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

June 28, 2018

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

Dear Ms. Miller:

We are pleased to inform you that the Centers for Medicare & Medicaid Services (CMS) has approved Pennsylvania's request for an amendment to the "Pennsylvania Medicaid Coverage for Former Foster Care Youth from a Different State" section 1115 demonstration (Project Number: 11-W-00308/3), which is now referred to as the "Pennsylvania Medicaid Coverage for Former Foster Care Youth from a Different State and Substance Use Disorder (SUD) Demonstration." This approval is effective beginning July 1, 2018 through September 30, 2022.

CMS's approval of this section 1115 demonstration amendment is subject to the limitations specified in the approved waiver and expenditure authorities as well as the compliance with the enclosed Special Terms and Conditions (STCs) defining the nature, character, and extent of federal involvement in this project. The state may deviate from the Medicaid state plan requirements only to the extent those requirements have been waived or specifically listed as not applicable to the expenditure authority.

This approval authorizes Pennsylvania to receive federal financial participation (FFP) for the continuum of services to treat addictions 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 Institution for Mental Diseases (IMD) and who receive services via managed care. FFP will not be available for opioid use disorder (OUD)/ SUD services in IMDs for beneficiaries who receive services via fee-for-service, although eligible fee-for-service beneficiaries will be able to access medically necessary inpatient OUD/SUD services in settings that do not meet the definition of an IMD.

Implementation of the demonstration amendment is likely to assist in promoting the objectives of the Medicaid program as it is expected to improve health outcomes for Medicaid beneficiaries by increasing access to high quality opioid use disorder/SUD care. Specifically, the demonstration is expected to assist the state in increasing the identification, initiation, and engagement in

treatment; increased adherence to and retention in treatment; reductions in overdose deaths, particularly those due to opioids; and reduced inappropriate or preventable utilization of emergency departments and inpatient hospital settings through improved access to other continuum of care services.

Both Pennsylvania and CMS received comments during the state and federal public comment periods. Consistent with federal transparency requirements, CMS reviewed all of the materials submitted by the state, as well as all of the comments it received, when evaluating whether the demonstration project as a whole was likely to assist in promoting the objectives of the Medicaid program.

During the state public comment period (November 18, 2017 through December 18, 2017), the vast majority of comments supported the demonstration application. Some commenters suggested changes to the Pennsylvania Medicaid Coverage for Former Foster Care Youth from a Different State SUD amendment such as retaining the Pennsylvania Client Patient Criteria (PCPC) instead of moving to the American Society of Addiction Medicine (ASAM) placement criteria. Other commenters shared their concern about the training costs associated with moving to the ASAM placement criteria.

Pennsylvania responded to all the state public comments and recommendations, including through a detailed action items chart in the public notice section of the demonstration amendment application. For example, to respond to concerns regarding transitioning to the ASAM placement criteria, the state explicitly stated in its application that guidance on the application of the ASAM criteria would be offered to ensure all services within the PCPC continuum of care are available under the ASAM criteria. The state has been educating providers on the ASAM criteria for over a year. Finally, some stakeholders asked the state to also request FFP for beneficiaries who are primarily in the IMD to receive mental health treatment. Pennsylvania responded that it recognizes the commenter's concern, but the section 1115 demonstration opportunity was only available for treatment for beneficiaries who are in the IMD primarily for SUD treatment.

During the federal public comment period (March 28, 2018 through April 27, 2018), commenters also expressed concern about moving from the PCPC criteria to the ASAM criteria. CMS reviewed the comments and determined that the state had adequately addressed the concerns raised by stakeholders who had concerns with the moving to the ASAM criteria by organizing multiple trainings and resources on ASAM criteria for providers. Overall, the commenters expressed support for the demonstration amendment.

The award is subject to your written acknowledgement of the award and acceptance of the STCs within 30 calendar days of the date of this letter. Please send your written acceptance to your project officer, Mr. Felix Milburn. He is available to answer any questions concerning your section 1115 demonstration. His contact information is as follows:

Mr. Felix Milburn
Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services

Mail Stop: S2-25-26
7500 Security Boulevard
Baltimore, MD 21244-1850
Telephone: (410) 786-1315
E-mail: Felix.Milburn@cms.hhs.gov

Official communication regarding official matters should be simultaneously sent to Mr. Felix Milburn and Mr. Francis McCullough, Associate Regional Administrator for the Division of Medicaid and Children's Health Operations in our Philadelphia Regional Office. Mr. McCullough's contact information is:

Mr. Francis McCullough
Associate Regional Administrator
Division of Medicaid and Children's Health Operations Program
Suite 216, The Public Ledge Building
150 South Independence Mall West
Philadelphia, PA 19106

If you have questions regarding this approval, please contact Ms. Judith Cash, Director, State Demonstrations Group, Centers for Medicaid & CHIP Services at (410) 786-9686.

We look forward to continuing to work with you and your staff.

Sincerely,

/s/

Timothy B. Hill
Acting Director

Enclosures

cc: Francis McCullough, Associate Regional Administrator, Philadelphia Regional Office

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, 2017 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, 2017 through September 30, 2022. 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 July 1, 2018 through September 30, 2022, unless otherwise specified, be regarded as expenditures under the state's title XIX plan.

The following expenditure authority 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 otherwise covered services furnished to otherwise eligible individuals enrolled in managed care who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD) as described in STC 28.

CENTERS FOR MEDICARE & MEDICAID SERVICES

SPECIAL TERMS AND CONDITIONS of APPROVAL

DEMONSTRATION NUMBER: 11-W-00308/3

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

DEMONSTRATION AWARDEE: Pennsylvania Department of Human Services

I. 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, 2017 through September 30, 2022 (the approval period) unless otherwise specified. The SUD component of the demonstration is effective July 1, 2018 through September 30, 2022.

The STCs have been arranged into the following subject areas:

Attachment D: Former Foster Care Youth Evaluation Design (reserved)
Attachment E: SUD Demonstration Evaluation Design (reserved)
Attachment F: SUD Implementation Plan Protocol; and
Attachment G: SUD Monitoring Protocol (reserved)

II. 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.

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, Pennsylvania intends 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. This demonstration component will provide the state with authority 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 demonstration will also 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 test whether the SUD section 1115 demonstration amendment described in these STCs 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. Increase 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.

III. GENERAL PROGRAM REQUIREMENTS

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

2. **Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program expressed in law, regulation, and/or 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), shall apply to the demonstration.

3. **Changes in Medicaid Law, Regulation, and Policy.** The state must, within the timeframes specified in law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is explicitly waived or identified as not applicable.

   CMS reserves the right to amend these STCs to reflect such changes and/or changes of an operational nature without requiring the state to submit an amendment to the demonstration per STC 7. CMS will notify the state thirty (30) days in advance of the expected approval date of the amended STCs to align with mandated changes in Medicaid law, regulation, and policy that directly impact this demonstration program.

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 may be required to adopt a budget neutrality agreement if CMS determines the impact of the changes in federal law, regulation, or policy necessitates such a requirement be implemented. The modified agreement will be effective upon the implementation of the change.

   b. If mandated changes in the federal law require state legislation, the changes must 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 law.

5. **State Plan Amendments**. For the SUD component of this demonstration, the state will not be required to submit Title XIX or Title XXI state plan amendments for changes affecting any population made eligible solely through the demonstration. If a population eligible through the Medicaid state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan may be required, except as otherwise noted in these STCs. Rules for state plan amendments for the FFCY component of this demonstration are set forth in STC 19.

6. **Changes Subject to the Amendment Process.** Changes related to demonstration features such as eligibility, enrollment, benefits, delivery systems, cost sharing, sources of non-federal share of funding, 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. Amendments to the demonstration are not retroactive and FFP will not be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7, except as provided in STC 3.

7. **Amendment Process.** Requests to amend this demonstration must be submitted to CMS for approval no later than 120 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 upon non-compliance with these STCs, including but not limited to failure by the state to submit required elements for an amendment request as outlined below, required progress reports, and other deliverables required by these STCs in a timely fashion according to the deadlines specified herein. Amendment requests must minimally include the following:

    a. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;

    b. An explanation of the public process used by the state consistent with the requirements of STC 8; and

    c. If applicable, a description of how the evaluation design will be modified to incorporate the proposed amendment.

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

    If the state has federally recognized tribes, the state must also comply with the tribal consultation requirements set forth in section 1902(a)(73) of the Act and implemented in regulation at 42 CFR section 431.408(b), and the tribal consultation requirements contained in the state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 6 or extension, are proposed by the state.

9. **Extension of the Demonstration.** No later than twelve (12) months prior to the expiration date of the demonstration, the Governor or Chief Executive Officer of Pennsylvania must

submit to CMS either a demonstration extension request that meets federal requirements at 42 CFR section 431.412(c) or a phase-out plan consistent with the requirements of STC 10.

10. Demonstration Phase Out. The state may suspend or terminate this demonstration in whole, or in part, at any time prior to the date of expiration.

a. Notification of Suspension or Termination: The state must promptly notify CMS in writing of the effective date and reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. At least six (6) months before the effective date of the demonstration's suspension or termination, the state must submit to CMS its proposed transition and phase-out plan, together with intended notifications to demonstration enrollees. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft plan for a thirty (30) day public comment period. In addition, the state must conduct tribal consultation in accordance with its approved tribal consultation State Plan Amendment. Once the thirty (30) day public comment period has ended, the state must provide a summary of public comments received, the state's response to the comments received, and how the state incorporated the received comments into the transition and phase-out plan submitted to CMS.

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

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

d. Phase-out Procedures: The state must comply with all notice requirements found in 42 CFR sections 431.206, 431.210, and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration participants as outlined in 42 CFR sections 431.220 and 431.221. If a demonstration participant requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR section 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category as found in 42 CFR section 435.916.

e. Exemption from Public Notice Procedures 42.CFR section 431.416(g): CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR section 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 (6) months of the demonstration, enrollment of new individuals into the demonstration must be suspended.

g. Federal Financial Participation (FFP): If the project is terminated or any relevant waivers suspended by the state, FFP shall be limited to normal closeout costs associated with terminating the demonstration including services and administrative costs of disenrolling participants.

11. CMS Right to Terminate or Suspend. CMS may suspend or terminate the demonstration, in whole or in part, at any time before the date of expiration, whenever it determines following a hearing that the state has materially failed to comply with the terms of the demonstration project. CMS must promptly notify the state in writing of the determination and the reasons for the suspension or termination, together with the effective date.

12. Finding of Non-Compliance. CMS will withhold payments to the state in the amount of $1,000,000 (for the FFCY component) per occurrence and up to $5,000,000 per occurrence for IMD claiming (as set forth in STC 27) when deliverables are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. The state does not relinquish its rights to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

a. Thirty (30) days after the deliverable was due, CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverables.

b. For each deliverable, the state may submit a written request for an extension in which to submit the required deliverable. 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. The deferral would be issued against the next quarterly expenditure report following the written deferral notification (subject to any extension granted under (b)).

d. When the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in the 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 extension, amendment or renewal, or for a new demonstration.

f. If applicable, CMS will consider with the state an alternative set of operational steps for implementing the intended deferral to align the process with the state's existing deferral process, for example, the structure of the state request for an extension, what quarter the

deferral applies to and how the deferral is released.

13. **Withdrawal of Waiver/Expenditure Authority.** CMS reserves the right to amend or withdraw waiver 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 amendment or 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 or amended, 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 participants.

14. **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 applicable to the demonstration; compliance with cost sharing requirements; and reporting on financial and other demonstration components.

15. **Federal Financial Participation (FFP).** No federal matching for administrative or medical assistance payments for services provided under this demonstration will take effect until the effective date identified in the CMS demonstration approval documents.

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

IV. ELIGIBILITY, BENEFITS, and BUDGET NEUTRALITY FOR THE FFCY COMPONENT OF THE DEMONSTRATION

17. **Eligibility for the FFCY Component.** Individuals eligible for this demonstration 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.

18. **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).

19. State Plan Amendments. As outlined in CMS' November 21, 2016 CMCS Informational Bulletin to *Allow Medicaid Coverage to Former Foster Care Youth Who Have Moved to a Different State,* the state shall submit conforming amendment(s) to the Medicaid State Plan for the out-of-state former foster care youth affected by the implementation of this demonstration. For any subsequent Medicaid State Plan changes approved affecting the eligibility of the out-of-state former foster care youth being covered under this demonstration, a conforming amendment to this demonstration project is required to be submitted as outlined in STC 7.

20. 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 6 and 7 that may impact costs associated with the FFCY demonstration component.

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

21. 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.

22. Opioid Use Disorder/Substance Use Disorder Program. Effective upon CMS's approval of the OUD/SUD Implementation Protocol, as described in STC 23, the demonstration benefit package for Pennsylvania Medicaid recipients will include OUD/SUD treatment services, including services provided in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD), which are not otherwise matchable expenditures under section 1903 of the Act. The state will be 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

pursuance to the SUD Monitoring Protocol as outlined in STC 24 below to ensure short-term residential treatment stays.

Under this program, 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 will expand the state's current OUD/SUD benefit package available to all Pennsylvania Medicaid beneficiaries as outlined in Table 1. 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.

Table 1: 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.

23. SUD Implementation Plan Protocol. The state must submit an OUD/SUD Implementation Plan Protocol within 90 calendar days after approval of the demonstration amendment. The state submitted the draft implementation protocol as part of the application and CMS is approving the SUD Implementation Plan Protocol as Attachment F. The state may not claim

FFP for services provided in IMDs until CMS has approved the Implementation Plan Protocol. Once approved, the Implementation Plan Protocol will be incorporated into the STCs, as Attachment F, and once incorporated, may be altered only with CMS approval. After approval of the Implementation Plan Protocol, FFP will be available prospectively, not retrospectively. Failure to submit an Implementation Plan Protocol will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the OUD/SUD program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral. At a minimum, the OUD/SUD Implementation Plan Protocol must describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives of the SUD program in this demonstration.

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 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 licensed organization, pursuant to the residential service provider qualifications described in Pennsylvania regulations. 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 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 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;

f. **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;

g. **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;

h. **SUD Health IT Plan:** Implementation of the milestones and metrics as detailed in STC 26; and

i. **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.

24. SUD Monitoring Protocol. The state must submit a SUD Monitoring Protocol within 150 calendar days after approval of the SUD program under this demonstration. The SUD Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs, as Attachment G. At a minimum, the SUD Monitoring Plan Protocol will include reporting relevant to each of the program implementation areas listed in STC 23. The protocol will also describe the data collection, reporting and analytic methodologies for performance measures identified by the state and CMS for inclusion. The SUD Monitoring Protocol will specify 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 STC 31 of the demonstration. In addition, for each performance measure, the SUD Monitoring Protocol will identify a baseline, a target to be achieved by the end of the demonstration and an annual goal for closing the gap between baseline and target expressed as percentage points.

Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings. CMS will closely monitor demonstration spending on services in IMDs to ensure adherence to budget neutrality requirements. Progress on the performance measures identified in the SUD Monitoring Protocol will be reported via the quarterly and annual monitoring reports.

25. Mid-Point Assessment. The state must conduct an independent mid-point assessment by October 31, 2020. The assessor must collaborate with key stakeholders, including representatives of MCOs, SUD treatment providers, beneficiaries, and other key partners in the design, planning and conducting of the mid-point assessment. The assessment will include an examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plan Protocol, and toward closing the gap between baseline and

target each year in performance measures as approved in the SUD Monitoring Protocol. The assessment will also include a determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date, and a determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and about the risk of possibly missing those milestones and performance targets. The mid-point assessment will also provide a status update of budget neutrality requirements. For each milestone or measure target at medium to high risk of not being met, the assessor will provide, for consideration by the state, recommendations for adjustments in the state's implementation plan or to pertinent factors that the state can influence that will support improvement. The assessor will 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. A copy of the report will be provided to CMS. CMS will be briefed on the report.

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 Protocol and SUD Monitoring Plan Protocol for ameliorating these risks subject to CMS approval.

26. SUD Health Information Technology (Health IT). The state will provide CMS with an assurance that it has a sufficient health IT infrastructure/"ecosystem" at every appropriate level (i.e. state, delivery system, health plan/MCO 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 will be included as a section of the state's "Implementation Plan" (see STC 23) to be approved by CMS. 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]

[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.

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 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.

    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

[2] *Ibid*.

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

h. The state will include in its monitoring Plan (see STC 24) 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 34).

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.

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

    ii. Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally-recognized ISA standards, barring no other compelling state interest.

27. 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 Protocol 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 thereafter until CMS has determined sufficient progress has been made.

28. 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.

VI. COST SHARING

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

VII. DELIVERY SYSTEM

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

VIII. GENERAL REPORTING REQUIREMENTS

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

32. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in the amount of $5,000,000 (federal share) when items required by these SUD 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 found to not be consistent with the requirements approved by CMS. Specifically:

    a. Thirty (30) calendar days after the deliverable was due, CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverables.

    b. For each deliverable, the state may submit a written request for an extension to submit the required deliverable. Extension requests that extend beyond the current fiscal quarter must include a Corrective Action Plan (CAP).

        i. CMS may decline the extension request.

        ii. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided.

        iii. If the state's request for an extension includes a CAP, CMS may agree to or further negotiate the CAP as an interim step before applying the deferral.

    c. The deferral would be issued against the next quarterly expenditure report following the written deferral notification.

    d. When the state submits the overdue deliverable(s) that are accepted by CMS, the deferral(s) will be released.

    e. As the purpose of a section 1115 demonstration is to test new methods of operation or services, a state's failure to submit all required deliverables may preclude a state from renewing a demonstration or obtaining a new demonstration.

    f. CMS will consider with the state an alternative set of operational steps for implementing the intended deferral to align the process with the state's existing deferral process, for example, what quarter the deferral applies to and how the deferral is released.

33. Compliance with Federal Systems Updates. As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state will work with CMS to:

a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;

b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and

c. Submit deliverables to the appropriate system as directed by CMS.

IX. MONITORING

34. Monitoring Reports. The state must submit three (3) Quarterly Reports and one (1) compiled Annual Report each DY. The information for the fourth quarter should be reported as distinct information within the Annual Report. The Quarterly Reports are due no later than sixty (60 calendar days) following the end of each demonstration quarter. The compiled Annual Report is due no later than ninety (90 calendar days) following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

a. Operational Updates – Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

b. Performance Metrics – Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

c. Budget Neutrality and Financial Reporting Requirements – Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately.

d. Evaluation Activities and Interim Findings – Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

e. SUD Health IT – The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 26.

35. Close-Out Report. Within 120 calendar days after the expiration of the demonstration, the state must submit a Draft Close-Out Report to CMS for comments.

a. The draft report must comply with the most current guidance from CMS.

b. The state will present to and participate in a discussion with CMS on the close-out report.

c. The state must take into consideration CMS' comments for incorporation into the final close-out report.

d. The final close-out report is due to CMS no later than 30 calendar days after receipt of CMS' comments.

e. A delay in submitting the draft or final version of the close-out report may subject the state to penalties described in STC 32.

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

a. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, enrollment and access, budget neutrality, and progress on evaluation activities.

b. CMS will provide updates on any amendments or concept papers under review, 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.

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

X. EVALUATION OF THE FORMER FOSTER CARE YOUTH COMPONENT OF THE DEMONSTRATION

38. 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.

39. Draft Evaluation Design. The draft Evaluation Design must be developed in accordance with Attachment B (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after the effective date of these STCs. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state must use an independent evaluator to develop the draft Evaluation Design.

40. Evaluation Design Approval and Updates. The state must submit a revised draft Evaluation Design within sixty (60) days after receipt of CMS' 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, including any required Rapid Cycle Assessments specified in theses STCs. Once CMS approves the evaluation design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

41. Evaluation Questions and Hypotheses. Consistent with Attachments B and C (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation

question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

42. 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 renewal, the Evaluation Report should be posted to the state's website with the application for public comment.

a. The interim evaluation report will discuss evaluation progress and present findings to date as per the approved evaluation design.

b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.

c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses, and how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.

d. The state must submit the final Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.

e. The Interim Evaluation Report must comply with Attachment C of these STCs.

43. Summative Evaluation Report. The draft Summative Evaluation Report must be developed in accordance with Attachment C of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period, October 1, 2017 through September 30, 2022, within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

a. Unless otherwise agreed upon in writing by CMS, the state must submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.

b. The final Summative Evaluation Report must be posted to the state's Medicaid website within 30 calendar days of approval by CMS.

44. 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.

45. Public Access. The state shall post the final documents (e.g., 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.

46. 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.

47. 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 32.

XI. EVALUATION OF THE SUD COMPONENT OF THE DEMONSTRATION

48. SUD Evaluation. The OUD/SUD Evaluation will be subject to the same requirements as the Former Foster Care demonstration evaluation, as listed in sections VIII General Reporting Requirements and X Evaluation of the Demonstration of the STCs.

49. Independent Evaluator. Upon approval of the demonstration, the state must begin to arrange with an independent party to conduct an evaluation of the SUD demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. 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

50. SUD Evaluation Design. The draft Evaluation Design must be developed in accordance with Attachment B (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a revision to the Evaluation Design to include the SUD program with implementation timeline, no later than one hundred eighty (180) days after the effective date of these amended STCs. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state must use an independent evaluator to develop the draft Evaluation Design.

a. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) days after receipt of CMS' 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 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 Quarterly and Annual Reports, including any required Rapid Cycle Assessments specified in these STCs. Once CMS approves the evaluation design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

b. **Evaluation Questions and Hypotheses Specific to OUD/SUD Program**. Consistent with Attachments B and C (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

XII. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

51. Reporting Expenditures under the Demonstration. The following describes the reporting of expenditures subject to the SUD Budget Neutrality agreement:

a. Tracking Expenditures. In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in section 2500 of the State Medicaid Manual.

All demonstration expenditures claimed under the authority of title XIX of the Act and subject to the budget neutrality expenditure limit must be reported each quarter on separate Forms CMS-64.9 Waiver and/or 64.9P Waiver, identified by the demonstration project number (11-W-00304/0) assigned by CMS, including the project number extension which indicates the Demonstration Year (DY) in which services were rendered.

b. Cost Settlements. For monitoring purposes, cost settlements attributable to the demonstration must be recorded 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.

c. Pharmacy Rebates. When claiming these expenditures the state may refer to the July 24, 2014 CMCS Informational Bulletin which contains clarifying information for quarterly reporting of Medicaid Drug Rebates in the Medicaid Budget and Expenditures (MBES) (http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-24-2014.pdf). The state must adhere to the requirement at section 2500.1 of the State Medicaid Manual that all state collections, including drug rebates, must be reported on the CMS-64 at the applicable Federal Medical Assistance Percentage (FMAP) or other matching rate at which related expenditures were originally claimed.

d. Use of Waiver Forms. For the SUD component in each demonstration year, separate Forms CMS-64.9 Waiver and/or 64.9P Waiver must be completed, using the waiver names listed below. Expenditures should be allocated to these forms based on the guidance which follows.

   i) **SUD IMD TANF:** All expenditures for costs of medical assistance that could be covered, were it not for the IMD prohibition under the state plan, provided to otherwise eligible TANF individuals during a month in an IMD.

   ii) **SUD IMD SSI Duals:** All expenditures for costs of medical assistance that could be covered, were it not for the IMD prohibition under the state plan, provided to otherwise eligible SSI dual eligibles during a month in an IMD.

   iii) **SUD IMD SSI Non-Duals:** All expenditures for costs of medical assistance that could be covered, were it not for the IMD prohibition under the state plan, provided to otherwise eligible SSI non-dual eligibles during a month in an IMD.

   iv) **SUD IMD HCE**: All expenditures for costs of medical assistance that could be covered, were it not for the IMD prohibition under the state plan, provided to otherwise eligible HealthChoices Expansion (HCE) eligibles during a month in an IMD.

e. Demonstration Years. The demonstration years are as follows:

Demonstration Year 1	July 1, 2018 to June 30, 2019	12 Months
Demonstration Year 2	July 1, 2019 to June 30, 2020	12 Months
Demonstration Year 3	July 1, 2020 to June 30, 2021	12 Months
Demonstration Year 4	July 1, 2021 to June 30, 2022	12 Months
Demonstration Year 5	July 1, 2022 to September 30, 2022	3 Months

52. Budget Neutrality Monitoring Tool. The state and CMS will jointly develop a SUD budget neutrality monitoring tool (using a mutually agreeable spreadsheet program) for the state to use for quarterly budget neutrality status updates including established baseline and member months data and other in situations when an analysis of budget neutrality is required. The tool will incorporate the "C Report" for monitoring actual expenditures subject to budget neutrality. A working version of the monitoring tool will be available for the state's first Annual Report.

53. Quarterly Expenditure Reports: The state must provide quarterly expenditure reports using the Form CMS-64 to report total expenditures for services provided through this under the Medicaid program, including those provided through the demonstration under section 1115 authority that are subject to budget neutrality. This project is approved for expenditures applicable to services rendered during the demonstration period. 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.

FFP will be provided for expenditures net of collections in the form of pharmacy rebates, cost sharing, or third party liability.

54. Expenditures Subject to the SUD Budget Neutrality Agreement. For the purpose of this section, the term "expenditures subject to the budget neutrality agreement" means expenditures for the EGs outlined in Section XIII, Monitoring Budget Neutrality for the Demonstration, except where specifically exempted. All expenditures that are subject to the budget neutrality agreement are considered demonstration expenditures and must be reported on Forms CMS-64.9 Waiver and/or 64.9P Waiver.

55. Administrative Costs. Administrative costs will not be included in the budget neutrality limit, but the state must separately track and report additional administrative costs that are directly attributable to the demonstration, using separate CMS-64.10 waiver and 64.10 waiver forms, with waiver name "ADM."

56. Claiming Period. All claims for expenditures subject to the budget neutrality limit (including any cost settlements) must be made within two (2) years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including any cost settlements) must be made within two (2) years

after the conclusion or termination of the demonstration. During the latter 2-year period, the state must continue to identify separately net expenditures related to dates of service during the operation of the section 1115 demonstration on the Form CMS-64 in order to properly account for these expenditures in determining budget neutrality.

57. Reporting Member Months. The following describes the reporting of member months for demonstration populations.

a. For the purpose of calculating the budget neutrality expenditure limit and for other purposes, the state must provide to CMS, as part of the budget neutrality Monitoring Tool required under STC 52, the actual number of eligible member months for the each MEG defined in subparagraph D below. The state must submit a statement accompanying the budget neutrality Monitoring Tool, which certifies the accuracy of this information. To permit full recognition of "in-process" eligibility, reported counts of member months may be subject to revision.

b. The term "eligible member/months" refers to the number of months in which persons are eligible to receive services. For example, a person who is eligible for 3 months contributes 3 eligible member months to the total. Two individuals who are eligible for 2 months each contribute 2 eligible member months to the total, for a total of 4 eligible member/months.

c. The state must report separate member month totals for individuals enrolled in the Medicaid Coverage for Former Foster Care Youth from a Different State and Substance Use Disorder Demonstration and the member months must be subtotaled according to the MEGs defined in STC 57(d)(i).

d. The required member month reporting MEGs are:

i) **SUD IMD TANF**: SUD IMD Member Months are months of Medicaid eligibility during which the TANF individual is an inpatient in an IMD under terms of the demonstration for any day during the month and must be reported separately for each SUD IMD MEG, as applicable.

ii) **SUD IMD SSI Duals**: SUD IMD Member Months are months of Medicaid eligibility during which the SSI Dual individual is an inpatient in an IMD under terms of the demonstration for any day during the month and must be reported separately for each SUD IMD MEG, as applicable.

iii) **SUD IMD SSI Non-Duals:** SUD IMD Member Months are months of Medicaid eligibility during which the SSI Non-Dual individual is an inpatient in an IMD under terms of the demonstration for any day during the month and must be reported separately for each SUD IMD MEG, as applicable.

iv) **SUD IMD HCE**: SUD IMD HCE Member Months are months of Medicaid eligibility during which the HCE individual is an inpatient in an IMD under terms of

the demonstration for any day during the month and must be reported separately for each SUD IMD MEG, as applicable

58. Standard Medicaid Funding Process. The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable Medicaid expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report those expenditures by quarter for each FFY on the Form CMS-37 (narrative section) for both Medical Assistance Payments (MAP) and state and Local Administrative Costs (ADM). As a supplement to the Form CMS-37, the state will provide updated estimates of expenditures subject to the budget neutrality limit. CMS will make federal funds available based upon the state's estimate, as approved by CMS. Within 30 calendar days after the end of each quarter, the state must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter just ended. CMS will reconcile expenditures reported on the Form CMS-64 quarterly with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

59. 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 limits described in Section XIII:

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.

60. Sources of Non-Federal Share. The state certifies that the matching non-federal share of funds for the demonstration is state/local monies. The state further certifies that such funds must not be used as the match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

a. CMS may review at any time the sources of the non-federal share of funding for the demonstration. The state agrees that all funding sources deemed unacceptable by CMS must be addressed within the time frames set by CMS.

b. Any amendments that impact the financial status of the program must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

c. The state assures that all health care-related taxes comport with section 1903(w) of the Act and all other applicable federal statutory and regulatory provision, as well as the approved Medicaid state plan.

61. State Certification of Funding Conditions. Under all circumstances, health care providers must retain 100 percent of the reimbursement amounts claimed by the state as demonstration expenditures. Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state government to return and/or redirect 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, and 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.

62. Program Integrity. The state must have a process in place to ensure that there is no duplication of federal funding for any aspect of the demonstration.

XIII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

63. Limit on Title XIX Funding. The state will be subject to a limit on the amount of federal title XIX funding that the state may receive on selected Medicaid expenditures during the period of approval of the demonstration. The limit is determined by using the per capita cost method described in STCs 64 and 65, and budget neutrality expenditure limits are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. Actual expenditures subject to the budget neutrality expenditure limit must be reported by the state using the procedures described in Section XII. The data supplied by the state to CMS to set the annual caps is subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit. CMS' assessment of the state's compliance with these annual limits will be done using the Schedule C report from the CMS-64.

64. Risk. The state will be at risk for the per capita cost (as determined by the method described below) for state plan and hypothetical populations, but not at risk for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the 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.

65. Calculation of the Budget Neutrality Limit and How It Is Applied. For the purpose of calculating the overall budget neutrality limit for the demonstration, annual budget limits will be calculated for each DY on a total computable basis, by multiplying the predetermined PMPM cost for each EG (shown on the table in STC 67) by the corresponding actual member months total, and summing the results of those calculations. The annual limits will then be

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 limit by Composite Federal Share, which is defined in STC 69 below. The demonstration expenditures subject to the budget neutrality limit are those reported under the following Waiver Names; SUD IMD.

66. Impermissible DSH, Taxes, or Donations. CMS reserves the right to adjust the budget neutrality ceiling 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 (if necessary adjustments must be made). 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 Social Security Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

67. Main Budget Neutrality Test. The trend rates and per capita cost estimates for each EG for each year of the demonstration are listed in the table below.

MEG	TREND	DY 1 PMPM	DY 2 PMPM	DY 3 PMPM	DY 4 PMPM	DY 5 PMPM
SUD IMD TANF	4.8%	$520.37	$545.35	$571.53	$598.96	$627.71
SUD IMD SSI DUALS	4.8%	$252.46	$264.58	$227.28	$290.59	$304.54
SUD IMD SSI NON-DUALS	4.8%	$2,024.02	$2,121.17	$2,222.99	$2,329.69	$2,441.52
SUD IMD HCE	4.8%	$741.38	$776.97	$814.26	$853.34	$894.30

68. Hypothetical Model. As part of the SUD initiative, the state may receive FFP for the continuum of services to treat OUD and other SUDs, provided to Medicaid enrollees in an IMD. These are state plan services that would be eligible for reimbursement if not for the IMD exclusion. Therefore, they are being treated as hypothetical for the purposes of budget neutrality. Hypothetical services can be treated in budget neutrality in a way that is similar to how Medicaid state plan services are treated, by including them as a “pass through” in both

the without-waiver and with-waiver calculations. However, the state will not be allowed to obtain budget neutrality "savings" from these services.

69. 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 Pennsylvania on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method.

70. Exceeding Budget Neutrality. The budget neutrality limits calculated in STC 65 will apply to actual expenditures for demonstration services as reported by the state under section XII of these STCs. If at the end of the demonstration period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

71. Enforcement of Budget Neutrality. CMS will enforce the budget neutrality agreement over the life of the demonstration, rather than on an annual basis. However, if the state exceeds the calculated cumulative target limit by the percentage identified below for any of the DYs, the state must submit a corrective action plan to CMS for approval.

Demonstration Year	Cumulative Target Definition	Percentage
DY 1	Cumulative budget neutrality limit	2.0 percent
DY 1 through DY 2	Cumulative budget neutrality limit	1.5 percent
DY 1 through DY 3	Cumulative budget neutrality limit	1.0 percent
DY 1 through 4	Cumulative budget neutrality limit	.5 percent
DY 1 through 5	Cumulative budget neutrality limit	0 percent

XIV. SCHEDULE OF DELIVERABLES

Date	Deliverable	STC
30 days after demonstration amendment approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
90 days after SUD program approval date	SUD Implementation Plan Protocol	STC 23

150 days after SUD program approval date	SUD Monitoring Protocol	STC 24
180 days after approval date	Draft Evaluation Design	STCs 39 & 50
60 days after receipt of CMS comments	Revised Draft Evaluation Design	STCs 39 & 50(a)
30 days after CMS Approval	Approved Evaluation Design published to state's website	STCs 39, 45, & 50(a)
November 16, 2020	Mid-Point Assessment	STC 25
One year prior to the end of the demonstration, or with renewal application	Draft Interim Evaluation Report	STC 42
60 days after receipt of CMS comments	Final Interim Evaluation Report	STC 42(d)
18 months of the end of the demonstration	Draft Summative Evaluation Report	STC 43
60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	STC 43(a)
30 calendar days of CMS approval	Approved Final Summative Evaluation Report published to state's website	STC 43(b)
Monthly Deliverables	Monitoring Calls	STC 36
Quarterly Deliverables Due 60 days after end of each quarter, except 4th quarter	Quarterly Monitoring Reports	STC 34
	Quarterly Expenditure Reports	STC 53
Annual Deliverables - Due 90 days after end of each 4th quarter	Annual Reports	STC 34
Within 120 calendar days after the expiration of the demonstration	Draft Close-out Operational Report	STC 35

30 calendar days after receipt of CMS comments	Final Close-out Operational Report	STC 35(d)

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.
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

Topic	Measure [Reported for each month included in the annual report]	Narrative
		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

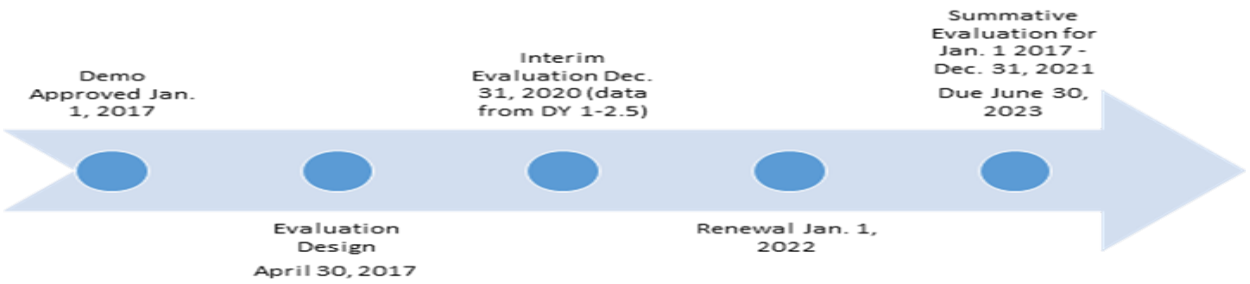
For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs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

Expectations for Evaluation Designs

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

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

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



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

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

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

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

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

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

5) Describe the population groups impacted by the demonstration.

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

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

2) Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and

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

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

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

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

C. Methodology – In this section, the state is to describe in detail the proposed research methodology. The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

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

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

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

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

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

submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:

a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
b. Qualitative analysis methods may be used, and must be described in detail.
c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

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

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

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

   a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.
   b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
   c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
   d. The application of sensitivity analyses, as appropriate, should be considered.

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

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

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

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

1) When the state demonstration is:
    a. Long-standing, non-complex, unchanged, or
    b. Has previously been rigorously evaluated and found to be successful, or
    c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)

2) When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
    a. Operating smoothly without administrative changes; and
    b. No or minimal appeals and grievances; and
    c. No state issues with CMS-64 reporting or budget neutrality; and
    d. No Corrective Action Plans (CAP) for the demonstration.

E. Attachments

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

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

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

ATTACHMENT C:

Preparing the Interim and Summative Evaluation Reports

Introduction

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

Expectations for Evaluation Reports

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

Intent of this Guidance

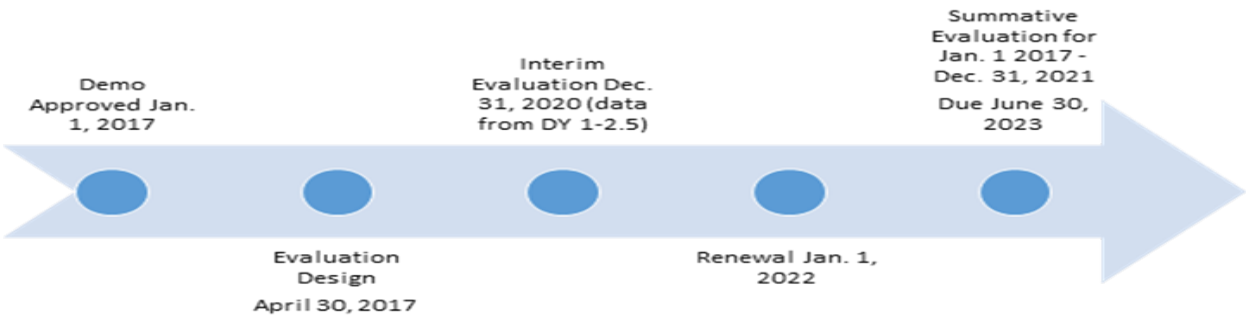
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved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

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

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

Submission Timelines

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



Required Core Components of Interim and Summative Evaluation Reports

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

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

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

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

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

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

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

5) Describe the population groups impacted by the demonstration.

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

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

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

D. Methodology – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design. The evaluation design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

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

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

1) Evaluation Design – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?

2) Target and Comparison Populations – Describe the target and comparison populations; include inclusion and exclusion criteria.

3) Evaluation Period – Describe the time periods for which data will be collected

4) Evaluation Measures – What measures are used to evaluate the demonstration, and who are the measure stewards?

5) Data Sources – Explain where the data will be obtained, and efforts to validate and clean the data.

6) Analytic methods – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).

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

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 show to whether and to what degree the evaluation questions and hypotheses of the

demonstration were achieved. The findings should visually depict the demonstration results (tables, charts, graphs). This section should include information on the statistical tests conducted.

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

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

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

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

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

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

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

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

F. Attachment

Evaluation Design: Provide the CMS-approved Evaluation Design

Attachment D:

Former Foster Care Youth Component Evaluation Design

(reserved)

Attachment E:

Substance Use Disorder (SUD) Evaluation Design

(reserved)

Attachment F

Substance Use Disorder (SUD) Implementation Plan Protocol

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	Covered by the state plan (see "*Clinic Services" – "**Drug and Alcohol and Methadone Maintenance Clinic Services**"* on Attachment 3.1A/3.1B, Page 4b of the state plan). **Applicable licensing regulations: Title 28 § 704, 705, 709, 711.** Required Services and Support Systems include: • 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	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	None needed. Service already provided.

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	• Psychotherapy, including individual, group, and family (per clinical evaluation) • Aftercare planning and follow-up • Transportation to treatment services, Recommended Services and Support Systems include the following: • 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) **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 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	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 months of the	

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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.	demonstration approval.	
Coverage of intensive outpatient services	Covered by the state plan (see "*Clinic Services" – "**Drug and Alcohol and Methadone Maintenance Clinic Services**"* on Attachment 3.1A/3.1B, Page 4b of the state plan). **Applicable licensing regulations: Title 28 § 704, 705, 709, 711.** Required Services and Support Systems include: • 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) • Aftercare planning and follow-up • Development of discharge plan and plan for referral into continuum of care • Transportation to treatment services	Already provided	None needed. Service already provided

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	Recommended Services and Support Systems include: • 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). **Required Staff:** The required Staff at an intensive outpatient care 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		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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.		
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)	Counseling and methadone maintenance covered by the state plan under "*Clinic Services"* – ***"Drug and Alcohol and Methadone Maintenance Clinic Services"*** on Attachment 3.1A/3.1B, Page 4b of the state plan. Methadone maintenance clinics are licensed by DDAP under Pennsylvania regulations, Title 28 § 715, *Standards for Approval of Narcotic Treatment Program*, which includes requirements for medication management and counseling. This chapter is available at: https://www.pacode.com/secure/data/028/chapter715/chap715toc.html Other medications (buprenorphine, vivitrol) covered under ***"Prescribed Drugs"*** **-** see Attachment 3.1A/3.1B, Page 5a of the state plan. Please also see **Medication Assisted Treatment** in *Section IV: Comprehensive Evidence-Based Benefit Design"* of this	Already provided	None needed. Service already provided

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	application as well as the Medicaid formulary available at https://papdl.com/sites/default/files/ghs-files/Penn%20PDL%2007252017%20v2017_1g.pdf (see **Opiate Dependence Treatments** on page 35 of this Formulary list)		
Coverage of intensive levels of care in residential and inpatient settings	**Medically Managed Inpatient Residential** - (corresponding to ASAM Level 4) covered by the state plan under ***"Inpatient Services"*** - see Attachment 3.1A/3.1B, Page 1b of the state plan. **Applicable licensing regulations: Title 28 § 704, 710.** Required Services and Support Systems include: • 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 • 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	Already provided	None needed. Service already provided

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	• 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 **Required Staff:** The required Staff in a Medically Managed Inpatient Residential facility 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		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	planned interventions according to the assessed needs of the individual. **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. ➢ **Halfway House** (corresponding to ASAM Level 3.1). A**pplicable licensing regulations: Title 28 § 704, 705, 709.** Required Services and Support Systems include: • 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 • 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	Already provided /available (Expenditure authority requested under this 1115 Demonstration	None needed, service already provided/ available (Expenditure authority requested under this 1115 Demonstration)

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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). Recommended Services and Support Systems include (these services need to be provided in order for a halfway house to receive state/grant funds): • 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). **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 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.		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	➢ **Medically Monitored Short Term Residential** (corresponding to ASAM Level 3.5 or 3.7) A**pplicable licensing regulations: Title 28 § 704, 705, 709, 710, 711.** 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. Required Services and Support Systems include: • 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 • 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)	Already provided/available (Expenditure authority requested under this 1115 Demonstration)	None needed, service already provided/available (Expenditure authority requested under this 1115 Demonstration)

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	• 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) Recommended Services and Support Systems include: • Case management (under in-lieu of authority), • 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		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	coordinated provision of services (non-Medicaid). **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. ➢ **Medically Monitored Long Term Residential** (corresponding to ASAM Level 3.5) **Applicable licensing regulations: Title 28 § 704, 705, 709, 711.** Required Services and Support Systems include: • 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	Already provided/available (Expenditure authority requested under this 1115 Demonstration)	None needed, service already provided/available (Expenditure authority requested under this 1115 Demonstration)

Milestone Criteria	Current State	Future State	Summary of Actions 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) • 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 Recommended Services and Support Systems include: • Peer groups (non-Medicaid) • Educational/instructional groups (non-Medicaid)		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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.		
Coverage of medically supervised withdrawal management	This is provided in **Medically Managed Inpatient Detoxification** (corresponding to ASAM Level 4 WM) covered by the state plan under *"Inpatient Services"* - see Attachment 3.1A/3.1B, Page 1b of the state plan. **Applicable licensing regulations: Title 28 § 704, 710.** Required Services and Support Systems include: • 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,	Already provided	None needed. Service already provided

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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 • 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		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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. **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. This service is also provided in **Medically Monitored Inpatient Detoxification** (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: **Applicable licensing regulations: Title 28 § 704, 705, 709, 711.** Required Services and Support Systems include: • 24-hour observation, monitoring, and treatment	Already provided/available (Expenditure authority requested under this 1115 Demonstration)	None needed. Service already provided/available (Expenditure authority requested under this 1115 Demonstration)

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	• 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, and recognized detoxification procedures • 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		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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) Recommended Services and Support Systems include: • 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)		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	• Family/significant other services, as appropriate (non-Medicaid). **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) 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

Milestone Criteria	Current State	Future State	Summary of Actions Needed
• **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%203%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**
Implementation of requirement that providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools that reflect evidence-based clinical treatment guidelines	Pennsylvania currently uses PCPC[4], 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.	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	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: **February/March 2017**: Pennsylvania made the decision to transition from PCPC to The ASAM Criteria and stakeholders were notified. **April – present**: Initiated an FAQ for the field regarding transition updates and concerns. Posted to DDAP's website. **April – May 2017**: Conducted a training survey to the field to determine impact and training need for the state.

[4] "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

		affirming this requirement.	**April – May 2017:** Announced the discontinuation of the PCPC training. **May 2017:** Summarized survey data for training considerations and planning purposes. **May 2017**: Convened the ASAM Transition Workgroup with various subcommittees to explore the implications of the transition. **June 2017**: PA's ASAM Transition Workgroup participated in a 2-day, in-person ASAM training with *The Change Company*. **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.

			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. **May 2018:** Guidance for application of ASAM in PA released. **July 1, 2018:** Target date for transition to ASAM.
Implementation of a utilization management approach such that (a) beneficiaries have access to SUD services at the appropriate level of care	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: The provider network must provide face-to-face treatment intervention within one hour for emergencies, within twenty-four (24) hours for	Pennsylvania will continue to contractually enforce current access standards.	Pennsylvania will continue to contractually enforce the current access standards. No other action needed.

	urgent situations, and within seven (7) days for routine appointments and for specialty referrals. Please also see "Utilization Management" under **Section X: Benefit Management.**	Pennsylvania will be replacing PCPC with ASAM effective July 1st, 2018.	
Implementation of a utilization management approach such that (b) interventions are appropriate for the diagnosis and level of care	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. 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. Please also see "Utilization Management" under **Section X: Benefit Management.**	Beginning July of 2018, Pennsylvania will replace PCPC with ASAM as the tool to determine the level of care and interventions needed.	Please see the actions outlined in the beginning of this table.
Implementation of a utilization management approach such that (c) there is an independent process for reviewing placement in	The BH-MCO is required to coordinate service planning and de-livery 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 SCA for placement and payment for care provided to members in residential treatment facilities	Will continue to follow the current processes.	No action needed

residential treatment settings	outside the HC zone. Managed Care contracts require prior approval for residential services, independently reviewed by a clinician and medical director. Please also see "Utilization Management" under **Section X: Benefit Management.**		

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
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,	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. Required full-time equivalents (FTE) for **Medically Monitored Residential** settings is one FTE counselor for every eight clients. Pennsylvania regulations, Title 28 § 709 – Subchapter E: *Standards for Inpatient Nonhospital Activities – Residential Treatment and Rehabilitation* 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 l residential facilities operate 24/7 and provide clinical treatment on a structured schedule, including individual, group, family therapy,	Will provide residential services to comply with ASAM criteria.	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

and credentials of staff for residential treatment settings	medication monitoring, psychoeducational groups, recovery support services. Pennsylvania regulations, Title 28 § 711 outlines the *Standards for Certification of Treatment Activities which are a Part of a Health Care Facility.* Available at: https://www.pacode.com/secure/data/028/chapter711/chap711toc.html		be an ongoing process beyond July 2018 and is expected to be completed within 24 months of the demonstration approval. **PCPC to ASAM Crosswalk available at:** http://www.ddap.pa.gov/Professionals/Documents/ASAM%20Crosswalk%20final.pdf. **Guidance for application of ASAM in PA's SUD system of care:** http://www.ddap.pa.gov/Professionals/Documents/ASAM%20Application%20Guidance%20Final.pdf.
Implementation of a state process for reviewing residential treatment providers to ensure compliance with these standards	All residential settings are licensed by DDAP on an annual basis. Complaints regarding facilities require an immediate onsite review by DDAP. Annual site inspections are conducted for all levels of care. The inspections include but not limited to the follow: a. Physical plant inspection b. Client chart review (hours of care, services provided included here among other things) c. Personnel (staffing) chart review (credentials of staff included here)	DDAP will continue to license the residential setting and ensure compliance with the standards.	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 months of the

	d. Level of care specific P&P e. Medication review (if applicable) f. Direct observation of services g. Staff and client interviews Licensing procedures are outlined in Pennsylvania regulations, Title 28 § 709 – Subchapter B available at: https://www.pacode.com/secure/data/028/chapter709/subchapBtoc.html **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		demonstration approval.
Implementation of requirement that residential treatment facilities offer MAT on-site or facilitate access off site	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. 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. In May 2018, DDAP issued "Guidance for Application of ASAM in Pennsylvania's SUD	The current regulations, which are the minimum standards, will stay in place. 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 expectation that clients will be	DDAP has revised the Treatment Manual to reflect the guidance referenced in the second column.

	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.	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). DDAP has revised the Treatment Manual to reflect this guidance.	

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
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: • **Outpatient Services;** • **Intensive Outpatient Services;** • **Medication Assisted Treatment (medications as well as**	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 **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. The BH-MCOs monitor their provider network to ensure capacity to serve their members, and expand their network as needed. The Commonwealth has 802 licensed Outpatient and Intensive Outpatient facilities with capacity to serve 91863 individuals. Additionally, there are 177 SUD Partial Hospitalization programs that can serve 4738 individuals. In November 2017, outpatient maintenance was provided by 75 providers serving 30291 individuals.	Will continue to ensure that access standards are met and required capacity is available.	None needed

counseling and other services);	Since 2002 till January 2018, 3717 Pennsylvania physicians have been certified under DATA 2000, with 2725 of those certified to treat up to 30 patients and the remaining 992 certified to treat up to 100 patients[Error! Bookmark not defined.] . Vivitrol can be administered by any licensed physician.		
• **Intensive Care in Residential and Inpatient Settings;**	Pennsylvania has 250 licensed facilities that provide intensive care in residential and inpatient settings, with a capacity to serve 10,071 individuals.		
• **Medically Supervised Withdrawal Management**	Pennsylvania has 87 licensed Detoxification facilities in various levels of care serving 1783 individuals.		

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	The Commonwealth has taken significant steps to improve prescribing practices for opioids. DOH and the DDAP have lead roles in the *Safe and Effective Prescribing Practices Task Force*. 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#.WlZm5K8o5iz. 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 must be reviewed and approved by the Department prior to implementation and at least annually.	Will continue to ensure the efficacy of the opioid prescribing guidelines.	None needed at this time.

	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. 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 *Prior Authorization Guidelines, Quantity Limits Lists,* and *Prior Authorization Forms.* 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. Additionally, the following link provides a searchable database for all drugs available in the Medical Assistance Preferred Drug List, with information on any *prior authorization requirements, preferred/non-preferred, quantity limits* etc.: **http://www.dhs.pa.gov/publications/forproviders/schedules/drugfeeschedule/index.htm.**		

Expanded coverage of, and access to, naloxone for overdose reversal	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 overdoes. 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. 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	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.
Implementation of strategies to increase utilization and improve functionality of	The following is a discussion of the activities undertaken by Pennsylvania's PDMP office: **Mass communication and Outreach** Starting May 2016, PDMP office conducted several communication and outreach activities to all the	The seven education modules discussed in the previous column under	The Commonwealth will continue to monitor practices and needs and take

prescription drug monitoring programs	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: • 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 **<u>Ensuring all authorized users can assign delegates</u>** 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	*PDMP and Opioid Prescriber Education Initiative* 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	steps as needed.

	busy addressing patient health concerns. This feature has overall improved the clinical workflows for the providers. **Interstate data sharing capability** 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 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. **Registration and query requirements of PA PDMP** *Achieving Better Care by Monitoring All Prescriptions Program* (ABC-MAP) Act 191 of 2014 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. **Integrate the PA PDMP system with Electronic Health Record (EHR) and Pharmacy Management System (PMS)** 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. **PDMP and Opioid Prescriber Education Initiative** 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 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.		
Other	Please see **Section XII: Strategies to Address Prescription Drug Abuse** and **Section XIII: Strategies to Address Opioid Use Disorder**		

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

Milestone Criteria	Current State		Summary of Actions Needed
Implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities	Please see Section VII: Care Coordination Design Additionally, Pennsylvania regulations **Tittle 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.	Already meeting the requirement	None needed
Additional policies to ensure coordination of care for co-occurring physical and mental health conditions	Please see the discussion on CCBHCs 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	The Commonwealth will review data from CCBHCs and decide on any future steps. The evaluation of Pennsylvania's CCBHC Demonstration is accomplished in two ways. A quality dashboard has been developed to allow the	The Commonwealth will review data from CCBHCs.

	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.	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.	

Attachment G:

SUD Monitoring Protocol

(reserved)