A/3.1B, Page 1b of the state plan.</p> <p>Applicable licensing regulations: Title 28 § 704, 710.</p> <p>Required Services and Support Systems include:</p> <ul style="list-style-type: none"> • 24-hour observation, monitoring, and treatment • Full resources of an acute care general or psychiatric hospital, or a medically managed intensive inpatient treatment service • Treatment for SUD and for coexisting medical and/or psychiatric disorders 	<p>Already provided</p>	<p>None needed. Service already provided</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<ul style="list-style-type: none"> • Access to detoxification or other more intensive medical/psychiatric services for related emotional/behavioral problems or family conditions which could jeopardize recovery • Assistance in accessing support services • Emergency medical services available • Referral to detox, if clinically necessary • Specialized professional/medical consultation, and testing such as HIV and TB tests, and other laboratory work if needed • Biopsychosocial Assessment • Individualized treatment planning, with review at least every 30 days (where treatment is less than 30 days, the review shall occur every 15 days) • Individual therapy • Group therapy (group size: no larger than 12) • Couples therapy and/or family therapy (if appropriate) • Occupational and vocational counseling • Monitoring of medication, as needed • Physical exam • Development of discharge plan and plan for referral into continuum of care <p>Required Staff: The required Staff in a Medically Managed Inpatient Residential facility</p>		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>are appointed according to the Joint Commission on the Accreditation of Hospital Organization's (JCAHO's) standard hospital practices. In addition, they must comply with DDAP staffing requirements. Additional staff may include SUD counselors or registered, certified SUD clinicians able to administer planned interventions according to the assessed needs of the individual.</p> <p>Other SUD residential services listed below are currently provided under the 1915(b) "in-lieu" of authority for all ages, including children, in non-IMD settings (16 or less beds), and for permissible ages (under 21, and 65 and above years of age) in IMD settings.</p> <p>➤ Halfway House (corresponding to ASAM Level 3.1).</p> <p>Applicable licensing regulations: Title 28 § 704, 705, 709.</p> <p>Required Services and Support Systems include:</p> <ul style="list-style-type: none"> • Physical exam • Regularly scheduled psychotherapy • Biopsychosocial Assessment • Specialized professional/medical consultation, and tests such as a psychiatric evaluation, HIV and TB testing, and other laboratory work, as needed • Individualized treatment planning, with reviews at least every 30 days 	<p>Already provided /available (Expenditure authority requested under this 1115 Demonstration</p>	<p>None needed, service already provided/ available (Expenditure authority requested under this 1115 Demonstration)</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<ul style="list-style-type: none"> • Development of a discharge plan and a plan for referral into continuum of care • Access to services for: vocational assessment, job readiness and job placement, GED preparation and testing, literacy and basic education tutoring, legal, medical and dental care, general health education (esp. AIDS awareness and support), budgeting, credit restoration, housing assistance, income support, and recreational/social activities (e.g. fitness, games, peer interaction). <p>Recommended Services and Support Systems include (these services need to be provided in order for a halfway house to receive state/grant funds):</p> <ul style="list-style-type: none"> • Peer group meetings (non-Medicaid) • Family therapy, if indicated by the individual's treatment plan (under in-lieu-of authority) • Educational or instructional groups (non-Medicaid). <p>Required Staff: The Required Staff in a halfway house include a director and counselor(s), and a clinical supervisor for every eight full-time counselors or counselor assistants, or both. The State of PA recognizes that, based on the agency size and profile, a</p>		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>single person may hold one or more of the above positions. Additional staff may include a clinical supervisor or lead counselor, social services counselor, a psychiatrist, a psychologist, a medical consultant, and any other health and human services staff or consultants (i.e. SUD counselors or other certified SUD clinicians) who may more effectively serve the facility's population.</p> <p>➤ Medically Monitored Short Term Residential (corresponding to ASAM Level 3.5 or 3.7)</p> <p>Applicable licensing regulations: Title 28 § 704, 705, 709, 710, 711.</p> <p>Note: While there are some population specific programs that would meet ASAM level 3.3, they are not widely available in the state at this time.</p> <p>Required Services and Support Systems include:</p> <ul style="list-style-type: none"> • 24-hour observation, monitoring, and treatment • Emergency medical services available • Referral to detoxification, if clinically needed • Specialized professional/medical consultation, and tests such as HIV and TB testing, and other laboratory work, as needed • Biopsychosocial Assessment 	<p>Already provided/available (Expenditure authority requested under this 1115 Demonstration)</p>	<p>None needed, service already provided/available (Expenditure authority requested under this 1115 Demonstration)</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<ul style="list-style-type: none"> • Individualized treatment planning, with reviews at least every 30 days (where treatment is less than 30 days, review shall occur every 15 days) • Individual therapy • Group therapy (group size: no more than 12 members) • Couples therapy (if appropriate) • Family therapy (if appropriate) • Access to occupational and vocational counseling • Monitoring of medication, if necessary • Physical exam • Development of discharge plan and plan for referral into continuum of care • Access to services for: vocational assessment, job readiness and job placement, GED preparation and testing, literacy and basic education tutoring, legal, medical and dental care, general health education (esp. AIDS awareness and support), budgeting, credit restoration, housing assistance, income support, and recreational/social activities (e.g. fitness, games, peer interaction) <p>Recommended Services and Support Systems include:</p> <ul style="list-style-type: none"> • Case management (under in-lieu of authority), 		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<ul style="list-style-type: none"> • Social services that allow the staff to assist with attendance monitoring, child care, transportation to treatment services, and the provision of stable shelter and other basic care needs (non-Medicaid) • Availability of conjoint treatment (Medicaid or in-lieu of) • Collaboration between the treatment team and various agencies for the coordinated provision of services (non-Medicaid). <p>Required Staff: The required Staff in Medically Monitored Short Term Residential treatment include a director and counselor(s), and a clinical supervisor for every eight full-time counselors or counselor assistants, or both. The State of PA recognizes that, based on the agency size and profile, a single person may hold one or more of the above positions. Additional staff may include a clinical supervisor or lead counselor, social services counselor, a psychiatrist, a psychologist, a medical consultant, and any other health and human services staff or consultants (i.e. SUD counselors or other certified SUD clinicians) who may more effectively serve the facility's population.</p> <p>➤ Medically Monitored Long Term Residential (corresponding to ASAM Level 3.5)</p>	<p>Already provided/available (Expenditure authority requested under this 1115 Demonstration)</p>	<p>None needed, service already provided/available (Expenditure authority requested)</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>Applicable licensing regulations: Title 28 § 704, 705, 709, 711.</p> <p>Required Services and Support Systems include:</p> <ul style="list-style-type: none"> • Regular, scheduled psychotherapy • Biopsychosocial Assessment • Specialized professional/medical consultation, and testing such as a psychiatric evaluation, HIV and TB tests, and other laboratory work, as needed • Individualized treatment planning, with reviews at least every 30 days • Access to services for: vocational assessment, job readiness and job placement, GED preparation and testing, literacy and basic education tutoring, medical and dental care, general health education (especially AIDS awareness and support), budgeting, credit restoration, housing assistance, income support, and recreational and social activities (e.g. fitness, games, peer interaction) • Monitoring of medication, as needed • 24-hour observation, monitoring, and treatment • Emergency medical services available • Referral to detoxification, if clinically necessary • Individual therapy • Couples therapy (if appropriate) 		<p>under this 1115 Demonstration)</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<ul style="list-style-type: none"> • Family therapy (if appropriate) • Physical exam (within 48 hours expected, but no later than 7 days) • Development of discharge plan and plan for referral into continuum of care <p>Recommended Services and Support Systems include:</p> <ul style="list-style-type: none"> • Peer groups (non-Medicaid) • Educational/instructional groups (non-Medicaid) <p>Required Staff: The required Staff in Medically Monitored Long Term Residential treatment include a director and counselor(s), and a clinical supervisor for every eight full-time counselors or counselor assistants, or both. The State of PA recognizes that, based on the agency size and profile, a single person may hold one or more of the above positions. Additional staff may include a clinical supervisor or lead counselor, social services counselor, a psychiatrist, a psychologist, a medical consultant, and any other health and human services staff or consultants (i.e. SUD counselors or other certified SUD clinicians) who may more effectively serve the facility's population.</p>		
Coverage of medically supervised	This is provided in Medically Managed Inpatient Detoxification (corresponding to ASAM Level 4 WM) covered by the state plan	Already provided	None needed. Service already provided

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p>withdrawal management</p>	<p>under “<i>Inpatient Services</i>” - see Attachment 3.1A/3.1B, Page 1b of the state plan.</p> <p>Applicable licensing regulations: Title 28 § 704, 710. Required Services and Support Systems include:</p> <ul style="list-style-type: none"> • Assessment and treatment of adults with SUDs or addicted individuals with concomitant acute biomedical and/or emotional/behavioral disorders. Clinicians in this setting must be knowledgeable about the biopsychosocial dimensions of SUDs, biomedical problems, and emotional/behavioral disorders. • 24-hour physician availability • 24-hour primary nursing care and observation • Professional therapeutic services • Referral agreements among different LOC • Biopsychosocial Assessment • Monitoring of medication, as needed • Health care education services • Services for families and significant others • Medication administered in accordance with the substance-specific withdrawal syndrome(s), other biomedical or psychiatric conditions, and recognized detoxification procedures • Comprehensive nursing exam upon admission 		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<ul style="list-style-type: none"> • Physician-approved admission • Physician who is responsible for a comprehensive history (including drug and alcohol) and a physical examination within 24 hours following admission • Specific assessments performed on an individualized basis, with consideration of risk guiding the evaluation (because this population frequently suffers from communicable, infectious, or transmittable diseases). Furthermore, the facility must have appropriate policies and procedures for identification, treatment, and referral of individuals found to have such illnesses, in order to protect other individuals and staff from acquiring these diseases. <p>Required Staff: The required Staff in a Medically Managed Inpatient Detox facility is chosen according to the Joint Commission on the Accreditation of Hospital Organization's (JCAHO's) standard hospital practices. In addition, they must comply with DDAP staffing requirements. Additional staff may include trained clinicians, SUD counselors, or registered, certified SUD clinicians able to administer planned interventions according to the assessed SUD needs of the individual.</p>	<p>Already provided/available</p>	<p>None needed. Service already</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p><u>This service is also provided in Medically Monitored Inpatient Detoxification</u> (corresponding to ASAM Level 3.7 WM) – provided under the 1915(b) “in-lieu” of authority for all ages in non-IMD settings, and for permissible ages (under 21, and 65 and above years of age) in IMD settings as discussed below:</p> <p>Applicable licensing regulations: Title 28 § 704, 705, 709, 711.</p> <p>Required Services and Support Systems include:</p> <ul style="list-style-type: none"> • 24-hour observation, monitoring, and treatment • Emergency medical services available • Referral to medically managed detox, if clinically appropriate • Specialized professional/medical consultation, and tests such as HIV and TB testing, and other laboratory work, as needed • Biopsychosocial Assessment • Monitoring of medication, as needed • Development of discharge plan, and plan for referral into continuum of care • Medications ordered by a licensed physician and administered in accordance with the substance-specific withdrawal syndrome(s), other biomedical or psychiatric conditions, 	<p>ble (Expenditure authority requested under this 1115 Demonstration)</p>	<p>provided/available (Expenditure authority requested under this 1115 Demonstration)</p>

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>and recognized detoxification procedures</p> <ul style="list-style-type: none"> • Physical examination by a physician within 24 hours following admission, or a physical examination which was conducted within 7 days prior to admission, and was evaluated by the facility physician within 24 hours following admission • Specific assessments performed on an individualized basis, with consideration of risk guiding the evaluation (because population frequently suffers from communicable, infectious, or transmittable diseases). Furthermore, the facility must have appropriate policies and procedures for identification, treatment, and referral of individuals found to have such illnesses, in order to protect other individuals and staff from acquiring these diseases. • Access to services for: vocational assessment, job readiness and job placement, GED preparation and testing, literacy and basic education tutoring, legal, medical and dental care, general health education (esp. AIDS awareness and support), budgeting, credit restoration, housing assistance, income support, and recreational/social activities (e.g. fitness, games, peer interaction) 		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	<p>Recommended Services and Support Systems include:</p> <ul style="list-style-type: none"> • 24-hour physician available by telephone (non-Medicaid) • Alcohol- or drug-focused nursing assessment by a registered nurse upon admission (in-lieu-of) • Professional counseling services available 12 hours a day, provided by appropriately qualified staff (in-lieu-of) • Health education services (non-Medicaid) • Clinical program activities designed to enhance the individual's understanding of his/her SUD (in-lieu-of) • Family/significant other services, as appropriate (non-Medicaid). <p>Required Staff: The required Staff at a medically monitored inpatient detox facility include a director and counselor(s), and a clinical supervisor for every eight full-time counselors or counselor assistants, or both. The State of PA recognizes that, based on the agency size and profile, a single person may hold one or more of the above positions. Additional staff may include a clinical supervisor or lead counselor, social services counselor, a psychiatrist, a psychologist, a medical consultant, and any other health and human services staff or consultants (i.e. SUD counselors or other certified SUD clinicians)</p>		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	who may more effectively serve the facility's population.		

References for Milestone 1

- **Title 28 § 704 – Staffing Requirements for Drug and Alcohol Treatment Facilities:**
<https://www.pacode.com/secure/data/028/chapter704/chap704toc.html>
- **Title 28 § 705 – Physical Plant Standards:**
<https://www.pacode.com/secure/data/028/chapter705/chap705toc.html>
- **Title 28 § 709 – Standards for Licensure of Freestanding Treatment Facilities:**
<https://www.pacode.com/secure/data/028/chapter709/chap709toc.html>
- **Title 28 § 710 – Drug and Alcohol Services (Inpatient Hospital):**
<https://www.pacode.com/secure/data/028/chapter710/chap710toc.html>
- **Title 28 § 711 – Standards for Certification of Treatment Activities Which Are Part of a Health Care Facility:** <https://www.pacode.com/secure/data/028/chapter711/chap711toc.html>
- **Title 28 § 715 – Standards for Approval of Narcotic Treatment Programs:**
<https://www.pacode.com/secure/data/028/chapter715/chap715toc.html>
- **Pennsylvania Client Placement Criteria (PCPC)- contains detailed information about all services / levels of care as well as staffing requirements for each level of care:**
[http://www.ddap.pa.gov/Manuals/PA%20Client%20Placement%20Criteria%20\(PCPC\)%20Edition%2003%20Manual.pdf](http://www.ddap.pa.gov/Manuals/PA%20Client%20Placement%20Criteria%20(PCPC)%20Edition%2003%20Manual.pdf)

**Milestone 2: Use of Evidence-based, SUD-specific Patient Placement
Criteria**

(Please also see Section V: Appropriate Standards of Care)			
Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p>Implementation of requirement that providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools that reflect evidence-based clinical treatment guidelines</p>	<p>Pennsylvania currently uses PCPC⁵, which is a set of guidelines designed to provide clinicians with a basis for determining the most appropriate care for individuals with SUDs. PCPC uses a multidimensional (six dimensions – Acute Intoxication and Withdrawal; Biomedical Conditions and Complications; Emotional/Behavioral Conditions and Complications; Treatment Acceptance/Resistance; Relapse Potential; Recovery Environment) approach in interpreting the information gathered through assessment.</p>	<p>The state is replacing PCPC with ASAM effective July 1st, 2018. DDAP has published on their website all information and timelines pertaining to transition to ASAM. Behavioral Managed Care contracts effective July 1, 2018 will contain language</p>	<p>Here’s a timeline/summary of the actions that have already been taken/or remain to be taken in order to transition to ASAM by July 1st, 2018:</p> <p>February/March 2017: Pennsylvania made the decision to transition from PCPC to The ASAM Criteria and stakeholders were notified.</p> <p>April – present: Initiated an FAQ for the field regarding transition updates and concerns. Posted to DDAP’s website.</p> <p>April – May 2017: Conducted a training survey to the field to determine impact and training need for the state.</p>

– ⁵ “Pennsylvania’s Client Placement Criteria,” Third Edition (2014). Available at: [http://www.ddap.pa.gov/Manuals/PA%20Client%20Placement%20Criteria%20\(PCPC\)%20Edition%203%20Manual.pdf](http://www.ddap.pa.gov/Manuals/PA%20Client%20Placement%20Criteria%20(PCPC)%20Edition%203%20Manual.pdf)

		<p>affirming this requirement.</p>	<p>April – May 2017: Announced the discontinuation of the PCPC training.</p> <p>May 2017: Summarized survey data for training considerations and planning purposes.</p> <p>May 2017: Convened the ASAM Transition Workgroup with various subcommittees to explore the implications of the transition.</p> <p>June 2017: PA’s ASAM Transition Workgroup participated in a 2-day, in-person ASAM training with <i>The Change Company</i>.</p> <p>August – Present: Ongoing internal reviews of Pennsylvania Web Infrastructure for Treatment Services (PA WITS) screening and assessment tools, licensing regulations, contractual language (DDAP’s Treatment Manual) to determine any conflicts or areas of concern to address as a department or with the ASAM Transition Workgroup.</p>
--	--	------------------------------------	---

			<p>Current: OMHSAS, in collaboration with DDAP is exploring options to support providers in the transition to the use of ASAM. This includes reviewing funding sources that may be utilized to support the training costs, recommending to providers that they identify the key staff that need to be trained, and collaborating regionally to schedule trainings for cost effectiveness.</p> <p>May 2018: Guidance for application of ASAM in PA released.</p> <p>July 1, 2018: Target date for transition to ASAM.</p>
<p>Implementation of a utilization management approach such that (a) beneficiaries have access to SUD services at</p>	<p>HealthChoices Managed Care contracts have access standards for services in all of the MCO agreements. These access standards will apply to 1115 Demonstration Waiver services as well:</p>	<p>Pennsylvania will continue to contractually enforce current access standards.</p>	<p>Pennsylvania will continue to contractually enforce the current access standards. No other action needed.</p>

<p>the appropriate level of care</p>	<p>The provider network must provide face-to-face treatment intervention within one hour for emergencies, within twenty-four (24) hours for urgent situations, and within seven (7) days for routine appointments and for specialty referrals.</p> <p>Please also see “Utilization Management” under Section X: Benefit Management.</p>	<p>Pennsylvania will be replacing PCPC with ASAM effective July 1st, 2018.</p>	
<p>Implementation of a utilization management approach such that (b) interventions are appropriate for the diagnosis and level of care</p>	<p>Pennsylvania statute, Act 152 of 1988 requires the utilization of placement criteria approved by DDAP to address the type, level, and length of stay in treatment for individuals SUD.</p> <p>HealthChoices contracts and DDAP Treatment Manual require that assessment be done within 7 days, and mandates the use of PCPC to determine the level of care.</p> <p>Please also see “Utilization Management” under Section X: Benefit Management.</p>	<p>Beginning July of 2018, Pennsylvania will replace PCPC with ASAM as the tool to determine the level of care and interventions needed.</p>	<p>Please see the actions outlined in the beginning of this table.</p>
<p>Implementation of a utilization management approach such that (c) there is an independent process for</p>	<p>The BH-MCO is required to coordinate service planning and delivery with human services agencies. The BH-MCO is required to have a letter of agreement with the county Drug & Alcohol agency that include procedures for coordination with the</p>	<p>Will continue to follow the current processes.</p>	<p>No action needed</p>

<p>reviewing placement in residential treatment settings</p>	<p>SCA for placement and payment for care provided to members in residential treatment facilities outside the HC zone.</p> <p>Managed Care contracts require prior approval for residential services, independently reviewed by a clinician and medical director.</p> <p>Please also see “Utilization Management” under Section X: Benefit Management.</p>		
---	---	--	--

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

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p>Implementation of residential treatment provider qualifications in licensure requirements, policy manuals, managed care 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,</p>	<p>Pennsylvania regulations, Title 28 § 704 available at https://www.pacode.com/secure/data/028/chapter704/chap704toc.html outlines the staffing requirements and qualifications of various staff positions for drug and alcohol treatment activities.</p> <p>Required full-time equivalents (FTE) for Medically Monitored Residential settings is one FTE counselor for every eight clients.</p> <p>Pennsylvania regulations, Title 28 § 709 – Subchapter E: <i>Standards for Inpatient Nonhospital Activities – Residential Treatment and Rehabilitation</i> outlines the standards for licensure of all Medically Monitored Residential Treatment settings (comparable to ASAM levels 3.1 through 3.7). Available at: https://www.pacode.com/secure/data/028/chapter709/subchapEtoc.html</p> <p>I residential facilities operate 24/7 and provide clinical treatment on a structured schedule, including individual, group, family therapy,</p>	<p>Will provide residential services to comply with ASAM criteria.</p>	<p>Pennsylvania has completed the cross walk of the ASAM criteria with our current system of care, including types of service, hours of clinical care and credentials of staff. Additionally, to assist the field in correctly applying ASAM, DDAP has developed an application guidance for PA’s current substance use system. While PA will begin to utilize The ASAM Criteria’s for admission determination of level of care on July 1, 2018, other details of aligning PA’s SUD system of care (services, hours of service, staff credentials, etc.) with the ASAM Criteria will</p>

<p>and credentials of staff for residential treatment settings</p>	<p>medication monitoring, psychoeducational groups, recovery support services.</p> <p>Pennsylvania regulations, Title 28 § 711 outlines the <i>Standards for Certification of Treatment Activities which are a Part of a Health Care Facility</i>. Available at: https://www.pacode.com/secure/data/028/chapter711/chap711toc.html</p>		<p>be an ongoing process beyond July 2018 and is expected to be completed within 24 months of the demonstration approval.</p> <p>PCPC to ASAM Crosswalk available at:</p> <p>http://www.ddap.pa.gov/Professionals/Documents/ASAM%20Crosswalk%20final.pdf.</p> <p>Guidance for application of ASAM in PA's SUD system of care:</p> <p>http://www.ddap.pa.gov/Professionals/Documents/ASAM%20Application%20Guidance%20Final.pdf.</p>
<p>Implementation of a state process for reviewing residential treatment providers to ensure compliance</p>	<p>All residential settings are licensed by DDAP on an annual basis. Complaints regarding facilities require an immediate onsite review by DDAP.</p> <p>Annual site inspections are conducted for all levels of care. The inspections include but not limited to the follow:</p> <ol style="list-style-type: none"> a. Physical plant inspection b. Client chart review (hours of care, services provided included here among other things) 	<p>DDAP will continue to license the residential setting and ensure compliance with the standards.</p>	<p>Aligning PA's SUD system of care (services, hours of service, staff credentials, etc.) with the ASAM criteria will be an ongoing process beyond July 2018 and is expected to be</p>

<p>with these standards</p>	<ul style="list-style-type: none"> c. Personnel (staffing) chart review (credentials of staff included here) d. Level of care specific P&P e. Medication review (if applicable) f. Direct observation of services g. Staff and client interviews <p>Licensing procedures are outlined in Pennsylvania regulations, Title 28 § 709 – Subchapter B available at: https://www.pacode.com/secure/data/028/chapter709/subchapBtoc.html</p> <p>Clicking on any county on the map in this link will show the providers in the county and the licensing surveys associated with each provider and other related information: http://sais.health.pa.gov/commonpoc/Content/PublicWeb/DAFind.aspx</p>		<p>completed within 24 months of the demonstration approval.</p>
<p>Implementation of requirement that residential treatment facilities offer MAT on-site or facilitate access off site</p>	<p>Facilities may be licensed to provide treatment approaches using a primary medication other than for detoxification. Licensing regulations also require the facilities to coordinate in obtaining other benefits as needed.</p> <p>As per the revised language in the DDAP Treatment Manual, Medication and clinical, therapeutic interventions should be available in all levels of care across the continuum, even if the SUD treatment provider is not the prescriber of the medication. If MAT is needed, the provider will ensure that the clients’ needs are met directly or through an appropriate referral to a prescriber and may not preclude the admission of individuals on MAT into services.</p>	<p>The current regulations, which are the minimum standards, will stay in place.</p> <p>Additionally, as outlined in the “Guidance for Application of ASAM in Pennsylvania’s SUD System of Care” issued in May 2018, it is DDAP’s</p>	<p>DDAP has revised the Treatment Manual to reflect the guidance referenced in the second column.</p>

	<p>In May 2018, DDAP issued "Guidance for Application of ASAM in Pennsylvania's SUD System of Care" that addresses the availability of MAT across the continuity of care, including residential treatment (please see page 25, bullets 3 and 4). This documents is available at http://www.ddap.pa.gov/Professionals/Documents/ASAM%20Application%20Guidance%20Final.pdf.</p>	<p>expectation that clients will be treated as individuals, and if medication is needed, that the provider will ensure that the clients' needs are met. (please see the link to this document in the previous column).</p> <p>DDAP has revised the Treatment Manual to reflect this guidance.</p>	
--	--	---	--

Milestone 4: Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment for OUD

Milestone Criteria	Current State	Future State	Summary of Actions Needed
<p>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 (or at least in participating regions of the state) including those that offer MAT:</p> <ul style="list-style-type: none"> • Outpatient Services; • Intensive Outpatient Services; 	<p>This is a link to a searchable database of all D&A facilities in the Commonwealth: http://sais.health.pa.gov/commonpoc/Content/PublicWeb/DAFind.aspx</p> <p>HealthChoices Managed Care contracts will require the following access standards for 1115 Demonstration Waiver services: The Provider network must provide face-to-face treatment intervention within one hour for emergencies, within twenty-four (24) hours for urgent situations, and within seven (7) days for routine appointments and for specialty referrals.</p> <p>The BH-MCOs monitor their provider network to ensure capacity to serve their members, and expand their network as needed.</p> <p>The Commonwealth has 802 licensed Outpatient and Intensive Outpatient facilities with capacity to serve 91863 individuals.</p> <p>Additionally, there are 177 SUD Partial Hospitalization programs that can serve 4738 individuals.</p>	<p>Will continue to ensure that access standards are met and required capacity is available.</p>	<p>None needed</p>

Milestone 5: Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Implementation of opioid prescribing guidelines along with other interventions to prevent opioid abuse	<p>The Commonwealth has taken significant steps to improve prescribing practices for opioids. DOH and the DDAP have lead roles in the <i>Safe and Effective Prescribing Practices Task Force</i>. The task force membership is drawn from various state agencies, representatives from medical associations, provider advocates and community members. The task force developed and adopted guidelines for ten medical specialties on the safe and effective use of opioids in the treatment of pain. The following link provides those guidelines: http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/M-P/opioids/Pages/Prescribing-Guidelines.aspx#.WIZm5K8o5iz.</p> <p>Pennsylvania's Medical Assistance fee for service (FFS) system requires prior authorization of all short acting opioids for prescriptions that exceed a 3 day supply for children under 21 (within the past year) or a 5 day supply for adults 21 and older (within the past 6 months). All long acting opioids require prior authorization. Quantity limits are based on 50 MME (morphine milligram equivalents) per day. The Department requires that the managed care organizations implement the same prior authorization guidelines for certain drug classes, including opioids. All other prior authorization policies developed by the MCOs</p>	<p>Will continue to ensure the efficacy of the opioid prescribing guidelines.</p>	<p>None needed at this time.</p>

	<p>must be reviewed and approved by the Department prior to implementation and at least annually.</p> <p>Automated approval applies at the pharmacy point of sale for beneficiaries with diagnosis of active cancer, sickle cell crisis, neonatal abstinence syndrome, or if the beneficiary is receiving palliative care or hospice services. If the conditions are not identified in the claims history, approval is issued for the opioid through the prior authorization process. These guidelines for medical necessity apply in both the Medicaid FFS and MCO delivery systems.</p> <p>Pennsylvania’s Medical Assistance FFS Preferred Drug List is available at https://papdl.com/sites/default/files/ghs-files/Penn%20PDL%2007252017%20v2017_1g.pdf (see page 33 for Oncology Agents and page 35 for Opiate Dependence Treatments). This also contains links to <i>Prior Authorization Guidelines, Quantity Limits Lists, and Prior Authorization Forms</i>. Managed care organizations can develop their own formulary/preferred drug list that must be submitted to the Department for review and approval prior to implementation.</p> <p>Additionally, the following link provides a searchable database for all drugs available in the Medical Assistance Preferred Drug List, with information on any <i>prior authorization requirements, preferred/non-preferred, quantity limits</i></p>		
--	--	--	--

	etc.: http://www.dhs.pa.gov/publications/forproviders/schedules/drugfeeschedule/index.htm .		
Expanded coverage of, and access to, naloxone for overdose reversal	<p>Pennsylvania’s Act 139 of 2014 allows first responders including law enforcement, fire fighters, EMS or other organizations the ability to administer naloxone to individuals experiencing an opioid overdose. The law also allows individuals such as friends or family members that may be in a position to assist a person at risk of experiencing an opioid related overdose to obtain a prescription for naloxone. This legislation also provides immunity from prosecution for those responding to and reporting overdoses.</p> <p>The Commonwealth has made naloxone available for any Pennsylvanian. Individuals can go to a participating pharmacy and secure naloxone for themselves or a family member under Commonwealth’s Physician General's standing order for prescription available at: http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/M-P/opioids/Documents/General%20Public%20Standing%20Order-001-2018.pdf _</p>	This order will be reviewed and updated as needed, if there is relevant new science about Naloxone administration. Even if no new science on this becomes available, the standing order will be reviewed and updated if needed, in at least in 4 years from the effective date of 01/10/2018. This standing order does not specifically address if it will be renewed every 4 years after that or not.	None needed at this time.

<p>Implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs</p>	<p>The following is a discussion of the activities undertaken by Pennsylvania’s PDMP office:</p> <p><u>Mass communication and Outreach</u></p> <p>Starting May 2016, PDMP office conducted several communication and outreach activities to all the prescribers and dispensers in PA. Additionally, the office partnered with the professional medical societies and associations, and executive leadership of the health care entities to send communications about the launch of the PDMP system, tutorials on how to use the PDMP system and identify red flags, etc. With the continued efforts, PA PDMP saw uptake in the registration and use of the system. As of Dec 2017, there are about 97,000 registered users of the system and on an average about 52,000 patient queries are conducted each day, with over 1.1 million patient searches completed by the users each month. The outreach activities included:</p> <ul style="list-style-type: none"> • E-mail blasts • Online tutorials • Mass mailings • Online video resources • Conference booths at various professional societies • Social media, radio and TV PSAs • Webinars • Outreach through medical professional societies and state licensing boards • PA – Health Alerts Network (PA-HAN) • County and municipal health department outreach 	<p>The seven education modules discussed in the previous column under <i>PDMP and Opioid Prescriber Education Initiative</i> will be available early Q1 2018 for prescriber and dispenser face to face education as well as through online training, and continuing medical education units (CME) will be provided. More information will be posted on www.doh.pa.gov/PDMP</p>	<p>The Commonwealth will continue to monitor practices and needs and take steps as needed.</p>
---	---	---	--

	<p><u>Ensuring all authorized users can assign delegates</u></p> <p>To ease the burden on the licensed medical professionals such as the prescribers and dispensers, PA PDMP allowed the authorized users to assign delegates that can run the patient searches on behalf of them. This is a very important feature especially when providers are busy addressing patient health concerns. This feature has overall improved the clinical workflows for the providers.</p> <p><u>Interstate data sharing capability</u></p> <p>Right after the launch of the PA PDMP system, the Commonwealth worked towards interstate data sharing with the neighboring states. This allows users of the PA PDMP system to search for their patients across state lines. The states that are now connected also allow their respective states to search PA PDMP system for their patients. This functionality is especially critical for the health care practices where they are closely bordered to another state and their patients are traveling across state line to locate multiples providers and pharmacies for controlled substances. These multiple provider episodes (doctor shopping) can be reduced or eliminated if providers have access to their patient’s prescription history from bordering states. In Pennsylvania, patients that went to 5+ prescribers and 5+ pharmacies in the span of 3 months have been reduced to 86% since the launch of the PA PDMP system. Additionally, patients that went to 10+ prescribers and 10+ pharmacies in the span of 3 months have been completely eliminated. As of December 2017, PA</p>		
--	---	--	--

	<p>PDMP is now connected with CT, DE, IL, LA, MA, MD, ME, MN, NJ, NY, OH, OK, SC, TX, VA, WV and Washington D.C.</p> <p><u>Registration and query requirements of PA PDMP</u></p> <p><i>Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act 191 of 2014</i> legislation required prescribers to query the PDMP system 1) before they prescriber any new controlled substances to their patients or 2) if they have reason to believe that their patients are involved in abuse, misuse or diversion of controlled substances. In November 2016, the legislation required all the licensed prescribers and dispensers to register with the program. With the effective date of Jan 1, 2017, PA PDMP system registrants increased. The use of the system almost doubled since the effective date. Additional query requirements were included for both prescribers and dispensers. Prescribers were now required to check the PDMP system each time they prescribe opioids or benzodiazepine. Dispensers shall query the PDMP before dispensing an opioid drug product or a benzodiazepine prescribed to a patient if any of the following apply: 1) The patient is a new patient of the dispenser. 2) The patient pays cash when they have insurance. 3) The patient requests a refill early. 4) The patient is getting opioid drug products or benzodiazepines from more than one prescriber.</p> <p><u>Integrate the PA PDMP system with Electronic Health Record (EHR) and Pharmacy Management System (PMS)</u></p>		
--	---	--	--

	<p>The Pennsylvania Department of Health (DOH) is integrating the Prescription Drug Monitoring Program (PDMP) system into electronic health records and pharmacy systems across the commonwealth. The goal is to minimize any workflow disruption by providing near-instant and seamless access to critical prescription history information to both prescribers and pharmacists. All health care entities in Pennsylvania legally authorized to prescribe, administer or dispense controlled substances are eligible to apply for integration. This includes ambulatory care units, acute care facilities, emergency care units, physician practices, pharmacies, drug treatment facilities and others. Once the integration with the health care entities that use the Certified Electronic Health Record Technology (CEHRT) is successfully completed, the Eligible Professionals (Eps) and Eligible Hospitals (EHs) also meet the definition of a Meaningful Use (MU) Stage 2 specialized registry.</p> <p><u>PDMP and Opioid Prescriber Education Initiative</u></p> <p>PA PDMP Office developed an Education Workgroup that consisted of PA Physician General's Office, staff from Department of Drug and Alcohol Programs, members of the ABC-MAP Advisory Committee, members of two Single county authority that help refer patients to treatment programs, health care administrators, pharmacists and physicians. The purpose of this workgroup was to provide recommendations to the PA PDMP office on the creation and development of innovative and evidence-based education</p>		
--	--	--	--

	<p>materials for prescribers and dispensers. The workgroup prioritized four topics that consisted of 1) how to effectively build the PDMP system into clinical workflows, 2) how to effectively use the PDMP data to make informed clinical decisions and refer patient to treatment, 3) how to safely taper high doses of opioids to recommended levels, and 4) how to create a culture of change and promote the above strategies in their respective clinical settings. Using these topics, the PDMP Office partnered with University of Pittsburgh and developed seven education modules that consisted of pocket cards, flow diagrams, resource flyers and guide documents.</p>		
<p>Other</p>	<p>Please see Section XII: Strategies to Address Prescription Drug Abuse and Section XIII: Strategies to Address Opioid Use Disorder</p>		

Milestone 6: Improved Care Coordination and Transitions between Levels of Care

Milestone Criteria	Current State		Summary of Actions Needed
<p>Implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities</p>	<p>Please see Section VII: Care Coordination Design</p> <p><i>Additionally, Pennsylvania regulations Title 28_ § 709.52. Treatment and Rehabilitation services is available at https://www.pacode.com/secure/data/028/chapter709/s709.52.html require that the Individual Treatment and Rehabilitation Plan include information about the various support services needed.</i></p>	<p>Already meeting the requirement</p>	<p>None needed</p>

<p>Additional policies to ensure coordination of care for co-occurring physical and mental health conditions</p>	<p>Please see the discussion on CCBHCs</p> <p>Based on a person and family-centered plan of care aligned with the requirements of Section 2402(a) of the ACA and aligned with state regulations and consistent with best practices, the CCBHC coordinates care across the spectrum of health services, including access to high-quality physical health (both acute and chronic) and behavioral health care, as well as social services, housing, educational systems, and employment opportunities as necessary to facilitate wellness and recovery of the whole person.</p>	<p>The Commonwealth will review data from CCBHCs and decide on any future steps.</p> <p>The evaluation of Pennsylvania’s CCBHC Demonstration is accomplished in two ways. A quality dashboard has been developed to allow the CCBHCs to submit data on three identified goals (30+ measures). This data is reviewed on a quarterly basis and shared with all the clinics and stakeholders at quarterly meetings. Data is also collected through encounter submission for the 21 CCBHC measures required by the Demonstration. The External Quality Review Organization will assist Pennsylvania in validating these measures. This data will also be shared with stakeholders.</p>	<p>The Commonwealth will review data from CCBHCs.</p>

Attachment F:
SUD Monitoring Protocol
(reserved)