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

State Demonstrations Group

February 17, 2026

Sally Kozak
Deputy Secretary Office of Medical Assistance Programs
Pennsylvania Department of Human Services
625 Forster Street, Room 333
Harrisburg, PA 17120

Dear Deputy Secretary Kozak:

The Centers for Medicare & Medicaid Services (CMS) completed its review of Pennsylvania's Evaluation Design, as required by the Special Terms and Conditions (STCs), specifically, STC #11, of the "Pennsylvania Medicaid Coverage for Former Foster Care Youth (FFCY) from a Different State and Substance Use Disorder (SUD)" section 1115 demonstration (Project Number 11-W-00308/3), effective through September 30, 2027. CMS has determined that the Evaluation Designs, which were submitted on August 29, 2023 and revised on January 5, 2026, meets the requirements set forth in the STCs and CMS's evaluation design guidance, and therefore approves the Evaluation Design.

CMS has added the approved Evaluation Designs to the demonstration's STCs as Attachment D. A copy of the STCs, which includes the new attachment, is enclosed with this letter. In accordance with 42 CFR 431.424, the approved Evaluation Designs may now be posted to the state's Medicaid website within 30 days. CMS will also post the approved Evaluation Designs as a standalone document, separate from the STCs, on Medicaid.gov.

Please note that an Interim Evaluation Report, consistent with the approved Evaluation Designs, is due to CMS one year prior to the expiration of the demonstration, or at the time of the extension application, if the state chooses to extend the demonstration. Likewise, a Summative Evaluation Report, consistent with the approved designs, is due to CMS within 18 months of the end of the demonstration period. In accordance with 42 CFR 431.428 and the STCs, we look forward to receiving updates on evaluation activities in the demonstration monitoring reports.

We appreciate our continued partnership with Pennsylvania on the section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

DANIELLE DALY -S

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Date: 2026.02.17 09:57:38 -05'00'

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

cc: Margaret Kosherzenko, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

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



State Demonstrations Group

June 25, 2025

Sally Kozak
Deputy Secretary
Office of Medical Assistance Programs
Pennsylvania Department of Human Services
625 Forster Street, Room 333
Harrisburg, PA 17120

Dear Deputy Secretary Kozak:

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

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

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

Updates to Demonstration Monitoring

Below are the updated aspects of demonstration monitoring for the Medicaid Coverage for Former Foster Care Youth from a Different State and SUD Demonstration (Project Number 11W-00308/3) demonstration.

Reporting Cadence and Due Date

CMS determined that, when combined with monitoring calls, an annual monitoring reporting cadence will generally be sufficient to monitor potential risks and vulnerabilities in

demonstration implementation, performance, and progress toward stipulated goals. Thus, pursuant to CMS's authority under 42 CFR 431.420(b)(1) and 42 CFR 431.428, CMS is updating the cadence for this demonstration to annual monitoring reporting (see also section 1115(d)(2)(D)-(E) of the Act). This transition to annual monitoring reporting is expected to alleviate administrative burden for both the state and CMS. In addition, CMS is extending the due date of the annual monitoring report from 90 days to 180 days after the end of each demonstration year to balance Medicaid claims completeness with the state's work to draft, review, and submit the report timely.

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

The Medicaid Coverage for Former Foster Care Youth from a Different State and SUD Demonstration will transition to annual monitoring reporting effective June 25, 2025. The next annual monitoring report will be due on March 30, 2026, which reflects the first business day following 180 calendar days after the end of the current demonstration year. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect the new reporting cadence and due date.

Structured Monitoring Report Template

As noted in STC 8.8, "Monitoring Reports," monitoring reports "must follow the framework provided by CMS, which is subject to change as monitoring systems are developed / evolve and be provided in a structured manner that supports federal tracking and analysis." Pursuant to that STC, CMS is introducing a structured monitoring report template to minimize variation in content of reports across states, which will facilitate drawing conclusions over time and across demonstrations with broadly similar section 1115 waivers or expenditure authorities. The structured reporting framework will also provide CMS and the state opportunities for more comprehensive and instructive engagement on the report's content to identify potential risks and vulnerabilities and associated mitigation efforts as well as best practices, thus strengthening the overall integrity of demonstration monitoring.

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

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

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

Demonstration Monitoring Calls

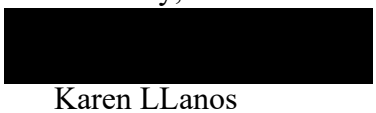
As STC 8.1 "Monitoring Calls" describes, CMS may "convene periodic conference calls with the state," and the calls are intended "to discuss ongoing demonstration operation, including (but not limited to) any significant actual or anticipated developments affecting the demonstration." Going forward, CMS envisions implementing a structured format for monitoring calls to provide consistency in content and frequency of demonstration monitoring calls across demonstrations. CMS also envisions convening quarterly monitoring calls with the state and will follow the structure and topics in the monitoring report template. We anticipate that standardizing the expectations for and content of the calls will result in more meaningful discussion and timely assessment of demonstration risks, vulnerabilities, and opportunities for intervention. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect that monitoring calls will be held no less frequently than quarterly.

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

In the coming weeks, CMS will reach out to schedule a transition meeting to review templates and timelines outlined above. As noted above, the pertinent Medicaid Coverage for Former Foster Care Youth from a Different State and SUD Demonstration section 1115 demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect these updates.

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

Sincerely,



Karen LLanos
Acting Director

Enclosure
cc: Margaret Kosherzenko, State Monitoring Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES

SECTION 1115 DEMONSTRATION WAIVER AUTHORITY

DEMONSTRATION NUMBER: 11-W-00308/3

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

DEMONSTRATION AWARDEE: Pennsylvania Department of Human Services

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

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

Title XIX Waiver Authority

1. Provision of Medical Assistance — Section 1902(a)(8) and 1902(a)(10)

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

CENTERS FOR MEDICARE & MEDICAID SERVICES

SECTION 1115 DEMONSTRATION EXPENDITURE AUTHORITY

NUMBER: **11-W-00308/3**

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

AWARDEE: **Pennsylvania Department of Human Services**

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

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

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

CENTERS FOR MEDICARE & MEDICAID SERVICES

SPECIAL TERMS AND CONDITIONS

NUMBER: **11-W-00308/3**

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

AWARDEE: **Pennsylvania Department of Human Services**

1. PREFACE

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

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

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

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

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

Attachment E: SUD Implementation Plan
Attachment F: SUD Monitoring Protocol
Attachment G: Expenditure Authorities and STCs for the Continuous Eligibility Amendment

2. PROGRAM DESCRIPTION AND OBJECTIVES

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

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

2018 Substance Use Disorder (SUD) Amendment

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

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

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

3. GENERAL PROGRAM REQUIREMENTS

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

3.2. **Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program expressed in federal law, regulation, and policy statement not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3.3. **Changes in Medicaid Law, Regulation, and Policy.** The state must, within the timeframes specified in the applicable federal law, regulation, or written policy, come into compliance with changes in law, regulation, or policy affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 3.7. CMS will notify the state 30 calendar days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

3.4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**

a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the State may seek an amendment to the demonstration (as per STC 3.7 of this section) as a result of the change in FFP.

b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

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

3.6. **Changes Subject to the Amendment Process.** Demonstration changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS through an approved amendment to the Medicaid state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 3.7 below, except as provided in STCs 3.3.

3.7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

a. An explanation of the public process used by the state, consistent with the requirements of STC 3.12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;

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

c. A data analysis that identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level though the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;

d. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the Evaluation Design and annual progress reports will be modified to incorporate the amendment provisions, as

3.8. **Extension of the Demonstration.** If the state intends to request an extension of the demonstration it must submit an application to CMS from the Governor of the state in accordance with the requirements of 42 CFR §431.412(c). States that do not intend to request

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

3.9. **Demonstration Phase Out.** The state may only suspend or terminate this demonstration, in whole or in part, consistent with the following requirements:

a. **Notification of Suspension or Termination**. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with the requirements of STC 3.12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

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

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

d. **Transition and Phase-out Procedures.** The state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e). The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206 through 431.214. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration

requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230.

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

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

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

3.10. **Withdrawal of Waiver or Expenditure Authority.** CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

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

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

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

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

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

3.15. **Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid program – including public benefit or service programs, procedures for obtaining Medicaid benefits or services, possible changes in or alternatives to Medicaid programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(d)(5).

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

4.1. **Eligibility for the FFCY Component.** Individuals eligible for the FFCY demonstration component are limited to "out-of-state former foster care youth" who are defined as youth under age 26 who were in foster care under the responsibility of a state other than Pennsylvania or a tribe in such other state when they turned age 18 (or such higher age as the state has elected for termination of federal foster care assistance under title IV-E of the Act), were enrolled in Medicaid at that time, are now applying for Medicaid in Pennsylvania, and are not otherwise eligible for Medicaid.

4.2. **Benefits and Cost-sharing provided under the FFCY Component.** Out-of-state former foster care youth ages 18, 19 or 20 will receive the same Medicaid State Plan benefits as set forth in the State Plan for all other beneficiaries under 21 years of age (i.e., Children). Out-of-state former foster care youth ages 21 to 26 will receive the same Medicaid State Plan benefits as set forth in the State Plan for beneficiaries 21 years of age and older (i.e., Adults). Out-of-state former foster care youth aged 18 to 26 will be subject to the same cost-sharing requirements and exclusions as set forth in the State Plan for the eligibility group under which the individual is enrolled in accordance with their age (i.e., Children or Adults).

4.3. **FFCY State Plan Amendment.** Section 1002 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("the SUPPORT Act") (Pub. L. 115-271) makes certain changes to Medicaid eligibility for former foster care youth, including a requirement to cover former foster care youth from other states. For individuals who turn age 18 and age out of foster care on or after January 1, 2023, the mandatory group for former foster care children under section 1902(a)(10)(A)(i)(IX) of the Act will cover otherwise eligible former foster care youth from any state.

4.4. **Budget Neutrality for FFCY.** CMS has determined that the FFCY component of the demonstration is budget neutral based on CMS' assessment that the waiver authorities granted for the FFCY demonstration component are unlikely to result in any increase in federal Medicaid expenditures, and that no expenditure authorities are associated with the FFCY component of the demonstration. The FFCY demonstration component will not include a budget neutrality expenditure limit, and no further test of budget neutrality will be required for the FFCY component. Accordingly, the state will not be allowed to obtain budget neutrality "savings" from the FFCY demonstration component. All expenditures associated with the FFCY population (with the exception of SUD IMD expenditures) will be reported on the CMS-64 base form(s) for Medicaid State Plan populations in accordance with section 2500 of the State Medicaid Manual.

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

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

5.1. **Eligibility Groups Affected by the Demonstration.** All affected groups derive their eligibility through the Medicaid state plan, and are subject to all applicable Medicaid laws and regulations in accordance with the Medicaid state plan.

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

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

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

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

5.3. **SUD Implementation Plan.** The state's SUD Implementation Plan, initially approved for the period from July 1, 2018 through September 30, 2022, remains in effect for the approval period from October 1, 2022 through September 30, 2027, and is affixed to the STCs as Attachment E. Any future modifications to the approved Implementation Plan will require CMS approval. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral. The approved SUD Implementation Plan describes the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives of this SUD demonstration project:

a. **Access to Critical Levels of Care for OUD and other SUDs:** Service delivery for new benefits, including residential treatment and withdrawal management, within 12-24 months of OUD/SUD program demonstration approval;

b. **Use of Evidence-based SUD-specific Patient Placement Criteria:** Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other comparable assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of OUD/SUD program demonstration approval;

c. **Patient Placement:** Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of SUD program demonstration approval;

d. **Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities:** Currently, residential treatment service providers must be a licensed organization, pursuant to the residential service provider qualifications described in the Preferred Provider Substance Use Disorder Treatment Standards of the Vermont Department of Health's Division of Alcohol and Drug Abuse Programs. The state will establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other comparable, nationally recognized, SUD-specific program standards regarding, in particular, the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of OUD/SUD program demonstration approval;

e. **Standards of Care:** Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of SUD program demonstration approval;

f. **Standards of Care:** Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of SUD program demonstration approval;

g. **Sufficient Provider Capacity at each Level of Care including Medication-assisted Treatment for OUD:** An assessment of the availability of providers in the key levels of care throughout the state, or in the regions of the state participating under this

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

h. **Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD:** Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;

i. **SUD Health IT Plan:** Implementation of the milestones and metrics as detailed in STC 5.3; and

j. **Improved Care Coordination and Transitions between Levels of Care:** Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of SUD program demonstration approval.

5.4. **SUD Mid-Point Assessment.** The state will contract with an independent entity to conduct a mid-point assessment by September 30, 2025. This timeline will allow for the Mid-Point Assessment Report to capture approximately the first two-and-a-half years of demonstration program data, accounting for data run-out and data completeness. In addition, if applicable, the state should use the prior approval period experiences as context, and conduct the Mid-Point Assessment in light of the data from any such prior approval period(s). In the design, planning and conduction of the mid-point assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: SUD treatment providers, beneficiaries, and other key partners.

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

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

a. An examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plans and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol,

b. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date,

c. A determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets,

d. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state's SUD Implementation Plan or to pertinent factors that the state can influence that will support improvement, and

e. An assessment of whether the state is on track to meet the budget neutrality requirements.

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

a. The SUD Health IT section of the Implementation Plan will include implementation milestones and dates for achieving them.

b. The SUD Health IT Plan must be aligned with the state's broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state's Behavioral Health (BH) "Health IT" Plan.

c. The SUD Health IT Plan will describe the state's goals, each DY, to enhance the state's prescription drug monitoring program's (PDMP).[1]

d. The SUD Health IT Plan will address how the state's PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[2] This will also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan will describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients' history of controlled substance

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

[2] *Ibid.*

prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.

e. The SUD Health IT Plan will, as applicable, describe the state's capabilities to leverage a master patient index (or master data management service, etc.) in support of SUD care delivery. Additionally, the SUD Health IT Plan must describe current and future capabilities regarding PDMP queries—and the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.

f. The SUD Health IT Plan will describe how the activities described in (a) through (e) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.[3]

g. In developing the Health IT Plan, states should use the following resources:

   i. States may use resources at Health IT.Gov (https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/) in "Section 4: Opioid Epidemic and Health IT."

   ii. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans, found at https://www.healthit.gov/topic/advancing-interoperability-medicaid.

   iii. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP plans and, more generally, to meet the goals of the demonstration

h. The state will include in its SUD Monitoring Protocol (see Attachment F an approach to monitoring its SUD Health IT Plan which will include performance metrics provided by CMS or State defined metrics to be approved in advance by CMS.

i. The state will monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in an addendum to its Annual Reports (see STC 8.8).

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

j. As applicable, the state should advance the standards identified in the 'Interoperability Standards Advisory—Best Available Standards and Implementation Specifications' (ISA) in developing and implementing the state's SUD Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.

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

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

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

a. Residential treatment services are provided in an Pennsylvania Department of Drug and Alcohol Programs (DDAP)-licensed facility that has been enrolled as a Medicaid provider and assessed by DDAP as delivering care consistent with ASAM or other nationally recognized, SUD-specific program standards for residential treatment facilities.

b. Residential treatment services can be provided in settings of any size.

c. The implementation date for residential treatment services is July 1, 2018.

d. Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

Covered services include:

a. Clinically-directed therapeutic treatment to facilitate recovery skills, relapse prevention, and emotional coping strategies.

b. Addiction pharmacotherapy and drug screening;

c. Motivational enhancement and engagement strategies;

d. Counseling and clinical monitoring;

e. Withdrawal management and related treatment designed to alleviate acute emotional, behavioral, cognitive, or biomedical distress resulting from, or occurring with, an individual's use of alcohol and other drugs;

f. Regular monitoring of the individual's medication adherence;

g. Recovery support services;

h. Counseling services involving the beneficiary's family and significant others to advance the beneficiary's treatment goals, when (1) the counseling with the family member and significant others is for the direct benefit of the beneficiary, (2) the counseling is not aimed at addressing treatment needs of the beneficiary's family or significant others, and (3) the beneficiary is present except when it is clinically appropriate for the beneficiary to be absent in order to advance the beneficiary's treatment goals; and,

i. Education on benefits of medication assisted treatment and referral to treatment as necessary.

6. COST SHARING

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

7. DELIVERY SYSTEMS

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

8. MONITORING AND REPORTING REQUIREMENTS

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

a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to), any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, budget neutrality, the status of investment submissions, and progress on evaluation activities.

b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.

c. The state and CMS will jointly develop the agenda for the calls.

8.2. **Post-Award Forum.** Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state shall afford the public with

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

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

8.4. **Compliance with Federal Systems Innovation**. As federal systems continue to evolve and incorporate 1115 waiver reporting and analytics functions, the state shall work with CMS to:

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

b. Ensure all 1115, Transformed Medicaid Statistical Information System (T-MSIS), and other data elements that have been agreed to for reporting and analytics are provided by the state; and

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

8.5. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

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

a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).

b. For each deliverable, the state may submit a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process described below can

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

c. If CMS agrees to an interim corrective process in accordance with subsection (b), and the state fails to comply with the corrective action steps or still fails to submit the overdue deliverable(s) that meets the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.

d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outline in these STCs, the deferral(s) will be released.

e. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations, and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

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

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

a. An assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 5.3 and reporting relevant information to the state's Health IT plan described in STC 5.3(i);

b. A description of the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Section 12 of the demonstration; and

c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.

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

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

b. **Performance Metrics**. Per applicable CMS guidance and technical assistance, the performance metrics will provide data to support tracking the state's progress towards meeting the demonstration's annual goals and overall targets as will be identified in the approved SUD Monitoring Protocol, and will cover key policies under this demonstration.

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

access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, and grievances and appeals.

The required monitoring and performance metrics must be included in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

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

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

e. **SUD Health IT**. The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 5.5(d).

8.9. **Corrective Action Plan Related to Demonstration Monitoring**. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS will withdraw an authority, as described in STC 3.10, when metrics indicate substantial, sustained directional change, inconsistent with state targets and goals, as applicable, and the state has not implemented corrective action. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

9. GENERAL FINANCIAL REQUIREMENTS

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

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

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

9.3. **Sources of Non-Federal Share**. As a condition of demonstration approval, the state certifies that the non-federal share is obtained from permissible state and/or local funds that, unless permitted by law, are not other federal funds. The state further certifies that such funds must not be used to match any other federal grant or contract, except as permitted by law. CMS approval of this demonstration does not constitute direct or indirect approval of any underlying source of non-federal share or associated funding mechanisms and all sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, CMS reserves the right to prohibit the use of any sources of non-federal share funding that it determines impermissible.

a. If requested, the state must submit for CMS review and approval documentation of any sources of non-federal share that would be used to fund the demonstration.

b. If CMS determines that any funding sources are not consistent with applicable federal regulations, the state must address CMS's concerns within the time frames allotted by CMS.

c. Without limitation, CMS may request information about the non-federal share sources for any amendments that CMS determines may financially impact the demonstration.

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

9.4. **State Certification of Funding Conditions**. As a condition of demonstration approval, the state certifies that the following conditions for non-federal share funding of demonstration expenditures have been met:

a. Units of state or local government, including health care providers that are units of state or local government, certify that state or local monies have been expended as the non-federal share of funds under the demonstration.

b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, the state must obtain CMS approval for a cost reimbursement methodology. This methodology must include a detailed explanation of the process, including any necessary cost reporting protocols, by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.

c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot be used as the non-federal share needed to receive other federal matching funds under 42 CFR 433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.

d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local revenues and are transferred by units of government within the state. Any transfers from units of government for purposes of Title XIX must be made in an amount not to exceed the non-federal share of title XIX payments and any payment derived from a proper IGT is not contingent upon receipt of the IGT.

e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local governments to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

f. The State Medicaid Director or his/her designee certifies that all state and/or local funds used as the state's share of the allowable expenditures reported on the CMS-64

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

9.5. **Financial Integrity for Managed Care and Other Deliery Systems**. As a condition of demonstration approval, the state attests to the following, as applicable:

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

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

a. All health care-related taxes as defined by Section 1903 (w)(3)(A) of the Social Security Act and 42 CFR §433.55 are broad-based as defined by Section 1903 (w)(3)(B) of the Social Security Act and 42 CFR § 433.68 (c).

b. All health care-related taxes are uniform as defined by Section 1903 (w)(3)(C) of the Social Security Act and 42 CFR § 433.68 (d).

c. If the health care-related tax is either not broad-based or not uniform, the state has applied for and received a waiver of the broad-based and/or uniformity requirements as specified by 1903 (w)(3)(E)(i) of the Social Security Act and 42 CFR § 433.72.

d. The tax does not contain a hold harmless arrangement as described by Section 1903 (w)(4) of the Social Security Act and 42 CFR § 433.68 (f).

e. All provider related-donations as defined by 42 CFR § 433.52 are bona fide as defined by Section 1903 (w)(2)(B) of the Social Security Act, 42 CFR § 433.66, and 42 CFR § 433.54.

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

a. Any agreement written or otherwise regarding the arrangement among the providers with counties, the state or other entities for each locality tax;

b. Number of hospitals in each locality of the taxing entities for each locality tax;

c. Whether or not all hospitals will be paying the assessment for each locality tax;

d. The assessment rate that the hospitals will be paying for each locality tax;

e. Whether any hospitals that pay the assessment will not be receiving payments funded by the assessment;

f. Number of hospitals that receive at least the total assessment back in the form of Medicaid payments for each locality tax;

g. The monitoring plan for the taxing arrangement to ensure that the tax comply with section 1903(w)(4) of the Social Security Act and 42 CFR 433.68(f); and

h. Information on whether the state will be reporting the assessment on the CMS form 64.11A as required under Section 1903(w) of the Act.

i. This deliverable is subject to the deferral as described in STC 8.5.

9.8. **Extent of Federal Finanical Participation for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole for the following, subject to the budget neutrality expenditure limits described in section 10:

a. Administrative costs, including those associated with the administration of the demonstration;

b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and

c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third-party liability.

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

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

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

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

9.11. **Reporing Expenditures and Member Months.** The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00194/1). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of payment associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

a. **Cost Settlements.** The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b, in lieu of lines 9 or 10c. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.

b. **Premiums and Cost Sharing Collected by the State.** The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by DY on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.

c. **Pharmacy Rebates.** Because pharmacy rebates are included in the base expenditures used to determine the budget neutrality expenditure limit, the state must report the portion of pharmacy rebates applicable to the demonstration on the appropriate forms CMS-64.9 WAIVER and 64.9P waiver for the demonstration, and not on any other CMS-64.9 form (to avoid double counting). The state must have a methodology for assigning a portion of pharmacy rebates to the demonstration in a way that reasonably reflects the actual rebate-eligible pharmacy utilization of the demonstration

population, and which identifies pharmacy rebate amounts with DYs. Use of the methodology is subject to the approval in advance by the CMS Regional Office, and changes to the methodology must also be approved in advance by the Regional Office. Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.

d. **Administrative Costs.** The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the Master MEG Chart table, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

e. **Member Months.** As part of the Quarterly and Annual Monitoring Reports described in section 8.8, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. The term "eligible member months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.

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

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

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

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

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

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

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

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

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

9.13. **Budget Neutrality Monitoring Tool**. The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the Performance Metrics Database and Analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing demonstration's actual expenditures to the budget neutrality expenditure limits described in Section 10. CMS will provide technical assistance, upon request.

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

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

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

b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget

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

9.16. **Budget Neutrality Adjustments**. To the extent that there are any changes to the federal Section 1115 demonstration budget neutrality approach during the demonstration period, the state has the opportunity to submit an adjustment aligning with these changes, along with detailed data to justify this, for CMS review without submitting an amendment pursuant to STC 3.7. All changes in budget neutrality would apply retroactively to the date of the federal policy changes.

9.17. **Budget Neutrality Adjustments for Increased Provider Rates**. The state may submit an adjustment to its budget neutrality for CMS review, upon receiving an appropriation for provider rate increases, without submitting an amendment pursuant to STC 3.7. All changes to budget neutrality would apply on the state's effective date for the increase.

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

10. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

10.1. **Limiting on Title XIX Funding**. The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The limit may consist of a Main Budget Neutrality Test, and one or more Hypothetical Budget Neutrality Tests, as described below. CMS' assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.

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

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

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

10.5. **Hypothetical Budget Neutrality**. When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be "hypothetical;" that is, the expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS's current view that states should not have to "pay for," with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state's WW hypothetical spending exceeds the supplemental test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending through savings elsewhere in the demonstration or to refund the FFP to CMS.

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

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

10.7. **Composite Federal Share Ratios**. The Composite Federal Share is the ratio that will be used to covert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through the MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

10.8. **Exceeding Budget Neutrality**. CMS will enforce budget neutrality agreement over the life of the demonstration, which extends from July 1, 2022 to December 31, 2027. If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is eliminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

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

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

11. EVALUATION OF THE DEMONSTRATION

11.1. **Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state shall cooperate fully and timely with CMS and its contractors' in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state shall include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they shall make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 8.5.

11.2. **Independent Evaluator.** Upon approval of the demonstration, the state must use an independent party to conduct an evaluation of the demonstration (except for the Former Foster Care Youth component) to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The independent party must sign an agreement to conduct the demonstration evaluation in an independent manner in accord with the CMS-approved draft Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

11.3. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design no later than 180 calendar days after the approval of the demonstration. The draft Evaluation Design must be developed in accordance with Attachment B (Developing the Evaluation Design for SUD) of these STCs, CMS's evaluation design guidance for SUD

and SMI/SED, and any other applicable CMS evaluation guidance and technical assistance for the demonstration's other policy components. The Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, including establishing valid comparison groups and assuring causal inferences in demonstration evaluations. The Draft Evaluation Design also must include a timeline for key evaluation activities, including the deliverables outlined in STCs 8.8. For any amendment to the demonstration, the state will be required to update the approved Evaluation Design to accommodate the amendment component. The amended Evaluation Design must be submitted to CMS for review no later than 180 calendar days after CMS's approval of the demonstration amendment. Depending on the scope and timing of the amendment, in consultation with CMS, the state may provide the details on necessary modifications to the approved Evaluation Design via the monitoring reports. The amendment Evaluation Design must also be reflected in the state's Interim (as applicable) and Summative Evaluation Reports, described below.

11.4. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) days after receipt of CMS's comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design to the state's website within thirty (30) days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the Monitoring Reports. Once CMS approves the Evaluation Design, if the state wishes to make changes, the state must submit a revised Evaluation Design to CMS for approval if the changes are substantial in scope; otherwise, in consultation with CMS, the state may include updates to the Evaluation Design in monitoring reports.

11.5. **Evaluation Questions and Hypotheses.** Consistent with Attachments B and C (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Reports) of these STCs, the evaluation deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS evaluation guidance and technical assistance, the evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact and also its effectiveness in achieving the goals. For example, hypotheses for the SUD component of the demonstration must support an assessment of the demonstration's success in achieving the core goals of the program through addressing, among other outcomes, initiation and compliance with treatment, utilization of health services in appropriate care settings, and reductions in key outcomes such as deaths due to overdose. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF). Furthermore, the evaluation must accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, and/or geography)—to the extent feasible—to inform a fuller understanding of existing disparities in access and health

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

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

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

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

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

c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted, or one year prior to the end of the demonstration, whichever is sooner. If the state is not requesting an extension for a demonstration, an Interim Evaluation Report is due one year prior to the end of the demonstration.

d. The state must submit the final Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report. Once approved by CMS, the state must post the final Interim Evaluation Report to the state's Medicaid website within 30 calendar days.

e. The Interim Evaluation Report must comply with Attachment C (Preparing the Interim and Summative Evaluation Reports) of these STCs.

11.8. **Summative Evaluation Report.** The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The draft Summative Evaluation Report must be developed in accordance with Attachment C (Preparing the Interim and Summative Evaluation Reports) of these STCs, and in alignment with the approved Evaluation Design.

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

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

11.9. **Corrective Action Plan Related to Evaluation**. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of an extension process when associated with the state's Interim Evaluation Report, or as part of the review of the Summative Evaluation Report. A corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

11.10. **State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the interim evaluation, and/or the summative evaluation.

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

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

12. SCHEDULE OF DELIVERABLES

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

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

Attachment A:

ANNUAL REPORT TEMPLATE FOR THE FORMER FOSTER CARE YOUTH COMPONENT

State: _____

Demonstration Year and Period: _____

Approved start and end date of the Demonstration _____

A. Introduction

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

B. Eligibility and Enrollment Information, including member month reporting

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

Topic	Measure [Reported for each month included in the annual report]	Narrative
		first annual report of your demonstration, please describe whether or not the number of disenrollees aligns with your expectations. Please also describe major reasons for to disenrollment (if known) and any actions taken to mitigate inappropriate disenrollment.

C. Utilization Monitoring

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

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

D. Grievances and Appeals

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

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

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

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

F. Demonstration Evaluation Activities and Interim Findings

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

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

ATTACHMENT B

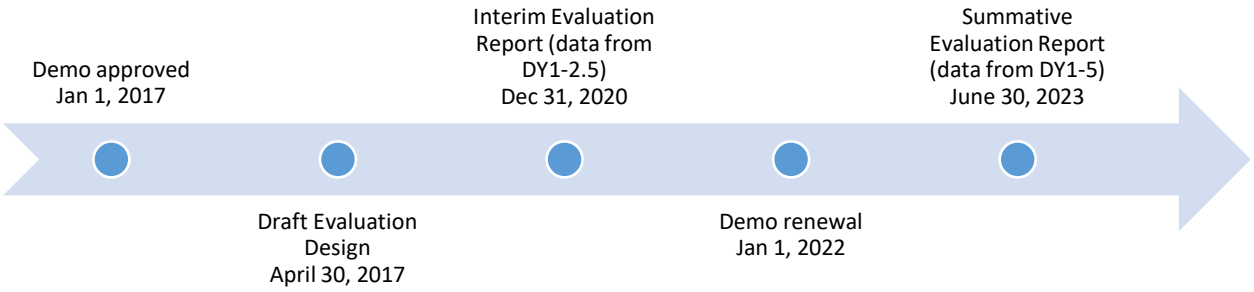
Developing the Evaluation Design

Introduction

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

Submission Timelines

There is a specified timeline for the state's submission of its draft Evaluation Design and subsequent evaluation reports. The graphic below depicts an example of this timeline for a 5-year demonstration. In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within thirty (30) calendar days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Designs

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

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

The roadmap begins with the stated goals for the demonstration, followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

The format for the Evaluation Design is as follows:

- **A.** General Background Information;
- **B.** Evaluation Questions and Hypotheses;
- **C.** Methodology;
- **D.** Methodological Limitations;
- **E.** Attachments.

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

1. The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).
2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.
3. A description of the population groups impacted by the demonstration.
4. A brief description of the demonstration and history of its implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration.
5. For renewals, amendments, and major operational changes: a description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

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

1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the evaluation questions align with the hypotheses and the goals of the demonstration.
2. Address how the hypotheses and research questions promote the objectives of Titles XIX and/or XXI.
3. Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets can be measured.
4. Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram, which includes information about the goals and features of

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

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

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

1. *Methodological Design* – Provide information on how the evaluation will be designed. For example, whether the evaluation will utilize pre/post data comparisons, pre-test or post-test only assessments. If qualitative analysis methods will be used, they must be described in detail.
2. *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, incorporating the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally, discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.
3. *Evaluation Period* – Describe the time periods for which data will be included.
4. *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. The state also should include information about how it will define the numerators and denominators. Furthermore, the state should ensure the measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval. When selecting metrics, the state shall identify opportunities for improving quality of care and health outcomes, and controlling cost of care. The state also should incorporate benchmarking and comparisons to national and state standards, where appropriate. The state also should include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating, securing, and submitting for endorsement, etc.) Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum. Proposed performance

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

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

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

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

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

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

1. When the demonstration is:
    a. Non-complex, unchanged, or has previously been rigorously evaluated and found to be successful; or
    b. Could now be considered standard Medicaid policy (CMS published regulations or guidance).
2. When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
    a. Operating smoothly without administrative changes;
    b. No or minimal appeals and grievances;

c. No state issues with CMS-64 reporting or budget neutrality; and
d. No Corrective Action Plans for the demonstration.

E. Attachments

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

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

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

4)

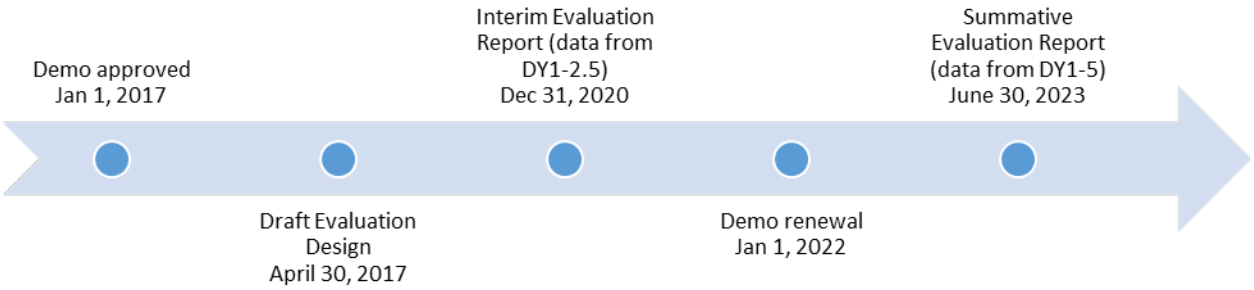
Attachment C:
Preparing the Interim and Summative Evaluation Reports

Introduction

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

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). The graphic below depicts an example of a deliverables timeline for a 5-year demonstration. In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish the Interim and Summative Evaluation Reports to the state's website within thirty (30) calendar days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Reports

All states with Medicaid section 1115 demonstrations are required to conduct evaluations that are valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). The already-approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow

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

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

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

Intent of this Attachment

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

Required Core Components of Interim and Summative Evaluation Reports

The Interim and Summative Evaluation Reports present research and findings about the section 1115 demonstration. It is important that the reports incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. The evaluation reports should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy.

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

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

J. Attachment(s).

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

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

1. The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation.
3. A description of the population groups impacted by the demonstration.
4. A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration.
5. For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes. Additionally, the state should explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable).

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

1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the goals of the demonstration align with the evaluation questions and hypotheses.
2. Address how the research questions / hypotheses of this demonstration promote the objectives of titles XIX and XXI.
3. Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.
4. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.

D. Methodology – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration, consistent with the approved Evaluation Design. The Evaluation Design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research,

(using references), meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

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

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used. The state also should report on, control for, and make appropriate adjustments for the limitations of the data and their effects on results, and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how, in sufficient detail so that another party could replicate the results. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

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

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

F. Results – In this section, the state presents and uses the quantitative and qualitative data to demonstrate whether and to what degree the evaluation questions and hypotheses of the demonstration were addressed. The findings should visually depict the demonstration results, using tables, charts, and graphs, where appropriate. This section should include findings from the statistical tests conducted.

G. Conclusions – In this section, the state will present the conclusions about the evaluation results. Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically, the state should answer the following questions:

1. In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
2. If the state did not fully achieve its intended goals, why not?
3. What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

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

I. Lessons Learned and Recommendations – This section of the evaluation report involves the transfer of knowledge. Specifically, it should include potential "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders. Recommendations for improvement can be just as significant as identifying current successful strategies. Based on the evaluation results, the state should address the following questions:

1. What lessons were learned as a result of the demonstration?
2. What would you recommend to other states which may be interested in implementing a similar approach?

Attachment D:

Commonwealth of Pennsylvania

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

Number 11-W-00308/3

Evaluation Design

Updated March 15, 2023

Revised August 29, 2023

Revised February 7, 2024

Revised August 27, 2024

Revised July 23, 2025

Revised January 5, 2026

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A. General Background Information

1. History and Overview

The Affordable Care Act (ACA) created a new mandatory Medicaid eligibility group (MEG) at Section 1902(a)(10)(A)(i)(IX) for Former Foster Care Youth (FFCY) who were in foster care and receiving Medicaid at age 18 years or older. Under this new group, former foster care (FFC) individuals can obtain coverage until age 26 years from the state responsible for their foster care and are not subject to income or resource limits. On January 22, 2013, in accordance with the ACA, the Centers for Medicare & Medicaid Services (CMS) issued a notice of proposed rulemaking that provided guidance on Medicaid eligibility under 42 CFR §435.250, which allowed states the option to cover individuals who are now residents of their state but were in foster care and enrolled in Medicaid at age 18 years or older in a different state.

On January 1, 2014, the Commonwealth of Pennsylvania (Commonwealth or Pennsylvania) began providing Medicaid coverage to FFCY from a different state as part of its Medicaid State Plan. On November 21, 2016, CMS published a final rule that changed the eligibility provision for this population. The provision no longer provides states with the option to cover youth who were not the responsibility of their own state while in care. Due to this change, the Commonwealth applied for a waiver to provide Medicaid coverage to these individuals under Section 1115 Demonstration authority. CMS approved this Demonstration on September 29, 2017, for the period of October 1, 2017 through September 30, 2022 and extended the Demonstration for the period of October 1, 2022 through October 1, 2027.

The purpose of this Demonstration is to provide coverage on a statewide basis to FFCY who currently reside in the Commonwealth and were in foster care and enrolled in Medicaid at age 18 years or older in a different state. As such, the Commonwealth will cover FFC individuals from a different state who have income at or below 133% Federal Poverty Level (FPL) under a mandatory coverage group or under the new adult group and will submit an eligibility State Plan Amendment to cover individuals above 133% FPL. The Commonwealth requested waivers of Sections 1902(a)(8) and 1902(a)(10) to limit the State Plan group to these individuals.

The Commonwealth proposed to test and evaluate how including FFCY individuals who “aged out” in a different state increases and strengthens overall coverage for FFCY and improves health outcomes for these youth. The Commonwealth expects these hypotheses will be proven correct and that the Demonstration will result in an increase and strengthening of overall coverage of FFCY as well as an improvement in their health outcomes.

History and Overview of the Substance Use Disorder (SUD) Demonstration Authority

The Commonwealth developed this Demonstration project in the midst of a public health crisis affecting both the well-being of its residents and the economic health of the Commonwealth. On January 10, 2018, Governor Wolf, in order to further bolster the fight against heroin and opioid addiction, signed a statewide disaster declaration to enhance Commonwealth response, increase access to treatment, and save lives. The declaration was the first of its kind for a public health emergency (PHE) in Pennsylvania and utilizes a command center at the Pennsylvania Emergency Management Agency to track progress and enhance coordination of health and public safety agencies.

Pennsylvania has provided residential treatment services to individuals based upon a comprehensive assessment and standardized level of care (LOC) placement criteria to ensure appropriate treatment. Access to residential treatment services has not been based upon an arbitrary length of stay (LOS) but upon the determination of clinical need and medical necessity for this LOC. The loss in federal matching dollars due to the changes to the managed care rule placed an enormous financial burden on the Commonwealth, thereby impacting its ability to provide adequate and appropriate residential treatment services to individuals who have been assessed and determined to require the LOC the residential treatment facility (RTF) provides if it meets the definition of an Institution for Mental Diseases (IMD). This severely impacted an individual's ability to remain in an appropriate level of treatment for adequate lengths of time, which may result in negative outcomes such as relapse, resulting in increased costs over time.

In addition to residential IMD services, the Demonstration was designed to support the delivery of the complete American Society of Addiction Medicine (ASAM) criteria of services including prevention, outpatient, intensive outpatient (IOP), partial hospitalization program (PHP), residential and inpatient, withdrawal management (WM), and medication-assisted treatment (MAT) for both methadone and buprenorphine. Pennsylvania already provides a comprehensive set of SUD treatment benefits that provide a full continuum of care through its fee-for-service (FFS) and managed care delivery systems, federal grants, and Commonwealth funds. Inpatient, outpatient, and MAT services are covered services within Pennsylvania's Medicaid State Plan. Residential drug and alcohol (D&A) detoxification and rehabilitation and certified recovery specialist services are provided under the capitated agreements as "in lieu of services." Federal grants and Commonwealth funds can be utilized for all allowable services.

SUD Demonstration Authority Approval

The "Pennsylvania Former Foster Care Youth from a Different State and Substance Use Disorder 1115(a) Medicaid Demonstration" amendment, which was approved on June 28, 2018, became effective July 1, 2018, and continued through September 30, 2022 (4 years and 3 months). As part of the Commonwealth's renewal application on March 30, 2022, the Commonwealth listed the following lessons from the 1115 SUD Demonstration: 1) placement criteria matters, 2) the pandemic disrupted service patterns, and 3) change management disrupted service patterns before improving access to care. The Commonwealth had two closely related recommendations: 1) a measured approach to change may create less provider abrasion and 2) acceptance of change takes time.

At the time of renewal, the Commonwealth reported encountering challenges to implementation of the ASAM criteria which will be discussed in greater detail in the Implementation Issues section of this

report. At a high level, the implementation challenges frequently centered around the transition process from the Pennsylvania Client Placement Criteria (PCPC) to the ASAM criteria. The Office of Mental Health and Substance Abuse Services (OMHSAS) and Department of Drug and Alcohol Programs (DDAP) closely collaborated to address any challenges while ensuring Pennsylvanians with SUDs continued to have access to treatment and recovery services.

In the renewal, all eligibility groups were budget neutral with the exception of the SUD IMD Supplemental Security Income (SSI) Duals MEG. For that particular MEG, the With-Waiver expenditures on a Per Member Per Month (PMPM) basis exceeded the hypothetical Without-Waiver PMPM amount. In addition, the total actual With-Waiver expenditures by eligibility group exceeded the Without-Waiver total expenditure amount. The Commonwealth has researched these expenditures and found that With-Waiver expenditures for the Dual Eligible MEG in Demonstration year (DY) 2 (2019 Q4) began to grow because of a change in the underlying case mix of the eligibility group. The number of Nursing Facility Clinically Eligible (NFCE) individuals with Medicare relative to the number of community well individuals with Medicare grew. The State's actuary, Mercer Government Human Services Consulting (Mercer), part of Mercer Health & Benefits LLC, analyzed the underlying case mix relative to the original data used to calculate the Without-Waiver PMPMs. The Commonwealth concluded that if the SSI Dual Eligible eligibility group were split into two populations using the original data and trend rates, the eligibility group would be budget neutral. **SSI Duals — NFCE/Nursing Facility Ineligible (NFI)** split the SSI Duals data between the NFCE and NFI populations. CMS approved this MEG split in the renewal and the Demonstration MEGs have been cost effective since then.

Description of the SUD Demonstration

The purpose of the Section 1115 Demonstration waiver was to afford continued access to high quality, medically necessary treatment for opioid use disorder (OUD) and other SUDs. The Commonwealth is testing a new paradigm for delivering SUD services for Medicaid enrollees. By providing comprehensive, quality SUD treatment, the SUD program will achieve the following goals:

1. Increased rates of identification, initiation, and engagement in treatment;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of emergency departments (EDs) 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 LOC where the readmission is preventable or medically inappropriate; and
6. Improved access to care for physical health (PH) conditions among beneficiaries.

The Commonwealth believes that these six goals will be achieved through Demonstration activities that increase access to high quality of care across the entire treatment continuum, increase treatment program retention, and improve care transition across the continuum of SUD services. The specific interventions include:

- Continuing federal reimbursement for residential treatment stays beyond the 15-day limit under the Medicaid managed care rule

- Adopting all ASAM LOCs and the ASAM patient placement criteria in Medicaid managed care
- Implementing nationally recognized SUD-specific program standards to set provider qualifications for RTFs
- Ensuring provider capacity at critical LOCs, including MAT for OUD
- Implementing comprehensive treatment and prevention strategies to address opioid abuse and OUD
- Improving care coordination and transitions between LOCs

ASAM Implementation Update, Including Demonstration Impact

The purpose of the Section 1115 Demonstration waiver was to afford access to high quality, medically necessary treatment for OUD and other SUDs. The Commonwealth recognized the importance of a full continuum of treatment services, including residential services provided in a cost-effective manner and for a LOS governed by appropriate clinical guidelines. This Demonstration has proven critical to continue the federal funding needed to support the continuation of medically necessary services and SUD treatment in residential facilities that meet the definition of IMDs for individuals 21 years–64 years of age.

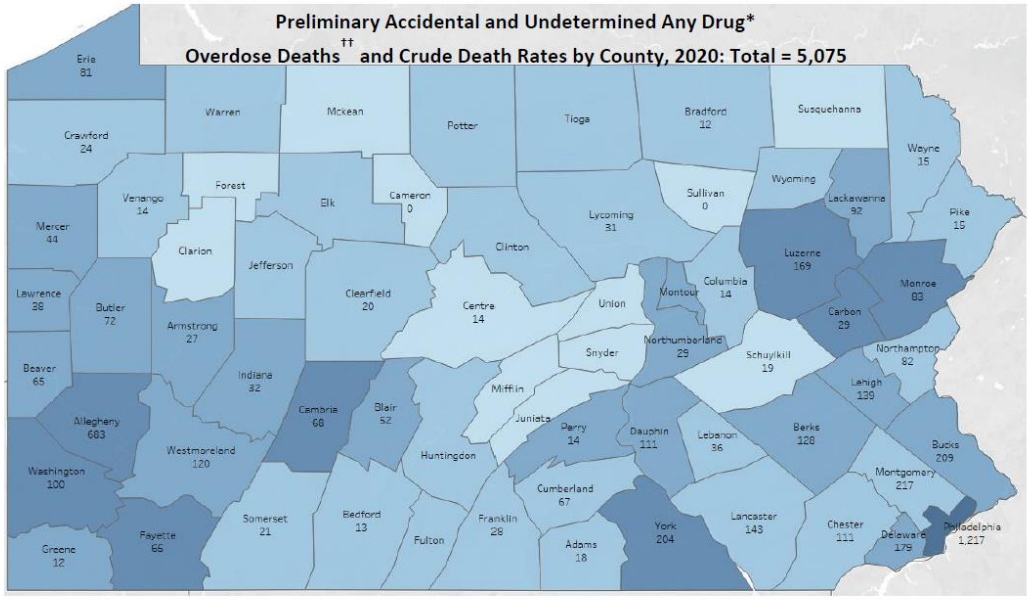
The Commonwealth has utilized the Demonstration authority to align its SUD service array with the ASAM, third edition criteria. The Commonwealth of Pennsylvania Department of Human Resources (DHS or Department) has made progress on implementation of the SUD component of the 1115 Demonstration waiver.

The Commonwealth continues to implement ASAM alignment as reported in its quarterly and annual reports to CMS. Providers were expected to have full compliance with ASAM alignment by July 1, 2022, in order to have contractual relationships for receipt of public funds. Milestone 5 and Milestone 6 are completed.

The Commonwealth developed workplans for the implementation of all activities under the implementation protocol to ensure the milestones are implemented consistently with the approved Standard Terms and Conditions (STCs). Several work groups meet weekly to discuss all aspects of the SUD 1115 project.

As of October 4, 2021, there were 5,075 Accidental and Undetermined Any Drug overdose deaths in the Commonwealth in 2020. This is a decrease of 6.1% since the Demonstration Application 2017, when there were 5,403 overdose deaths.[1] This overall decrease occurred despite a spike in overdose deaths in the middle of the Coronavirus Disease 2019 (COVID-19) PHE.

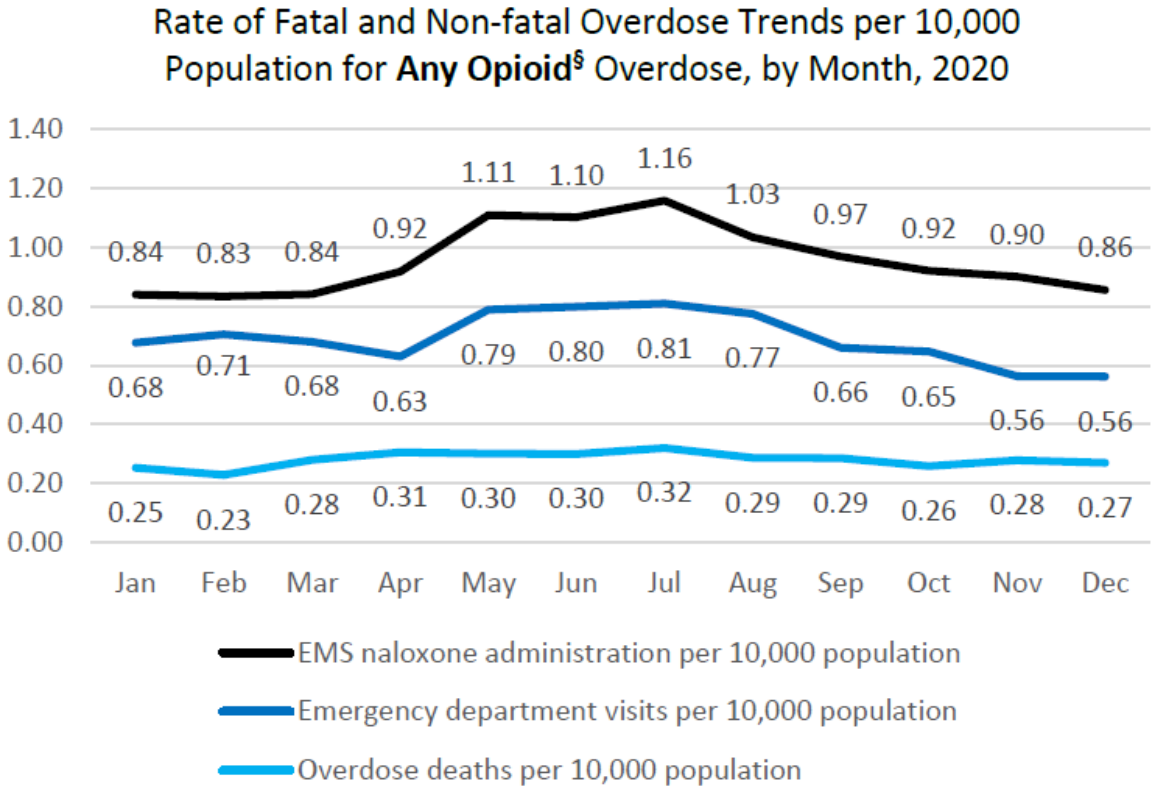
[1] Pennsylvania Department of Health. Fatal and Non-fatal Drug Overdoses in Pennsylvania, 2020. Retrieved from https://www.health.pa.gov/topics/Documents/Programs/PDMP/Pennsylvania%20Overdose%20Data%20Brief%202020.pdf, accessed on October 29, 2021. The trend continued in 2022, when Statewide, there were 4,703 reported overdoses in Pennsylvania according to the ODIN data, or 36.2 overdoses per 100,000 residents. Retrieved from Drug Overdoses in Rural and Urban Pennsylvania: A Progress Report (pa.gov) on January 31, 2024.



† Fatal overdose data includes death record data from the Bureau of Health Statistics and Registries at DOH, as well as toxicology and coroner/medical examiner records data through partnerships with individual county coroners/medical examiners and the Department of Drug and Alcohol Programs. Counts do not include Homicides or Suicides. Non-fatal overdose data includes syndromic surveillance data through our partnerships with emergency departments.

†† Counts for counties with overdose death counts between 1 and 9 are suppressed.

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Other relevant information Demonstration impacts include:

- Preliminary estimates show that of the 5,075 Accidental and Undetermined Any Drug* overdose deaths identified in 2020, 85% (4,314) were confirmed to be opioid-related, a 16% increase in opioid-related deaths compared to 2019 (3,728), and a 7% decrease compared to 2017 (4,645).
- Of the 4,314 confirmed opioid-related overdose deaths, 44% (1,887) also involved a stimulant such as cocaine or methamphetamine contributing to death, a 22% increase compared to 2019 (1,553).
- In 2020, 8% (426) of overdose deaths involved a stimulant without an opioid. For comparison, 10% (424) of overdose deaths involved a stimulant without an opioid in 2019.
- Four percent (189) of 2020 overdose deaths are missing toxicology information. Similarly, 3% (155) of 2019 overdose deaths were missing toxicology information.
- On average, nearly 14 Pennsylvanians died from a drug overdose every day in 2020.
- There was a statistically significant increase in drug overdose deaths in the Commonwealth (14%) in 2020 compared to 2019. 2017 remains the year with the most accidental and undetermined overdose deaths at 5,403.
- Based on death record data, over half of drug overdose deaths occurred in the decedent's own home (57%), highlighting the importance of getting naloxone into the hands of community members, particularly friends and family of people who use opioids.
- Of Any Drug* overdose deaths, 70% occurred among males.
- The highest percentage (27%) of Any Drug* overdose deaths occurred among those 35 years–44 years old, followed by 25% among those 25 years–34 years old.
- 74% of Any Drug* overdose decedents were White, 19% were Black, 6% were of all additional races, and less than 1% were of unknown race.
- 92% of Any Drug* overdose decedents were non-Hispanic, 8% were Hispanic, and less than 1% were of unknown ethnicity.
- Percentage change in rates‡ per 10,000 population for 2020 versus 2019 were highest among the following demographic groups: 65+ age group (27% increase), males (14% increase), Blacks (40% increase), and non–Hispanics (14% increase). As of September 27, 2021, there were 272 death records still pending for 2020, meaning the cause and manner of death have not yet been determined and results may change.

Milestone 1: Access to critical LOCs for OUD and other SUDs including:

- Outpatient
- IOP services
- MAT (medications, as well as counseling and other services with sufficient provider capacity to meet the needs of Medicaid beneficiaries in the Commonwealth)
- Intensive LOCs in residential and inpatient settings
- Medically supervised WM

System transformation: The Commonwealth continues to work with two sister agencies, forging a major system transformation across the entire Commonwealth. During the waiver period to date, DHS has made the following progress on implementation of the SUD component of the 1115 Demonstration waiver:

- An internal impact analysis regarding the adoption of the service descriptions was conducted to determine if regulation will allow full adoption of services as indicated by the criteria. The review of ASAM criteria descriptions was then compared to licensing requirements. This analysis was utilized to guide implementation of types of services, service hours, and staffing requirements.
- DDAP/DHS/Transition Workgroup engaged in an ongoing impact analysis (both independently and collaboratively) regarding service descriptions as they exist in the ASAM criteria. This process was necessary to anticipate the impact and changes to the field for residential/inpatient and non-residential services such as (outpatient/IOP/PHP/WM).
- DDAP created a guidance document on the application of the ASAM criteria to ensure all services within the PCPC continuum of care were available under the ASAM criteria. As a result of feedback from the field in response to the first publication of this document, modifications were made to better facilitate the transition and ensure stability of the Commonwealth's continuum of care. The changes contributed to some delay in the implementation of the 1115 Demonstration timeline.
- Current capacity for utilization of IOP and PHP using historic non-ASAM definitions (historical requirements are that PHP requires 10 hours of treatment weekly [instead of 20]) were reviewed to determine the impact to the Commonwealth's system should the service descriptions, as indicated in the ASAM criteria, be fully adopted as written.
- DDAP began draft guidance on the delivery of WM, specifically the ambulatory LOCs 1-WM and 2-WM. Consideration has been given to obtaining subject matter experts via a subcommittee representative of WM providers to ensure accurate reflection of the ASAM criteria, regulatory compliance, etc.
- At the advisement of the ASAM Transition Workgroup, a subcommittee was formed to develop best practice for the delivery of individualized care. This guidance will assist the field in applying the criteria holistically as a guide for clinical practice and decision-making rather than just a LOC placement tool.
- The ASAM Guidance document was updated to eliminate redundancy and to assist with closer compliance with the criteria. Other changes that occurred were the addition of information that had not been included in the first publication, such as admission, continued stay, and discharge guidelines. The revised ASAM Guidance document has been widely disseminated and is posted on the DDAP website.
- **Alignment of service definitions with ASAM:** Throughout 2020, the Commonwealth conducted a systematic "roll out" of service delivery descriptions and expectations beginning with residential services (3.0). DDAP and DHS communicated changes through in-person discussions, listserv communications, web postings, etc. The Commonwealth has significant buy-in from providers, behavioral health managed care organizations (BH-MCOs), and Single County Authorities (SCAs), with training and webinars they have been conducting. As part of the alignment, DHS and DDAP have worked together to develop ASAM service descriptions and delivery standards and guidance,

including admission, continuing stay and discharge criteria, the types of services, hours of clinical care, credentials of staff, and implementation of requirements for each LOC. DHS is continuing work to ensure that the OMHSAS encounter coding is consistent with any needed changes.

- **Oversight of provider transition to aligned ASAM service definitions:** Initially, the Commonwealth faced many political issues that caused significant delays. The Commonwealth has 800 licensed providers involved in this transition, of which approximately 450 contracts with an SCA and/or an BH-MCO. The Commonwealth completed an impact analysis to try to anticipate the challenges with alignment of the system of care (e.g., services, hours, staff credentials, etc.) with the ASAM LOC criteria. Finally, DHS and DDAP will work to ensure a cohesive provider monitoring program is in place. The SCA, along with the BH-MCOs, will work together to monitor compliance with the ASAM alignment. Capacity monitoring is anticipated to be embedded in the provider monitoring effort. There are 16 providers who have provider agreements under Medicaid who do not have contracts with the SCAs.
- Service delivery alignment began, including hours, service description, and staff qualifications, with the expectation that providers were significantly aligned by July 1, 2021, and fully aligned by July 1, 2022. Alignment has taken longer than expected and providers are continuing to align services to the expectations set forth. Providers participated in information-gathering sessions and technical assistance calls and have submitted policies and procedures for the DDAP alignment process with the ASAM criteria. The providers continued to submit questions via roundtable discussions, resource accounts, and email. Common challenges for the SUD providers were aligning the ASAM criteria for daily clinical services, staffing, and training. DDAP continues to offer support through technical assistance and clarification documents.
- DDAP has assisted the provider network by providing the service descriptions for 1.0, 2.0, 3.0, and 4.0 LOCs through written documentation, webinars, frequently asked questions (FAQs), and technical assistance. Information posted to the DDAP website includes Levels 1.0, 2.0, 3.0, and 4.0 self-assessment checklists, service characteristics, webinars, and FAQs. DDAP has issued a clarification and flexibility document on the ASAM alignment process on various aspects of the ASAM alignment. The clarification documents addressed staffing, training, and substantially aligned program LOCs. DDAP continues to respond to questions from the providers on all LOCs and works with them by offering technical assistance through conference calls, email correspondence, and FAQs. DDAP continues to work in collaboration with DHS regarding co-occurring services for individuals with SUD and mental health (MH) diagnoses to replace current DHS guidance and bulletins.
    - **ASAM 2.1:** DDAP continues to participate in roundtable discussions for Level 2.1.
    - **ASAM 2.5:** DDAP completed the alignment for Level 2.5 PHP services for the providers under contract with the SCAs. DDAP will continue to review requests of providers who want to contract with the SCA and align with PHP services. DDAP has reviewed policies and procedures for Level 2.5 PHP services and is conducting technical assistance calls with the providers of Level 2.5.
    - **ASAM 3.5:** DDAP continues to participate in roundtable discussions for Level 3.5. DDAP will continue to align with the ASAM criteria by no longer delineating two types of 3.5 LOC, (i.e., 3.5 Rehabilitative and 3.5 Habilitative). Services including LOS within a 3.5 LOC will be determined based on the identified needs of the individual within those programs. Specialized 3.5 programs,

such as pregnant women and women with children services, and those programs that have a criminal justice component will utilize the amount of time needed to address needs identified in the six-dimensional assessment/reassessment.

- **ASAM 3.7:** DDAP has also completed the Level 3.7 alignment for SCA-contracted providers. This newly updated LOC will increase staffing hours.
- **Residential standards:** OMHSAS and DDAP have had challenges implementing residential provider alignment with ASAM because of the number of providers affected, the number of changes required for ASAM alignment, and the timing of the changes. The Commonwealth has heard concerns from providers about staffing/client ratios and credentialing. Providers are expressing concern about the rates paid by Medicaid managed care. Preliminary designations for residential services were issued based on provider reported staffing. However, staffing alone does not ensure that the services described by the criteria are being delivered in residential or ambulatory treatment settings.
- **WM standards:** DDAP is working on providing information to the field regarding WM, specifically the ambulatory LOCs 1WM and 2WM. DDAP has been working on guidance for aligning ambulatory and residential WM services to the ASAM criteria and is currently working with physician advisors to ensure that the guidance for alignment to the criteria is sufficient and appropriate. With the exception of OUD medication induction, ambulatory WM has not been widely utilized across the Commonwealth, and therefore, this service has warranted added study and consideration. DDAP anticipates releasing direction and guidance regarding WM services in 2022, with alignment to begin immediately, with continued implementation throughout the year. DDAP and DHS are preparing criteria for alignment of cooccurring enhanced services that will replace a 2006 guidance document.
- **MAT:** The Commonwealth is working to ensure that all residential providers have accessibility to MAT for its residents, but there remains some degree of stigma regarding MAT and philosophical barriers with providers. The Commonwealth is trying to address this via education, awareness campaigns, etc. MAT accessibility is addressed in 5-year contracts with SCAs as part of the full continuum of care. DDAP continues to educate providers and the SCAs regarding MAT across the continuum. The Case Management and Clinical Services Manual addresses the requirements around MAT. In addition, the ASAM criteria, 2013 also addresses MAT for all LOCs.

- **Contractual changes:** The Commonwealth is making the ASAM alignment transition through SCA and HealthChoices contractual and agreement changes. Staff will evaluate whether additional addendums or other requirements are needed. DDAP/DHS expects requirements to be fully aligned with ASAM service delivery in 2021. Provider compliance with the fully aligned ASAM continuum is expected by July 2022.

Milestone 2: Use of evidence-based, SUD-specific patient placement criteria including:

- Implementation of requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the ASAM criteria or other patient placement assessment tools, which reflect evidence-based clinical treatment guidelines
- Implementation of a utilization management approach such that:
  - Beneficiaries have access to SUD services at the appropriate LOC
  - Interventions are appropriate for the diagnosis and LOC

- There is an independent process for reviewing placement in residential treatment settings

Use of ASAM in assessments and treatment planning: The transition to the use of ASAM in assessments and treatment planning is proceeding well. The Commonwealth has had both in-person and online training active as of January 1, 2020. To date, approximately 12,750 individuals have been trained in the ASAM criteria through either a 2-day classroom offering through Train for Change or on-demand modules through The Change Companies. These individuals are trained in use of ASAM skills, the LOC tool, and placement determinations.

- Commonwealth prior authorization guidelines were issued as of December 31, 2018.
- The 2020 Block Grant Agreement included references to application of the ASAM criteria.

Use of ASAM for patient placement: The transition to using ASAM LOC for a placement tool is also going well given the caveat that the Commonwealth has not fully transitioned to the ASAM service descriptions. DDAP issued guidance to the counties to use the ASAM admission criteria as of May 1, 2018. On March 1, 2019, the ASAM criteria was required for treatment plans, continued stay, and discharge criteria. Providers are utilizing ASAM criteria for admission determinations of LOC, but because the service definitions are not yet fully aligned, the service delivery is not fully aligned with ASAM. The Commonwealth staff are unable to fully assess how transition to the criteria is affecting access because services do not yet align with the placement criteria.

The field has primarily been using ASAM criteria as a LOC placement tool. DDAP issued guidance to the counties to use the ASAM admission criteria as of May 1, 2018, for SCA-funded services and ASAM treatment plan, continuing stay, and discharge criteria as of March 1, 2019. OMHSAS added language to the Program Standards and Requirement document effective January 1, 2019, that ASAM was to be used as medical necessity criteria for Medicaid-funded services. Any licensed treatment provider who is a Medicaid managed care provider is required by managed care agreements to conduct D&A assessments in accordance with the most recent version of the ASAM criteria.

Milestone 3: Use of nationally recognized SUD-specific program standards to set provider qualifications for RTFs, including:

- Implementation of residential treatment provider qualifications in licensure requirements, policy manuals, or other guidance. Qualification should meet program standards in the ASAM criteria or other nationally recognized, evidence-based SUD-specific program standards regarding, in particular, the types of services, hours of clinical care, and credentials of staff for residential treatment settings.
- Implementation of Commonwealth process for reviewing residential treatment providers to ensure compliance with these standards.
- Requirement that RTFs offer MAT on-site or facilitate access off-site.

The Commonwealth is utilizing three separate delivery systems to ensure compliance under the Demonstration: the Medicaid BH-MCOs, the Medicaid FFS delivery system, and the SCA who contract with the DDAP to provide the Substance Abuse and Mental Health Services Administration (SAMHSA) block grant funded services. The SCAs, along with the BH-MCOs, will work together to monitor compliance with the ASAM alignment.

Use of the ASAM criteria is required in the SCA contracts with licensed treatment providers. DDAP has also been able to identify licensed treatment providers that are non-contracted with the SCA.

There are 16 providers who are Medicaid-only providers and not subject to SCA monitoring for ASAM requirements. The HealthChoices-Behavioral Health (HC-BH) agreements require that all D&A reviews be conducted in accordance with ASAM criteria. OMHSAS will monitor compliance with this requirement.

In 2018, DDAP conducted a survey of the residential providers that included an initial self-assessment of the staffing levels at the provider. The self-assessment from providers was based on staffing, not on service description or delivery of service, as described by ASAM criteria. DDAP considers inpatient non-hospital residential providers to be aligned with the ASAM criteria Level 3.5 by virtue of being in compliance with regulatory requirements for this activity. The ASAM Level 3.7 did not previously exist in the Commonwealth; therefore, DDAP aligned providers who were interested in providing this LOC through technical assistance calls and review of policy and procedures related to the ASAM criteria for Level 3.7. There are 10 providers who are aligned for Level 3.7 services. In addition to the initial alignment, providers may request to align with Level 3.7 on an ongoing basis by participating in the alignment process with DDAP. Confirmation of service delivery will occur in 2022.

Milestone 4: Sufficient provider capacity at critical LOCs, including MAT for OUD:

- Completion of assessment of the availability of providers enrolled in Medicaid and accepting new patients in the critical LOCs throughout the Commonwealth (or at least in participating regions of the Commonwealth), including those that offer MAT.

Capacity: With the alignment of provider standards to ASAM, DDAP and OMHSAS believe there will be sufficient outpatient and IOP capacity. However, as the alignment occurs, it is unclear if there will be sufficient PHP access. This LOC has changes in the service descriptions. ASAM 3.5 should have sufficient access. However, ASAM 3.7 capacity is undetermined. This LOC also has changes from the previous definitions. The WM roll out has not started yet, so there may be some capacity issues that may need to be addressed.

Milestone 5: Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD, including:

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

The Commonwealth's work to address the opioid crisis focuses on three areas: prevention, rescue, and treatment. Working with Commonwealth agencies and local, regional, and federal officials have resulted in significant action to address the opioid crisis.

Prescribing Guidelines and Other Initiatives

The Commonwealth's initiatives with prescribing guidelines and other initiatives have resulted in:

- The waiver of birth certificate fees for those with OUD has helped close to 2,700 people, enabling easier entry into recovery programs.
- More than 6,000 health care professionals have been visited and provided training on how to prescribe opioids cautiously and judiciously.
- There have been 813 drug take-back boxes that have helped Pennsylvanians properly dispose of unwanted drugs, including 482,000 pounds of unwanted drugs in 2018.
- Commonwealth prescribing guidelines were issued as of December 31, 2018.
- Commonwealth prior authorization guidelines were issued as of December 31, 2018.
- On September 9, 2019, Governor Tom Wolf's office announced that recent data shows that in 2018, more than 4,400 people died from a drug overdose. This represents a nearly 18% decrease in drug overdose deaths from 2017.

Naloxone and Other Overdose Prevention Efforts

Commonwealth efforts to improve access to naloxone include:

- A standing order signed by Dr. Rachel Levine, Pennsylvania's Physician General, in 2018 allowed Emergency Medical Services (EMS) to leave behind nearly 2,400 doses of naloxone.
- The "Good Samaritan" law for drug overdose (2014 Act 139, Public Law 2487) was passed September 30, 2014.
- The Commonwealth has ensured that naloxone is available via standing order with the passage of Act 139 of 2014.
- The Get Help Now Hotline received more than 87,095 calls since inception in 2016, with nearly half of all callers connected directly to a treatment provider.
- The Commonwealth's prison system has expanded its MAT program, which is viewed as a model program for other states.
- Education regarding opioids and naloxone has been provided to more than 9,500 prescribers through either online or face-to-face education under the disaster declaration.
- Several agencies have worked together to collaborate on the seizure and destruction of illicit opioids across the Commonwealth.
- From 2016 to 2019, 3,055 cases of neonatal abstinence syndrome were reported to the Opioid Command Center.
- The coordination with seven major commercial insurers has expanded access to naloxone and MH care while also working to make it more affordable.
- Naloxone has been made available to first responders through the Commission on Crime and Delinquency, with more than 75,000 kits made available and more than 16,241 overdose reversals reported through that program since November 2017. In addition, EMS have administered more

than 49,000 doses of naloxone, and more than 10,000 doses were made available to members of the public during the Commonwealth's naloxone distribution last year.

PDMP

- In December 2019, the PDMP sent a message to all Commonwealth prescribers to raise awareness of common misapplications of the Centers for Disease Control and Prevention and Pennsylvania Opioid Prescribing Guidelines and the PDMP system.
- As of December 19, 2018, Attorney General Josh Shapiro's suspicious activity reporting tool was available for health care professionals and the public to report suspicious activity involving prescription medications.
- Pennsylvania launched a continuing education curriculum for prescribers titled Evidence-Based Prescribing: Tools You Can Use to Fight the Opioid Epidemic.
- The Pennsylvania PDMP is integrating the PDMP system with the electronic health records and pharmacy management systems of all eligible health care entities in Pennsylvania.
- The PDMP reduced opioid prescriptions by 27% and has virtually eliminated doctor shopping.
- The Opioid Data Dashboard and Data Dashboard 2.0 provides public facing data regarding prevention, rescue, and treatment.

Milestone 6: Improved care coordination and transitions between LOCs, including:

- Implementation of policies to ensure residential and inpatient facilities link beneficiaries, especially those with OUD, with community-based services and supports following stays in these facilities.

Transition and care coordination: The ASAM alignment will emphasize the provider standards for transition between LOCs. Licensure regulations within the Commonwealth require linkage/referral to services as necessary.

DDAP is planning to provide case management services separate from the clinical counselors by distinct teams/individuals, including ancillary services. DDAP is working on a separate 5-year strategic plan for improving case management services. Any individual with SUD in the Commonwealth who needs case management will be able to receive it.

DDAP continues to emphasize a separation of clinical services from care coordination. DDAP's Case Management and Clinical Services Manual discusses the requirements around case management services and clinical services being separate and distinct services.

DDAP continues to provide education to providers regarding MAT across the continuum of care. DDAP's Case Management and Clinical Services Manual includes the requirement for treatment providers to not exclude individuals on MAT from being admitted into services and for contracted providers to admit and provide services to individuals who use MAT for SUD.

Implementation Issues

As noted earlier, the interim evaluation found that OMHSAS and DDAP have had challenges implementing residential provider alignment with ASAM due to the size of the system and efforts to coordinate the transition with so many providers. The Commonwealth has heard concerns about staffing/client ratios and credentialing. Providers have expressed concern about the costs associated

with ASAM implementation. DHS is pursuing CMS approval for a minimum fee schedule directed payment, which should address concerns of providers in the BH-MCO delivery system regarding rates.

The Commonwealth has had objections from some of the provider community that is opposed to the implementation of ASAM. Admittedly, this has created some delay in maintaining adherence to the original timelines for full transition to ASAM. However, both DHS and DDAP have been working diligently to abate any concerns and respond to misinformation that surrounds ASAM implementation as the Commonwealth continues to move forward with the transition/implementation process.

The majority of providers have implemented ASAM criteria as an admission placement tool with relative ease. There have been few difficulties brought to DDAP's attention related specifically to the use of the placement criteria. DDAP has received positive feedback from some of the stakeholders regarding use of the placement criteria.

DDAP is also working to educate the field and legislature on individualized and person-centered care and the benefits of evidence-based practices. There continues to be some apprehension from certain stakeholder groups and organizations regarding the ASAM alignment, so DDAP is continually meeting with these entities and the legislature to address their concerns.

Evaluation Design

Mercer, the independent evaluator, facilitated meetings with The Commonwealth team to develop the evaluation design plan for the waiver. These meetings included development of driver diagrams, development of research questions, development of hypotheses, development of the analytic methods to be employed in the evaluation, and assessment of the methodological limitations. The meetings began on October 12, 2018. The Commonwealth finalized the draft evaluation design and submitted the plan to CMS on March 31, 2019. CMS approved the evaluation design on May 22, 2020. Following the Demonstration renewal approved on October 1, 2022 (through September 30, 2027), the updated evaluation design for this approval period was initially submitted on March 15, 2023.

Monitoring Protocol

The Commonwealth has fully complied with all requirements surrounding the monitoring protocol. The Commonwealth submitted the monitoring protocol to CMS on May 15, 2019. The Commonwealth programmed the performance metrics through PeopleStat, its internal data analysis group. CMS issued technical specification updates to metrics on August 28, 2020, and September 11, 2021. CMS approved the SUD monitoring protocol on December 15, 2020. The Commonwealth has submitted regular quarterly and annual monitoring reports for all quarters.

To complete these activities, the Commonwealth held meetings with the External Quality Review Organization, PeopleStat (part of DHS), DDAP, and Mercer to review required performance measure specifications and discuss the evaluation design and waiver milestones. Pennsylvania and its contractors completed service and coding crosswalks to ensure that the performance measures are calculated consistently. The deviations in coding and programming from CMS specifications for performance measures based on factors, such as data availability, and Pennsylvania-specific coding practices were identified, evaluated, and documented. In addition, OMHSAS met with the PDMP team to select Health

Information Technology (HIT) performance measures. A reporting schedule of performance measures was developed.

2. Demonstration Approval

The "Pennsylvania Former Foster Care Youth from a Different State and Substance Use Disorder 1115(a) Medicaid Demonstration" was originally approved on October 1, 2017, with the SUD authority becoming effective July 1, 2018 through September 30, 2022. The Commonwealth applied for, and received approval for, an extension of the Demonstration, which became effective October 1, 2022, and will continue through September 30, 2027.

3. Description of the Demonstration

The purpose of the Section 1115 Demonstration, and its subsequent extension, is to afford continued access to high-quality, medically necessary treatment for OUD and other SUDs and to provide access to FFC individuals. The evaluation design developed and described throughout this document will apply to this SUD Demonstration waiver amendment, except for the next subsection affiliated with the foster care evaluation.

FFC Individuals Evaluation

Medicaid Coverage for FFCY from a Different State

In the modified evaluation design submitted by Pennsylvania to CMS on June 26, 2018, the following goals for the Demonstration were identified:

1. Ensure access to Medicaid services for FFC individuals between the ages of 18 years and 26 years who previously resided in another state (the "target population.")
2. Improve or maintain health outcomes for the target population.

The extension evaluation design would apply to the next 5 DYs of the 1115 Demonstration waiver through September 2027:

- DY1: October 1, 2017 to September 30, 2018
- DY2: October 1, 2018 to September 30, 2019
- DY3: October 1, 2019 to September 30, 2020
- DY4: October 1, 2020 to September 30, 2021
- DY5: October 1, 2021 to September 30, 2022
- DY6: October 1, 2022 to September 30, 2023
- DY7: October 1, 2023 to September 30, 2024
- DY8: October 1, 2024 to September 30, 2025
- DY9: October 1, 2025 to September 30, 2026
- DY10: October 1, 2026 to September 30, 2027

The tables below outline how each goal for the FFC portion of the Demonstration will be measured.

Goal 1: Ensure access to Medicaid services for FFC individuals between the ages of 18 years and 26 years who previously resided in another state.					
Hypothesis 1: Beneficiaries will be continuously enrolled for 12 months.					
Research question 1.1: Does the Demonstration provide continuous health insurance coverage?					
Measure	**Numerator**	**Denominator**	**Data Source**	**Measurement Period & Reporting Frequency**	**Analytic Method**
Number of beneficiaries continuously enrolled	The number of unique beneficiaries (de-duplicated total) continuously enrolled in the measurement period	NA	Pennsylvania's Medicaid eligibility system	Annual	Frequency distribution (counts)
Hypothesis 2: Beneficiaries will access health services.					
Research question 2.1: How did beneficiaries utilize health services?					
Number of beneficiaries who had an ambulatory care visit	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state who had an ambulatory or preventive care visit during the measurement year	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state enrolled in Medicaid managed care for at least 1-month (30 consecutive days) during the measurement period	Encounter data/claims	Annual	Frequency distribution (counts and percentages)
Number of beneficiaries who had an ED visit	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state who had an ED visit during the measurement year	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state enrolled in Medicaid managed care for at least 1-month (30 consecutive days) during the measurement period	Encounter data/claims	Annual	Frequency distribution (counts and percentages)
Number of beneficiaries who had an inpatient visit	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state who had an inpatient visit during the measurement year	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state enrolled in Medicaid managed care for at least 1-month (30 consecutive days) during the measurement period	Encounter data/claims	Annual	Frequency distribution (counts and percentages)

Goal 1: Ensure access to Medicaid services for FFC individuals between the ages of 18 years and 26 years who previously resided in another state.					
Number of beneficiaries who had a BH encounter	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state who had a BHN encounter	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state enrolled in Medicaid managed care for at least 1-month (30 consecutive days) during the measurement period	Encounter data/claims	Annual	Frequency distribution (counts and percentages)

Goal 2: Improve or maintain health outcomes for the target population.					
Hypothesis 3: With access to healthcare for the out-of-state FFC group, health outcomes will improve over time.					
Research question 3.1: What do health outcomes look like for beneficiaries?					
Measure	**Numerator**	**Denominator**	**Data Source**	**Measurement Period & Reporting Frequency**	**Analytic Method**
Number of beneficiaries with appropriate follow up care for hospitalizations	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state with appropriate follow up care for hospitalizations	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state enrolled in Medicaid managed care for at least 1-month (30 consecutive days) during the measurement period	Pennsylvania's Medicaid eligibility system	Annual	Frequency distribution (counts)
Number of beneficiaries with appropriate medication management for asthma	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state with appropriate medication management for asthma	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state enrolled in Medicaid managed care for at least 1-month (30 consecutive days) during the measurement period	Encounter data/claims	Annual	Frequency distribution (counts and percentages)
Number of beneficiaries on persistent medication, with annual monitoring	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state on persistent medication, with annual monitoring	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state enrolled in Medicaid managed care for at least 1-month (30 consecutive days) during the measurement period	Encounter data/claims	Annual	Frequency distribution (counts and percentages)

Goal 2: Improve or maintain health outcomes for the target population.					
Number of beneficiaries with an annual preventive visit	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state with an annual preventive visit	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state enrolled in Medicaid managed care for at least 1-month (30 consecutive days) during the measurement period	Encounter data/claims	Annual	Frequency distribution (counts and percentages)
Number of beneficiaries eligible, with a cervical cancer screening	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state with a cervical cancer screening	FFC individuals between the ages of 18 years and 26 years previously enrolled in another state enrolled in Medicaid managed care for at least 1-month (30 consecutive days) during the measurement period	Encounter data/claims	Annual	Frequency distribution (counts and percentages)

SUD Demonstration Evaluation Description

The Demonstration will continue to test a new paradigm for delivering SUD services for Medicaid enrollees. By providing comprehensive, quality SUD treatment, the SUD program will achieve the following goals:

1. Increased rates of identification, initiation, and engagement in treatment;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of EDs 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 LOC where the readmission is preventable or medically inappropriate; and
6. Improved access to care for PH conditions among beneficiaries.

The Commonwealth believes that these six goals will be achieved through Demonstration activities that increase access to high-quality care across the entire treatment continuum, increase treatment program retention, and improve care transition across the continuum of SUD services. The specific interventions include:

- Continuing federal reimbursement for residential treatment stays beyond the 15-day limit under the Medicaid managed care rule
- Continuing to provide all ASAM LOCs and the ASAM patient placement criteria in Medicaid managed care
- Ensuring provider capacity at critical LOCs, including MAT for OUD
- Maintaining nationally recognized SUD-specific program standards to set provider qualifications for RTFs
- Maintaining and improving comprehensive treatment and prevention strategies to address opioid abuse and OUD
- Improving care coordination and transitions between LOCs

Medicaid and Medicaid Managed Care

In the HealthChoices program, BH services (MH and substance use services) are “carved out” and administered separately from PH managed care. The HealthChoices program is administered by five BH prepaid inpatient health plans and eight PH-MCOs operating under the 1915(b) waiver authority. OMHSAS in DHS oversees the HC-BH managed care program. With a few exceptions, Medicaid beneficiaries are automatically enrolled in the HC-BH program in the county of their residence. As of February 1, 2019, 2.62 million individuals were enrolled in HC-BH, supported by projected total funding of $3.9 billion in fiscal year (FY) 2019–2020.

DDAP

Although DDAP is not responsible for Medicaid in Pennsylvania, the below information outlines how this department functions as part of the SUD service delivery system in the Commonwealth. Pennsylvania established DDAP in 2010. DDAP has the statutory authority to oversee substance use services, except for the responsibility for managing substance use services in Medicaid and HC-BH, which remain under OMHSAS. Both DHS and DDAP are cabinet agencies under the governor. DDAP maintains the

responsibility for the development of the Commonwealth D&A Plan and for the control, prevention, intervention, treatment, rehabilitation, research, education, and training aspects of substance use issues.

DDAP is responsible for the allocation of the federal Substance Abuse Prevention and Treatment Block Grant in combination with Commonwealth appropriations to the SCAs. The SCA system provides the administrative oversight to local substance use programs that provide prevention, intervention, and treatment services. The SCA contracts with the local licensed treatment providers for a full continuum of care for individuals who qualify for substance use services within their geographical region.

DDAP requires the SCA to provide screening, assessment, and coordination of services as part of the case management function. Screening includes evaluating the individual's need for a referral to emergent care, including detoxification, prenatal, perinatal, and psychiatric services. Assessment includes LOC assessment and placement determination. All individuals who present for D&A treatment services must be screened and, if appropriate, referred for LOC assessment. Through coordination of services, the SCA ensures that the individual's treatment and non-treatment needs are addressed as well as ensuring the individual is enrolled in the appropriate health care coverage.

The SCA is responsible for ensuring the individual has access to available D&A treatment and treatment-related services, which is facilitated through the case management system. The provision of case management services will vary from county to county in terms of how these functions are organized and delivered. In some instances, the SCA may choose to contract for certain case management functions and activities while retaining others.

HC-BH contracts require BH-MCOs to have a letter of agreement with SCAs to coordinate service planning and delivery. The letter of agreement includes:

- A description of the role and responsibilities of the SCA
- Procedures for coordination with the SCA for placement and payment for care provided to members in RTFs outside the HealthChoices zone

Treatment Service Array

Pennsylvania has developed a comprehensive set of SUD treatment benefits that provide a full continuum of care through its FFS and managed care delivery systems, federal grants, and Commonwealth funds. The continuum includes:

- Inpatient D&A (detoxification and rehabilitation services)
- Outpatient D&A, including methadone maintenance services
- MAT
- Residential D&A detoxification and rehabilitation
- Certified recovery specialist services

Inpatient, outpatient, and MAT services are covered services within Pennsylvania's Medicaid State Plan. The last two services listed above are not available under the Medicaid State Plan and are provided under Pennsylvania's 1915(b) HealthChoices waiver as "in lieu of services" (IMD restrictions in Medicaid managed care apply to residential services). Federal grants and Commonwealth funds can be used for all

allowable services. SCAs at the local level receive federal grants, as well as Commonwealth and local funds, to support treatment needs of individuals who are uninsured or underinsured. In 2022, almost 70,000 Medicaid enrollees were receiving Medicaid-reimbursed SUD services each month.

For HealthChoices members, the continuum of care consists of an array of treatment interventions as well as additional ancillary services to support a recovery environment. Each BH-MCO contracts with a variety of providers to complete the LOC assessment. This may include the SCA, licensed intake and evaluation providers, or licensed outpatient providers. Clinical services are determined based upon a comprehensive assessment process and the application of standardized placement criteria such as the ASAM patient placement criteria.

OMHSAS-DDAP Coordination

Although OMHSAS is responsible for the administration of HC-BH, DDAP is the entity that has the statutory authority for the licensing of SUD treatment programs. OMHSAS and DDAP collaborate closely at various levels to ensure synergy across systems and to maintain consistency in the application of program requirements.

The Consolidated Appropriations Act, 2023, Drug Addiction Treatment Act of 2000 and the SUD Delivery System

Section 1262 of the Consolidated Appropriations Act, 2023 removes the federal requirements for practitioners to submit a Notice of Intent (NOI) (have a waiver) to prescribe medications, like buprenorphine, for the treatment of OUD. SAMHSA no longer accepts NOIs (waiver applications). All practitioners who have a current Drug Enforcement Administration (DEA) registration that includes Schedule III authority, may now prescribe buprenorphine for opioid disorder in their practice if permitted by applicable state law. Through this new statute, SAMHSA encourages practitioners to treat patients within their practices who require treatment for SUD. Historically, The Drug Addiction Treatment Act of 2000 (DATA 2000) expanded the clinical context of medication -assisted opioid dependency treatment by allowing qualified physicians to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications in settings other than an opioid treatment program (OTP) such as a methadone clinic. The legislation waived the requirement for obtaining a separate DEA registration as a narcotic treatment program for qualified physicians administering, dispensing, and prescribing specific Food and Drug Administration approved controlled substances, such as buprenorphine, in settings beyond OTPs. DATA 2000 increased options for treating opiate dependence and gives individuals the ability to coordinate both BH and PH care by the use of qualified physicians. Since the beginning of 2002, 3,717 Pennsylvania physicians have been certified under DATA 2000, with 2,725 of those certified to treat up to 30 patients and the remaining 992 certified to treat up to 100 patients.[2]

[2] Number of DATA-Waived Practitioners Newly Certified Per Year. Retrieved from https://www.samhsa.gov/medication-assisted-treatment/physician-program-data/certified-physicians?field_bup_us_state_code_value=PA&=Apply on January 31, 2020. Note: the DATA X waivers are no longer required, so this website has since been removed.

With the removal of the DATA-waiver requirements through Section 1262 of the Consolidated Appropriations Act of 2023 and the elimination of waiver applications effective on January 12, 2023, it is anticipated that the use of MAT will increase even more.

4. Population Impacted

This Demonstration will target all Pennsylvania Medicaid managed care recipients in need of OUD/SUD treatment services, including services provided in residential and inpatient treatment settings that qualify as an IMD, which are expenditures not otherwise eligible for match under section 1903 of the Social Security Act.

Pennsylvania reported that in FY2015–2016, 118,716 individuals (unduplicated) received SUD services funded by Pennsylvania's Medicaid program; 37,804 of those individuals received SUD residential services, which was a substantial increase from FY2014–2015, when 30,421 individuals received residential services. In FY2016–2017, the number of individuals covered by Medicaid with SUD was 235,748. This was an increase of 6% from FY2015–2016 and a 34% increase from FY2014–2015. The percentage increase is due, in part, to Medicaid expansion implemented in 2015. According to the Pennsylvania Open Portal data, the number of individuals covered by Medicaid with an OUD in calendar year (CY) 2017 was 119,523, with 61% being newly eligible diagnosed because of the Medicaid expansion. In FY2017–2018, 38,565 individuals received SUD residential services that included non-hospital SUD detoxification, non-hospital SUD halfway houses and non-hospital SUD rehabilitation. Of those individuals, 59.73% had at least one primary diagnosis of OUD. Additionally, according to the Bureau of Labor Statistics, Pennsylvania has an unemployment rate of 5.1%, which is one of the highest in the country.[3] Pennsylvania also has a poverty rate of 12.9%, which increases to 26.4% in Philadelphia, the country's poorest large city, which has endured a spike in opioid overdoses in recent years.[4] These socio-economic factors, combined with the growing number of individuals with SUDs, present a challenge for the Medicaid program to provide a continuum of care for beneficiaries in need of the full array of substance use treatment services.

B. SUD Evaluation Questions and Hypothesis

Evaluation questions and hypotheses to be addressed were derived from and organized based on the Driver Diagram below. The overall aim of the project is to reduce overdose deaths, particularly those due to opioids. To forward this aim, the Commonwealth will address six goals, as described in the State Medicaid Director's letter:

1. Increased rates of identification, initiation, and engagement in treatment
2. Increased adherence to and retention in treatment
3. Reductions in overdose deaths, particularly those due to opioids
4. Reduced utilization of ED and inpatient hospital settings for treatment, where the utilization is preventable or medically inappropriate through improved access to other continuum of care services

[3] Local Area Unemployment Statistics Map. Retrieved from https://www.samhsa.gov/medication-assisted-treatment/legislation-regulations-guidelines.
[4] United States Census Bureau. Population Estimates. Retrieved from https://www.census.gov/quickfacts/fact/table/PA/PST045216.

5. Fewer readmissions to the same or higher LOC, where the readmission is preventable or medically inappropriate
6. Improved access to care for PH conditions among beneficiaries

These goals are supported by six secondary drivers, which are interventions:

- Increase access to critical LOCs for OUD and other SUDs
- Implement evidence-based, SUD -specific patient placement criteria
- Ensure sufficient provider capacity at critical LOCs, including MAT for OUD
- Implement nationally recognized SUD-specific program standards to set provider qualifications for RTFs
- Implement comprehensive treatment and prevention strategies to address opioid abuse and OUD
- Improve care coordination and transitions between LOCs

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

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

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

1. Targets for Improvement

Each objective is translated into quantifiable targets for improvement so that the performance of the Demonstration in relation to these targets can be measured. These objectives will be achieved by increasing beneficiary access to appropriate LOCs and treatment duration, ensuring high-quality care across the entire treatment continuum and increasing treatment program retention by improving care transition across the continuum of SUD services. The corresponding improvement target for each of the Demonstration objectives is identified in the table below.

Each target was set originally in consultation with OMHSAS leadership. Targets for improvement were initially set based on conditions very specific to the Commonwealth. Because many services were available prior to the Demonstration, which would have gone away without implementation of the waiver, the State's targets were to maintain and gradually increase access to those services.

One consideration regarding target setting is the Commonwealth's concern that without waiver funding, much of the services already in place would be unavailable, leading to significant decreases in these targets. Therefore, the expectation is that the extension of the waiver will lead to stabilization and modest increases in the measures. The corresponding improvement target for each of the Demonstration objectives is identified in the following table.

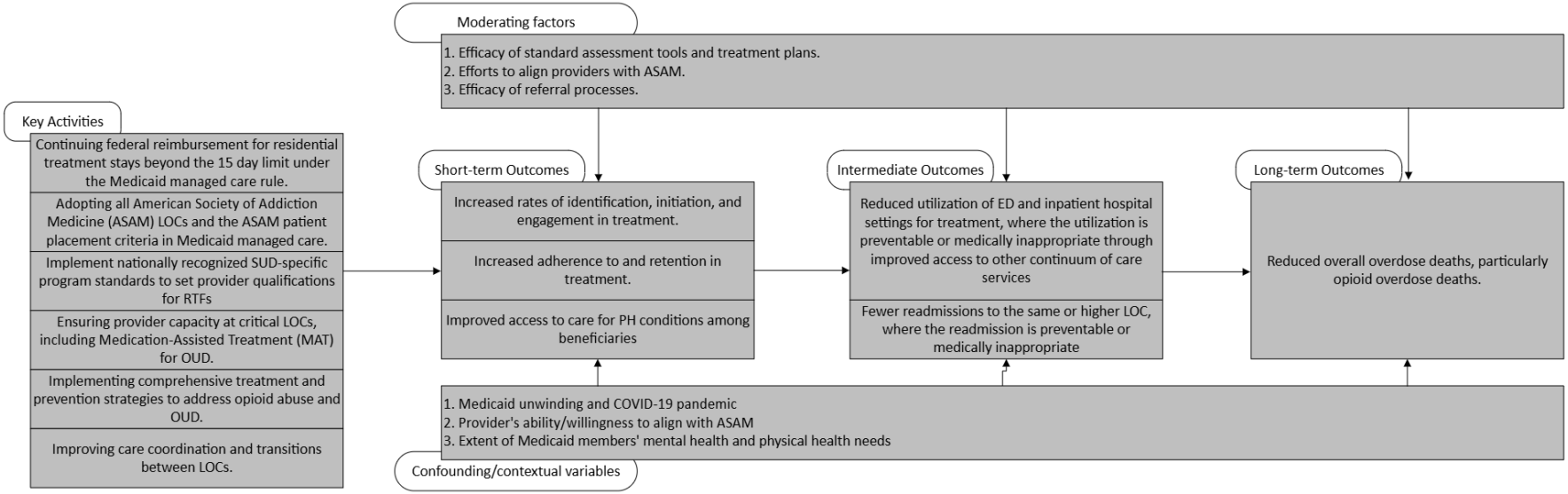
DHS/OMHSAS Objectives	Targets for Improvement
1. Increased rates of identification, initiation, and engagement in treatment;	• Annual increase of 1% in each alcohol or other drug (AOD) Initiation and Engagement of Alcohol and other Drug Dependence Treatment (IET) measure (National Committee for Quality Assurance [NCQA], National Quality Forum [NQF] #0004, Medicaid Adult Core set). *(Note: There are two rates reported; the goal will be 1% annual increase in each rate.)*
2. Increased adherence to and retention in treatment;	• Annual increase of 1% in continuity of pharmacotherapy for OUD (RAND, NQF #3175).
3. Reductions in overdose deaths, particularly those due to opioids;	• Annual decrease of 1% in the use of opioids at high dosage (Pharmacy Quality Alliance [PQA], NQF #2940, Medicaid Adult Core set). • Annual decrease of 1% in concurrent use of prescribed opioids and benzodiazepines (PQA). • Decrease of 1% in the rate of overdose deaths in the Commonwealth.
4. Reduced utilization of EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services;	• Increase of 1% in the rate of follow-up after discharge from the ED within 7 days and within 30 days for MH or alcohol and other drug dependence (NCQA, NQF #2605, Medicaid Adult Core set). *(Note: There are four rates reported; the goal will be 1% annual increase in each rate.)*
5. Fewer readmissions to the same or higher LOC where the readmission is preventable or medically inappropriate; and	• Decrease of 1% in the rate of readmissions among beneficiaries with SUD.
6. Improved access to care for PH conditions among beneficiaries.	• Annual increase of 1% in utilization of preventive/ambulatory visits for adult Medicaid managed care beneficiaries with SUD.

2. Logic Model, Research Questions and Hypotheses

The program aims to represent the ultimate goals of the waiver. The Logic Model below depicts how the Commonwealth's SUD Demonstration affects outcomes accounting for moderating factors and confounding/contextual variables that are known to the evaluator at the time of writing this evaluation design. Through qualitative data collection methods like focus groups and interviews, moderating factors and confounding or contextual variables may be updated to more accurately represent what occurred, based on stakeholders' experiences. Any such updates will be appropriately documented in the final Interim and Summative Evaluation Reports. The Key Activities outline the main interventions of the SUD Demonstration. Short-term outcomes are those most directly influenced by these interventions. For instance, by enhancing care coordination and transitions between LOCs, the Commonwealth is expected to see increased treatment adherence and retention. These short-term outcomes are anticipated to lead to intermediate outcomes, such as a decrease in ED visits for

treatment. Ultimately, in the long term, the SUD Demonstration aims to reduce overdose deaths, particularly those related to opioid overdoses.

Logic Model


Moderating factors
1. Efficacy of standard assessment tools and treatment plans.
2. Efforts to align providers with ASAM.
3. Efficacy of referral processes.
Key Activities
Continuing federal reimbursement for residential treatment stays beyond the 15 day limit under the Medicaid managed care rule.
Adopting all American Society of Addiction Medicine (ASAM) LOCs and the ASAM patient placement criteria in Medicaid managed care.
Implement nationally recognized SUD-specific program standards to set provider qualifications for RTFs
Ensuring provider capacity at critical LOCs, including Medication-Assisted Treatment (MAT) for OUD.
Implementing comprehensive treatment and prevention strategies to address opioid abuse and OUD.
Improving care coordination and transitions between LOCs.
Short-term Outcomes
Increased rates of identification, initiation, and engagement in treatment.
Increased adherence to and retention in treatment.
Improved access to care for PH conditions among beneficiaries
Intermediate Outcomes
Reduced utilization of ED and inpatient hospital settings for treatment, where the utilization is preventable or medically inappropriate through improved access to other continuum of care services
Fewer readmissions to the same or higher LOC, where the readmission is preventable or medically inappropriate
Long-term Outcomes
Reduced overall overdose deaths, particularly opioid overdose deaths.
1. Medicaid unwinding and COVID-19 pandemic
2. Provider's ability/willingness to align with ASAM
3. Extent of Medicaid members' mental health and physical health needs
Confounding/contextual variables

Measuring Progress on the Goals of the SUD Demonstrations

CMS has established goals and performance measures to measure achievement of the waiver. The performance measures are used to indicate that progress is being made to meet the Demonstration goals:

1. Increased rates of identification, initiation, and engagement in treatment;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of EDs 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 LOC where the readmission is preventable or medically inappropriate; and
6. Improved access to care for PH conditions among beneficiaries.

Additional detail about data collection methods and sources are noted in the "Evaluation Measures and Data Sources" section.

Goal 1: Qualitative data will be collected to describe each of the activities being undertaken to support increasing rates of identification, initiation and engagement in treatment; each of the performance measures in the Summary Design table will be used to demonstrate observed changes in provider capacity, to better assign patients to the appropriate LOC, and, therefore, to provide better access to care for the waiver population. Interrupted time series (ITS) analysis will be used to show changes in the number of individuals with an SUD diagnosis, the rate of individuals receiving any SUD treatment service, facility claim, or pharmacy claim, and the rate of individuals receiving treatment at each critical LOC.

Descriptive time series analysis will show changes in initiation and engagement of AOD treatment.

Descriptive time series analyses will also be used to show changes in the availability of providers in Medicaid (1) accepting new patients, (2) who provide MAT, and (3) in ambulatory and residential LOC.

Goal 2: Qualitative and quantitative data will be collected to describe each of the activities being undertaken to support increasing adherence to and retention in treatment. A descriptive times series analysis will be used to determine the number and percentage of individuals enrolled in Medicaid managed care treated in an IMD for SUD and the average LOS for those individuals.

Qualitative analysis of contracts and compliance reviews will be used to determine whether providers are following ASAM guidelines. Quantitative data will support assessment of (1) the number and percentage of contracts that require utilization review based on ASAM criteria for all LOCs and (2) the number of BH-MCOs whose prior authorization and utilization reviews are based on ASAM residential placement criteria.

Qualitative data will be used to assess the extent of ASAM alignment, and activities undertaken to review providers for alignment. Next, quantitative data gathered from on-site reviews will examine the number of providers reviewed for compliance and the rate of compliance.

Descriptive frequency analysis using member satisfaction survey data will be used to measure member access to treatment and satisfaction with services.

Goal 3: Descriptive time series analysis will be used to show changes in the rate of overdose deaths in the Commonwealth and hypothesis testing will be performed to assess whether changes are statistically significant. The number of overdose deaths is calculated using Vital Statistics data. Vital Statistics information on overdose deaths is maintained on the Vital Statistics website and is calculated by PeopleStat.

Goal 4: For the outcome evaluation, each of the performance measures outlined in the Summary Design table will use descriptive time series analysis to demonstrate observed changes in the use of opioids at high dosage, use of opioids from multiple prescribers and pharmacies, concurrent use of opioids and benzodiazepines, and continuity of pharmacotherapy for OUD.

Goal 5: For the outcome evaluation, a descriptive time series design will be used to show change over time in the following outcomes:

- Follow-up after discharge from the ED for MH or alcohol or other drug dependence within 7 or 30 days (NCQA, NQF #2605, Medicaid Adult Core set)
- Number and percentage of readmissions among beneficiaries with SUD
- Inpatient stays for SUD per 1,000 Medicaid beneficiaries

Goal 6: For the outcome evaluation, to show improvements in care coordination, a descriptive time series design will be used to show change over time in the following outcomes:

- Access to preventive/ambulatory health services for adult Medicaid managed care beneficiaries with SUD

Pennsylvania will also assess the following performance measures via descriptive time series analyses to determine the relationship between the SUD Demonstration and cost:

- Total Medicaid SUD spending in Medicaid managed care during the measurement period
- Total Medicaid SUD spending on residential treatment within IMDs in Medicaid managed care during the measurement period
- Costs by source of care for high-cost individuals with SUD in Medicaid managed care during the measurement period

C. Methodology

1. Evaluation Design

The evaluation of the Pennsylvania 1115 waiver will utilize a mixed-methods evaluation design with three main objectives:

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

Mercer will utilize a combination of qualitative and quantitative methods to evaluate the Demonstration. Quantitative methods will include a combination of descriptive statistics (such as time series analyses and frequencies), pre/post hypothesis testing, and where sufficient data is available, ITS analyses to support an understanding of the impact of the 1115 Demonstration. Hypothesis testing will allow Mercer to assess whether a change from the pre- to post-period was statistically significant. Depending on the type of measure (e.g., proportions versus means) and the nature of the data, Mercer will adjust the type of hypothesis testing as appropriate and will document these analytical decisions in final Interim and Summative Evaluation Reports. For example, z-tests are more appropriate testing measures that are proportions, such as the rate of individuals being treated in an IMD for SUD. However, in cases where the outcome is rare, an alternative test such as a Poisson exact test will be considered. T-tests are more appropriate for tests examining differences in means, for example, the average LOS measure. ITS analyses will be leveraged to the extent possible when adequate pre- and post-data are available. For example, an ITS analysis of the SUD component would examine outcome trends in the pre-period to the post-period. Additional detail on the pre- and post-period are described in the "Evaluation Period" section. The evaluation will also include analysis of specific subpopulations of interest, including children and adolescents, adults 21 years–64 years, adults age 65+ years, dual-eligible members, and pregnant members. Separate descriptive time series, hypothesis testing, and ITS analyses (as appropriate depending on data availability and adequate statistical power) will be performed for these subgroups. *Note: The Commonwealth does not have any data on criminal justice populations. CMS has approved this deviation in both the Commonwealth's monitoring protocol and original evaluation design.*

Qualitative methods will include a series of interviews and/or focus groups with key informants at different timepoints in the Demonstration:

- October 2025 before the Mid-Point Assessment is due.
- March 2026 before the Interim Evaluation Report is due.
- November 2028 before the Summative Evaluation Report is due.

The timing of the qualitative data collection will support Mercer in understanding the barriers and facilitators to implementation and the role of the Commonwealth's actions in implementing the Demonstration. This qualitative data will also support contextualizing the evaluation's quantitative findings to provide a more comprehensive understanding of Pennsylvania's Demonstration impacts. Key informants will include:

- OMHSAS staff
- DDAP staff
- BH-MCOs and PCs
- Providers
- PDMP/PeopleStat/eHealth (IT staff)

Thematic analysis (TA) and content analysis will be used to draw conclusions from data collected for qualitative review. TA is a method for identifying, analyzing, and interpreting patterns of meaning within qualitative data. Since key informant interview and focus group data includes individual opinions and

subjective perspectives, TA allows for comparisons across different stakeholders and stakeholder groups.

The evaluation will also assess Pennsylvania's implementation progress against its CMS approved implementation plan. Both planned changes that are part of the Demonstration design (e.g., implementation of ASAM) and operational and policy modifications Pennsylvania makes based on changing circumstances will be identified. Implementation progress will be assessed through ongoing communication with the Commonwealth. This will include information on how Pennsylvania has implemented each intervention, including how it has structured the ASAM implementation, identified providers at each ASAM level, implemented PDMP and other HIT changes, and how it structured care coordination between LOCs. The evaluation will analyze the scope of each of these interventions as implemented by the Commonwealth, the extent to which they conduct these functions directly or through contract, and internal structures established to promote implementation of the interventions. Finally, it is anticipated that, in some instances, changes in the policy environment in the Commonwealth will trigger alterations to the original Demonstration Implementation plan.

2. Target and Comparison Populations

Mercer reviewed the possibility of constructing a comparison population, however, because data availability limitations precluded more rigorous analytical methods such as difference-in-differences analyses. Where an adequate number of data points are available in the pre- and post-period, Mercer will leverage ITS analyses (additional details on this method are described in the "Analytical Methods" section. In ITS, a pseudo-comparison group is constructed by projecting out pre-period trends. Additional details on the ITS methodology as it applies to this evaluation are discussed in the "Analytic Methods" section.

The target population for the SUD component of the evaluation any Medicaid beneficiary with a SUD enrolled in the Commonwealth's HC-BH managed care plans. The HC-BH population consists of seven different eligible groups, or aid categories, which may change from time to time. Qualification for the HC-BH program is based on a combination of factors, including family composition, income level, insurance status, and/or pregnancy status, depending on the aid category in question. The scope of benefits and program requirements vary by the Medical Assistance (MA) category. Should the Department choose to implement cost-sharing options at a future date, these options may also be determined by MA category. The eligible groups are:

- *Temporary Assistance to Needy Families (TANF) and TANF-Related MA*: A federal block grant program, matched with Commonwealth funds, which provides cash payments and MA, or MA only (Medically Needy Only and Non-Money Payment), to families that contain dependent children who are deprived of the care or support of one or both parents due to absence, incapacity, or unemployment of a parent.
- *Healthy Horizons*: An MA program that provides Non-Money Payment MA and/or payment of the Medicare premium, deductibles, or coinsurance to disabled persons and persons age 65 years and over. Exception: An individual who is determined eligible for Healthy Horizons for cost sharing coverage only (categories PG and PL) will not be enrolled in the HealthChoices program.

- *SSI without Medicare*: Monthly cash payments made to persons who are aged, blind, or have been disabled for less than 2 years and will become eligible for Medicare when the disability has lasted for 2 years, under the authority of Title XVI of the Social Security Act, as amended, Section 1616(A) of the Social Security Act, or Section 212(A) of Pub. L. 93-66. This category automatically receives MA.
- *SSI-Related*: An MA category that has the same requirements as the corresponding category of SSI. Persons who receive MA in SSI-related categories are aged, blind, or disabled. This includes Medically Needy Only and Non-Money Payment.
- *State-Only General Assistance*: (Note: not under the Demonstration): A State-funded program that provides cash grants and MA (Categorically Needy) or MA only (Medically Needy Only and Non-Money Payment) to Pennsylvania individuals and families whose income and resources are below established standards and who do not qualify for the TANF program.
- *Eligible Groups Under Modified Adjusted Gross Income (MAGI) Rule:* MAGI Group 00 (MG 00) — Children ages 1 year–5 years inclusive and income at or below 157% FPL. Youth ages 6 years–18 years inclusive and income at or below 119% FPL. Infants and pregnant women at or below 215% FPL. MG 19 — Youth ages 6 years–18 years inclusive with income at or below 119% FPL. MG 27 — Income at or below 33% FPL. MG 71 — Transitional Medical Assistance.
- *Newly Eligible Groups under ACA*: Childless adults with income less than or equal to 133% of the applicable FPL. Parents and designated care takers and individuals ages 19 years or 20 years with income between 4% and 133% of the applicable FPL.

3. Evaluation Period

Mercer will leverage the approval date of the current approval period (October 1, 2022) as the cut-off date for classifying a pre- vs post-period. This cut-off date will be leveraged for several reasons:

1. Key components of the SUD Demonstration were only implemented in 2022 following resolution of litigation between the Commonwealth and its SUD providers. The alignment of SUD providers with ASAM guidelines was generally delayed, resulting in many providers in the Commonwealth not coming into alignment with ASAM standards until after 2022. Therefore, given that ASAM alignment is an essential aspect of the 1115 SUD Demonstrations as outlined in SMD # 17-003 “RE: Strategies to Address the Opioid Epidemic,” Mercer believes that leveraging a pre/post cut-off accounts for the delayed ASAM adoption in the Commonwealth.
2. Upon reviewing pre-2021 data, the evaluator identified data quality concerns and recommended dropping them from the analysis to allow for a more meaningful evaluation of the program. When pre-2021 and post-2021 are plotted on a graph, they indicate a significant drop/increase occurring at the January 2021 mark that we could not find a plausible explanation for. As such, without a better understanding of why such significant shifts in the data occurred, Mercer recommended dropping pre-2021 data.
3. The COVID-19 pandemic beginning early 2020 created fundamental changes to health care delivery, utilization, and Medicaid enrollment patterns. The Commonwealth also experienced several pandemic related challenges when implementing its SUD Demonstration. Therefore, restricting analyses to January 2021 onwards also ensures that evaluation findings are based on a more consistent policy and operational environment.

The following table shows data cutoffs for different types of data:

Measurement Frequency	Pre-Period	Post-Period in Interim Evaluation Report	Post-Period in Summative Evaluation Report
Monthly	1/1/2021–9/30/2022	10/1/2022–12/31/2025	10/1/2022–9/30/2027
Yearly (DY and CY)*	CY2021; FY2022	CY2022–CY2024; FY2023–2025	CY2022–CY2027; FY2023–2028

*Note(s): The * serves as an acknowledgement from Mercer that in some instances, the cut-off of October 1, 2022 cannot be cleaning applied for measures that are collected on an annual basis. For example, some of CY2022 will actually be in the "pre-period" and may be treated as a "post-period" broadly. To address such concerns, Mercer will conduct sensitivity checks around the cutoff for yearly measures. Examples of such sensitivity checks include (1) dropping CY2022 data and comparing CY2021 to CY2023–CY2027 or (2) classifying CY2022 as part of the "pre-period" which would bias estimates downwards (in other words deriving more conservative estimates).*

4. Evaluation Measures and Data Sources

This section describes the data that will be leveraged in the evaluation, organized by data source, and offers an overview of other supplementary data sources that will be considered.

Medicaid Claims and Encounter Data

PeopleStat acts independently of OMHSAS and the Office of Medical Assistance Programs (OMAP) and has direct access to the data warehouse used by the Medicaid agency for encounter data and claims. Medicaid claims data provides data related to service utilization, along with associated cost. Encounter data provides detailed records of services provided to Medicaid beneficiaries regardless of whether the service is reimbursed.

The data will be automatically updated any time a provider submits a claim or encounter data. PeopleStat will calculate the quantitative performance measures either monthly, quarterly, or annually and provide aggregated numerators and denominators to Mercer for the evaluation. Mercer and the Commonwealth explored the possibility of utilizing individual member level data, however, due to the way data is processed across several different BH-MCOs within Pennsylvania with different coding schemes, the cleanest way the evaluator can receive the data for the evaluation is in this aggregated form. Moreover, since the data utilized for the evaluation is stored on the state's servers and processed independently by the state rather than the independent evaluator, it is subject to an additional level of review by both the state and its quality assurance team. Limitations of this approach and its implications for interpretation are further discussed in the "Methodological Limitations" section.

As an additional data validation step, measures calculated by PeopleStat will be reviewed and compared against historical trends, as well as independent calculations produced with data available to the evaluator, to look for obvious inconsistences or discrepancies. Encounter data is submitted by the PC and its BH-MCO. These encounters are first processed through the SeGOV encryption software, and then the Health Insurance Portability and Accountability Act (HIPAA) Translator, and then Pennsylvania DHS HIPAA-compliant PROMISe. In PROMISe, the encounters are edited to ensure that federal and

Commonwealth requirements are met and that service combinations are consistent with our Behavioral Health Services Reporting Classification Chart.

An example of the edits that are in place to ensure validity of the encounter data include edits that check for duplicate billing of a BH encounter, invalid combination for professional BH encounter, and date of death is prior to date of service.

Vital Statistics Data

Commonwealth level Vital Statistics Data captures deaths along with an attributable cause, such as those attributable to opioid overdoses. The Commonwealth is unable to obtain Medicaid specific Vital Statistics Data, or the Vital Statistics on a DY basis. The implication of this limitation is discussed in the Methodological Limitations section of this design.

Key Informant Interviews/Focus Groups

Mercer will collect data through interviews and focus groups with beneficiaries, providers, and other key stakeholders. Potential interview and focus group questions are identified in the "Summary Design Tables" but may be updated to reflect implementation progress, address quantitative findings that require additional qualitative context, and incorporate emerging themes or stakeholder feedback as the evaluation evolves.

PDMP and eHealth Data

As part of the Demonstration, CMS requires the Commonwealth to perform activities with a goal towards improving PDMP, user interface and operability, as well as the interoperability of health information data exchanges, including the state's P3N Health Information Exchange (HIE). This data monitors the number of opioid prescriptions dispensed annually, incidence of multiple prescribers/multiple dispensers, and how data technology is used to improve substance use dispensing monitoring, especially for opioid prescriptions.

Member Satisfaction Survey

The Commonwealth conducts Member Satisfaction Surveys annually. The survey is sent directly to eligible members, who have the option of filling out the survey online or returning a written survey by mail. The 2022 survey had a response rate of approximately 13%, which is expected again in 2023. The survey is sent to all eligible members but is not stratified by subpopulations of interest. See the table below illustrating the survey questions related to SUD services that are assessed via a Likert scale.

Complete questions 45–47 if you received services to help with alcohol or other non-prescribed drugs.

About my substance use services:	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Not Applicable
45. I found it easy to get the care I needed.	1	2	3	4	5	9

About my substance use services:	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Not Applicable
46. I felt I was able to get the care I needed in a reasonable amount of time.	1	2	3	4	5	9
47. I feel the services I received have helped my overall health and well-being.	1	2	3	4	5	9

On-Site Reviews

As a part of milestone 3, CMS requires the Commonwealth's providers to align with ASAM and the Commonwealth to ensure providers are following these standards. The Commonwealth has an active monitoring process through on-site reviews to ensure providers are aligned with ASAM. This process is set up by the Commonwealth to ensure that providers comply with ASAM standards. On-site reviews are performed initially for all providers, and providers are given a 6-month, 1-year, or 3-year certification based on the initial review. Providers are then reviewed either every 6 months or annually until they are fully aligned with ASAM.

Capitation Rate Documentation and Number of Capitation

This evaluation plan relies on encounter data, which will reflect the service delivered, but not the actual cost to Medicaid. To account for this, cost measures will be included as a portion of the Medicaid capitation rate.

Other Data Sources

Some additional data sources that will be considered as part of the evaluation are:

- OMAP Medicaid provider enrollment database records
- State-specific IMD database
- BH-MCO and PC contracts (with OMHSAS)
- DDAP bulletins on ASAM, including ASAM placement guidelines
- OHMSAS bulletins
- OHMSAS instructions to BH-MCOs and PCs

Evaluation Measures and Data Sources

The following tables summarize both process (implementation) and outcome measures for the evaluation. It includes both qualitative and quantitative data sources.

Measuring Primary Drivers/Goals Hypotheses			
Primary Driver/Goal 1: Increased rates of identification, initiation, and engagement in treatment			
Hypothesis 1: The 1115 SUD Demonstration will increase the rates of initiation and engagement in SUD treatment for individuals in Pennsylvania Medicaid managed care compared to prior to the waiver.			
Measure Type	**Measure**	**Data Type**	**Data Source**
Process	Number and percentage of individuals enrolled in Medicaid managed care with a SUD diagnosis	Quantitative	Claims/encounters (PeopleStat)
Outcome	Number and percentage of individuals enrolled in Medicaid managed care using any SUD treatment service, facility claim, or pharmacy claim	Quantitative	Claims/encounters (PeopleStat)
Outcome	Number and percentage of individuals enrolled in Medicaid managed care using each of the following critical LOCs: early intervention, outpatient services, IOP and partial hospitalization services, residential and inpatient services, WM, and MAT	Quantitative	Claims/encounters (PeopleStat)
Outcome	Initiation and engagement of AOD treatment	Quantitative	Claims/encounters (PeopleStat)

Hypothesis 2: The 1115 SUD Demonstration will increase or maintain sufficient provider capacity to promote access to SUD treatment at critical LOCs for individuals in Pennsylvania Medicaid managed care.[5]			
Measure Type	**Measure**	**Data Type**	**Data Source**
Process	Number and percentage of providers enrolled in Medicaid and qualified to deliver SUD services and meet the standards to provide buprenorphine or methadone as part of MAT and providing MAT	Quantitative	• OMAP Medicaid provider enrollment database records • Claims/encounters data (PeopleStat)
Process	The number of SUD providers accepting new Medicaid patients	Quantitative	OMHSAS, DDAP, BH-MCO on-site reviews
Process	Number and percentage of providers enrolled in Medicaid and providing the following critical LOCs: early intervention, outpatient services, IOP and partial hospitalization services, residential and inpatient services, WM, and MAT	Quantitative	• OMAP Medicaid provider enrollment database records • Claims/encounters data (PeopleStat)

[5] The state originally included IMD utilization (Metric #5) and IMD ALOS (Metric #36) as measures for Hypothesis 2. These metrics have been moved to Hypothesis 3.

Measuring Primary Drivers/Goals Hypotheses			
Primary Driver/Goal 2: Increased adherence to and retention in treatment			
Hypothesis 3: The 1115 SUD Demonstration will sustain use of ASAM placement criteria by all providers for the duration of the Demonstration project to ensure individuals are served in the right LOC and to facilitate coordination of transitions across LOCs.			
Measure Type	**Measure**	**Data Type**	**Data Source**
Outcome	Number and percentage of individuals enrolled in Medicaid managed care treated in an IMD for SUD	Quantitative	Claims/encounters (PeopleStat)
Outcome	Average LOS for individuals enrolled in Medicaid managed care treated in an IMD for SUD	Quantitative	Claims/encounters (PeopleStat) State-specific IMD database
Process	Number and percentage of contracts that require utilization review based on ASAM admission, continuing stay, and discharge criteria for all ASAM LOCs	Quantitative	OMHSAS BH PC contracts
Process	Number and percentage of BH-MCOs whose prior authorization and utilization reviews are based on ASAM residential placement criteria	Quantitative	• OMHSAS results from BH organization PC on-site reviews • OMHSAS BH PC contracts • DDAP bulletins, including ASAM placement guidelines • OMHSAS bulletins • OMHSAS instructions to BH contractors
Process	Number and percentage of residential SUD providers found to have policies and procedures consistent with ASAM criteria and using ASAM assessment and residential placement criteria to drive facility admission	Quantitative	Residential provider on-site reviews

Measuring Primary Drivers/Goals Hypotheses			
Primary Driver/Goal 2: Increased adherence to and retention in treatment			
Hypothesis 4: The 1115 SUD Demonstration will monitor provider qualifications for all residential facilities based on ASAM criteria and program standards.			
Measure Type	**Description**	**Data Type**	**Data Source**
Process	Number and percentage of providers reviewed for compliance	Quantitative	• OMHSAS results from BH organization PC on-site reviews • OMHSAS and DDAP on-site provider reviews
Process	Number and percentage of providers in compliance	Quantitative	Document review, including: • OMHSAS results from BH organization PC on-site reviews • OMHSAS and DDAP on-site provider reviews
Hypothesis 5: Members receiving SUD services will report access to needed care and satisfaction with the SUD treatment received.			
Measure Type	**Measure**	**Data Type**	**Data Source**
Outcome	I found it easy to get the care I needed.	Quantitative	Member Satisfaction Survey (OMHSAS)
Outcome	I felt I was able to get the care I needed in a reasonable amount of time.	Quantitative	Member Satisfaction Survey (OMHSAS)
Outcome	I feel the services I received have helped my overall health and well-being.	Quantitative	Member Satisfaction Survey (OMHSAS)

Measuring Primary Drivers/Goals Hypotheses			
Primary Driver/Goal 3: Reductions in overdose deaths, particularly those due to opioids			
Hypothesis 6: The 1115 SUD Demonstration will reduce opioid deaths of individuals in Pennsylvania Medicaid managed care.			
Measure Type	**Measure**	**Data Type**	**Data Source**
Outcome	Rate of overdose deaths in the Commonwealth	Quantitative	Vital Statistics Data (PeopleStat)

Measuring Primary Drivers/Goals Hypotheses			
Primary Driver/Goal 4: Reduced utilization of EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services			
Hypothesis 7: The 1115 SUD Demonstration will improve outcomes for individuals in Pennsylvania Medicaid managed care.			
Measure Type	**Measure**	**Data Type**	**Data Source**
Outcome	Use of opioids at high dosage in persons without cancer	Quantitative	Claims/encounters (PeopleStat)
Outcome	Number and percentage of individuals prescribed opioids from multiple providers (three or more prescribers and three or more dispensers)	Quantitative	PDMP data
Outcome	Concurrent use of opioids and benzodiazepines	Quantitative	Claims/encounters (PeopleStat)
Outcome	Continuity of pharmacotherapy for OUD	Quantitative	Claims/encounters (PeopleStat)

Measuring Primary Drivers/Goals Hypotheses			
Primary Driver/Goal 5: Fewer readmissions to the same or higher LOC where the readmission is preventable or medically inappropriate			
Hypothesis 8: The 1115 SUD Demonstration will reduce readmissions for individuals in Pennsylvania Medicaid managed care.			
Measure Type	**Measure**	**Data Type**	**Data Source**
Outcome	Follow-up after ED visit for mental illness	Quantitative	Claims/encounters (PeopleStat)
Outcome	Follow-up after ED visit for AOD	Quantitative	Claims/encounters (PeopleStat)
Outcome	Readmissions among beneficiaries with SUD	Quantitative	Claims/encounters (PeopleStat)
Outcome	Inpatient stays for SUD per 1,000 Medicaid beneficiaries	Quantitative	Claims/encounters (PeopleStat)

Measuring Primary Drivers/Milestone Hypotheses			
Primary Driver/Goal 6: Improved access to care for PH conditions among beneficiaries			
Hypothesis 9: The 1115 SUD Demonstration will improve access to care for PH conditions.			
Measure Type	**Measure**	**Data Type**	**Data Source**
Outcome	Access to preventive/ambulatory health services for adult Medicaid managed care beneficiaries with SUD	Quantitative	Claims/encounters (PeopleStat)

5. Summary Design Tables for the Evaluation of the Demonstration

Primary Driver/Goal 1: Increased rates of identification, initiation, and engagement in treatment							
Hypothesis 1: The 1115 SUD Demonstration will increase the rates of initiation and engagement in SUD treatment for individuals in Pennsylvania Medicaid managed care compared to prior to the waiver.							
Research question 1.1: Since the development of the 1115 SUD waiver, are more individuals receiving services at critical LOCs when compared to the numbers prior to the waiver onset?							
Measure	**Steward**	**Numerator**	**Denominator**	**Data Source**	**Measurement Period & Reporting Frequency**	**Analytic Method**	**Target**
Number and percentage of individuals enrolled in Medicaid managed care with an SUD diagnosis	CMS (Metric #3)	The number of unique beneficiaries (de-duplicated total) enrolled in the measurement period who receive MAT or have qualifying facility, provider, or pharmacy claims with a SUD diagnosis and a SUD-related treatment during the measurement period and/or in the 11 months before the measurement period	All Medicaid managed care beneficiaries enrolled for any amount of time during the measurement period	Claims/ encounters	Measured monthly Reported quarterly	ITS analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Increase the identification/ number of individuals enrolled in Medicaid managed care with a SUD diagnosis.

Primary Driver/Goal 1: Increased rates of identification, initiation, and engagement in treatment							
Number and percentage of individuals enrolled in Medicaid managed care using any SUD treatment service, facility claim, or pharmacy claim	CMS (Metric #6)	The number of unique beneficiaries (de-duplicated total) enrolled in the measurement period who receive MAT or have qualifying facility, provider, or pharmacy claims with a SUD diagnosis and a SUD-related treatment during the measurement period and/or in the 12 months before the measurement period	All Medicaid managed care beneficiaries enrolled for any amount of time during the measurement period	Claims/ encounters	Measured monthly Reported quarterly	ITS analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Annual increase of 2.5% in the rate of members with a SUD accessing any services.
Number and percentage of individuals enrolled in Medicaid managed care using each of the following critical LOCs: early intervention, outpatient services, IOP and partial hospitalization services, residential and inpatient services, WM, and MAT	CMS (Metrics #7–#12)	The total number of unique beneficiaries (de-duplicated total) with a service claim for early intervention services (such as procedure codes associated with screening, brief intervention, and referral to treatment) during the measurement period Create this performance measure for each LOC: early intervention, outpatient services, IOP and partial hospitalization services, residential and inpatient services, WM, and MAT	All Medicaid managed care beneficiaries with a SUD diagnosis enrolled for any amount of time during the measurement period	Claims/ encounters	Measured monthly Reported quarterly	ITS analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Annual increase of 1% in the rate of the members with a SUD diagnosis (members) accessing each LOC.

Primary Driver/Goal 1: Increased rates of identification, initiation, and engagement in treatment							
Initiation and engagement of AOD treatment	NCQA, NQF #0004, Medicaid Adult Core set CMS Metric #15	• Initiation of AOD Treatment — number of beneficiaries who initiate treatment • Engagement of AOD Treatment — number of beneficiaries who initiated treatment and who were engaged in ongoing AOD treatment within 34 days of the initiation visit	Patients with a new episode of AOD abuse or dependence: age 18 years and older as of December 31 of the measurement year Continuous enrollment 60 days (2 months) prior to the IESD through 48 days after the IESD (109 total days)	Claims/ encounters	Year	Descriptive time series analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Annual increase of 1% in each AOD Initiation and Engagement of AOD Dependence Treatment (IET) measure (NCQA, NQF #0004, Medicaid Adult Core set). *Note: There are eight rates reported; the goal will be 1% annual increase in each rate.)*

Primary Driver/Goal 1: Increased rates of identification, initiation, and engagement in treatment							
Hypothesis 2: The 1115 SUD Demonstration will increase or maintain sufficient provider capacity to promote access to SUD treatment at critical LOCs for individuals in Pennsylvania Medicaid managed care.							
Research question 2.1: Has the availability of providers in Medicaid accepting new patients, including MAT, continued to improve under the Demonstration?							
Measure	**Steward**	**Numerator**	**Denominator**	**Data Source**	**Measurement Period & Reporting Frequency**	**Analytic Method**	**Target**
Number and percentage of providers enrolled in Medicaid and qualified to deliver SUD services and meet the standards to provide buprenorphine or methadone as part of MAT and providing MAT	CMS #14	Number of providers enrolled in Medicaid and qualified to deliver SUD services and meet the standards to provide buprenorphine or methadone as part of MAT and providing MAT	Number of providers enrolled in Medicaid and qualified to deliver SUD services	OMAP Medicaid provider enrollment database records Claims/encounter	Year	Descriptive statistics: change over time in frequency distributions	Maintain or increase annually.

Primary Driver/Goal 1: Increased rates of identification, initiation, and engagement in treatment							
Number of SUD providers accepting new Medicaid patients A. Ambulatory (number of providers) B. Residential (number of beds)	NA	The total number of eligible SUD providers that are accepting new Medicaid patients A. Ambulatory B. Residential	Number of providers enrolled in Medicaid A. Ambulatory B. Residential	Results from OMHSAS, DDAP, BH-MCO on-site reviews	Year	Quantitative: counts from document review	Maintain number of providers.
Number and percentage of providers enrolled in Medicaid and providing the following critical LOCs: early intervention, outpatient services, IOP and partial hospitalization services, residential and inpatient services, WM, and MAT	CMS Metric #13	The total number of eligible SUD providers A. Ambulatory (number of providers) B. Residential (number of beds)	SUD providers who were enrolled in Medicaid and qualified to deliver Medicaid SUD services during the measurement period A. Ambulatory (number of providers) B. Residential (number of beds)	Provider enrollment database and claims (if necessary) Claims/encounter	Year	Descriptive time series analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Continue to increase in the number of providers accepting Medicaid patients.

Primary Driver/Goal 1: Increased rates of identification, initiation, and engagement in treatment							
A. Ambulatory (number of providers) B. Residential (number of beds)							

Primary Driver/Goal 2: Increased adherence to and retention in treatment							
Hypothesis 3: The 1115 SUD Demonstration will sustain use of ASAM placement criteria by all providers for the duration of the Demonstration project to ensure individuals are served in the right LOC and to facilitate coordination of transitions across LOCs.							
Research question 3.1: Has the use of evidence-based SUD-specific patient placement criteria (ASAM criteria) been implemented across all LOCs for all patient populations? Are there remaining challenges? Does the use of these criteria persist?							
Analytic Approach: Qualitative narrative analysis; counts							
Driver: Access to care (primary); use of evidence-based placement criteria (secondary)							
Potential Key Informant Interview Questions (OMHSAS and DDAP): • What is the patient placement criteria in the Pennsylvania Medicaid program under the Demonstration and how do they differ from the Commonwealth's previous system? • To what extent did Pennsylvania implement the ASAM placement criteria? • What are the activities undertaken to ensure continued implementation of the ASAM placement criteria for individuals in Medicaid managed care?							
Measure	**Steward**	**Numerator**	**Denominator**	**Data Source**	**Measurement Period**	**Analytic Method**	**Target**
Number and percentage of individuals enrolled in Medicaid managed care treated in an IMD for SUD	CMS (Metric #5)	The number of unique beneficiaries (de-duplicated total) enrolled in the measurement period who have a service or pharmacy claim with a SUD diagnosis and who received inpatient/residential treatment in an IMD	All Medicaid managed care beneficiaries enrolled for any amount of time during the measurement period	Claims/ encounters	Year	Descriptive time series analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Annual increase of 1% in the rate of members with an SUD treated in an IMD.

Primary Driver/Goal 2: Increased adherence to and retention in treatment							
		within the measurement period					
Average LOS for individuals enrolled in Medicaid managed care treated in an IMD for SUD	CMS (Metric #36)	The total number of days in an IMD for all beneficiaries with an identified SUD	The total number of discharges from an IMD for beneficiaries in managed care with a residential treatment stay for SUD	Claims/ encounters State-specific IMD database	Year	Descriptive time series analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Maintain an IMD LOS less than 30 days.
Number and percentage of contracts that require utilization review based on ASAM admission, continuing stay, and discharge criteria for all ASAM LOCs	Pennsylvania	Number of contracts modified	Total number of contracts	OMHSAS BH PC contracts	Year	Descriptive frequency distributions	All OMHSAS BH PC contracts executed after July 2020 will reflect new guidance.
Number and percentage of BH-MCOs whose prior authorization and utilization reviews are based on ASAM residential placement criteria	Pennsylvania	Number of PCs conducting prior authorization and utilization review based on ASAM	Total number of PCs	OMHSAS results from BH organization PC on-site reviews OMHSAS BH PC contracts DDAP bulletins, including ASAM placement guidelines	Year	Descriptive frequency distributions	After 2020, all BH-MCOs will base prior authorization and utilization reviews based on ASAM residential criteria.

Primary Driver/Goal 2: Increased adherence to and retention in treatment							
				OMHSAS bulletins OMHSAS instructions to BH contractors			
Number and percentage of residential SUD providers found to have policies and procedures consistent with ASAM criteria and using ASAM assessment and residential placement criteria to drive facility admission	Pennsylvania	Percentage of residential treatment providers found to have policies and procedures and be using ASAM assessment and residential placement criteria to drive facility admission	Total number of residential SUD providers	Residential provider on-site reviews	Measured in on-going reviews Reported annually	Descriptive frequency distributions	After 2023, providers will have policies and procedures and use ASAM assessment and residential placement criteria to drive facility admission.

Primary Driver/Goal 2: Increased adherence to and treatment for OUD and other SUDs.							
Hypothesis 4: The 1115 SUD Demonstration will monitor provider qualifications for all residential facilities based on ASAM criteria and program standards.							
Research question 4.1: Do residential facilities continue to meet provider qualification standards?							
Potential Key Informant Interview Questions (Interviewees: OMHSAS and DDAP): • To what extent did Pennsylvania implement the ASAM placement LOC? Are there remaining challenges? • What activities have been undertaken to review for compliance with those program standards?							
Measure	**Steward**	**Numerator**	**Denominator**	**Data Source**	**Measurement Period**	**Analytic Method**	**Target**
Number and percentage of	Pennsylvania	Number of providers reviewed	Total number of providers	OMHSAS results from BH organization PC on-site reviews	Year	Descriptive frequency distributions	All residential providers will be reviewed for ASAM compliance

Primary Driver/Goal 2: Increased adherence to and treatment for OUD and other SUDs.							
providers reviewed for compliance				OMHSAS and DDAP on-site provider reviews			initially and at least every 3 years thereafter or as needed.
Number and percentage of providers in compliance	Pennsylvania	Number of providers in compliance	Number of providers reviewed	OMHSAS results from BH organization PC on-site reviews OMHSAS and DDAP on-site provider reviews	Year	Descriptive frequency distributions	Increase annually.
Hypothesis 5: Members receiving SUD services will report access to needed care and satisfaction with the SUD treatment received.							
Research Question 5.1: Do members report having access to needed treatment?							
Measure	**Steward**	**Numerator**	**Denominator**	**Data Source**	**Measurement Period**	**Analytic Method**	**Target**
Survey Question: I found it easy to get the care I needed.	OHMSAS	Number of responses that are agree/strongly agree	Number of valid question responses	Member Satisfaction Survey	Year	Descriptive frequency distributions	Increase each year.
I felt I was able to get the care I needed in a reasonable amount of time.	OHMSAS	Number of responses that are agree/strongly agree	Number of valid question responses	Member Satisfaction Survey	Year	Descriptive frequency distributions	Increase each year.
Research Question 5.2: Do members report satisfaction with treatment?							
Survey Question: I feel the services I received have helped my overall health and well-being.	OHMSAS	Number of responses that are agree/strongly agree	Number of valid question responses	Member Satisfaction Survey	Year	Descriptive frequency distributions	Increase each year.

Primary Driver/Goal 3: Reductions in overdose deaths, particularly those due to opioids.							
Hypothesis 6: The 1115 SUD Demonstration will reduce opioid deaths of individuals in Pennsylvania Medicaid managed care.							
Research question 6.1: Will improvements in treatment and prevention strategies in Medicaid managed care reduce overdose deaths, particularly those due to opioids?							
Measure	**Steward**	**Numerator**	**Denominator**	**Data Source**	**Measurement Period**	**Analytic Method(s)**	**Target**
Rate of overdose deaths in the Commonwealth	CMS Metric #27	The number of overdose deaths among eligible beneficiaries	Beneficiaries enrolled in Medicaid managed care for at least 1-month (30 consecutive days) during the measurement period	Vital Statistics Data	Year	Descriptive time series analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Annual decrease of 1% in the rate of overdose deaths in the Commonwealth.

Primary Driver/Goal 4: Reduced utilization of EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.

Hypothesis 7: The 1115 SUD Demonstration will improve outcomes for individuals in Pennsylvania Medicaid managed care under the following measures:

- Use of prescription opioids at high dosage
- Use of prescribed opioids from multiple prescribers (3 or more) and pharmacies.
- Concurrent use of opioids and benzodiazepines
- Continuity of pharmacotherapy for OUD for at least 180 days

Research question 7.1: Will improvements in treatment and prevention strategies in Medicaid managed care improve outcomes of individuals with a SUD in Medicaid managed care as demonstrated by: more effective initiation of treatment, decreased use of opioid at high dosages, reduced use of multiple opioids from multiple providers, reduced concurrent use of opioids and benzodiazepines, and improved continuity of pharmacotherapy for OUD.

Potential Key Informant Interview questions (Interviewees: the DHS PeopleStat program, the Pennsylvania PDMP, and the Pennsylvania eHealth Partnership Program)

- Were the performance measures calculated correctly?
- What are the HIT/Health Information Exchange/PDMP initiatives under the Demonstration, and how do they differ from the Commonwealth's previous system?
- What is the status of the PDMP and HIT elements of the implementation design plan?

Primary Driver/Goal 4: Reduced utilization of EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.							
Measure	**Steward**	**Numerator**	**Denominator**	**Data Source**	**Measurement Period**	**Analytic Method(s)**	**Target**
Use of opioids at high dosage in persons without cancer	NCQA, NQF #2940, Medicaid Adult Core set CMS Metric #18	Medicaid managed care enrollees with an average daily dosage ≥ 90 Morphine Milligram Equivalent during the opioid episode (see Adult Core Set Measure specifications for additional detail)	Medicaid managed care enrollees aged 18 years and older who received prescriptions for opioids (see Adult Core Set Measure specifications for additional detail) Exclude beneficiaries who met one of the following during the year: • Hospice • Cancer diagnosis • Sickle Cell Disease diagnosis • Palliative care	Claims/ encounters	Year	Descriptive time series analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Annual decrease of 1% in the use of opioids at high dosage (Pharmacy Quality Alliance [PQA], NQF #2940, Medicaid Adult Core set).

Primary Driver/Goal 4: Reduced utilization of EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.							
Number and percentage of individuals prescribed opioids from multiple prescribers (three or more prescribers and three or more dispensers)	PDMP calculated metric	The percentage of individuals greater than 18 years of age who received prescriptions for opioids from greater than or equal to three prescribers AND greater than or equal to three dispensers	Any adult individual in Pennsylvania age 18 years and older as of January 1 of the measurement year	PDMP data	Year	Descriptive time series analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Annual decrease of 1%.
Concurrent use of opioids and benzodiazepines	PQA, Medicaid Adult Core set CMS Metric #21	Beneficiaries aged 18 years and older with concurrent use of prescription opioids and benzodiazepines (see Adult Core Set Measure specifications for additional detail)	Medicaid managed care enrollees aged 18 years and older who received prescriptions for opioids (see Adult Core Set Measure specifications for additional detail) Exclude beneficiaries who met one of the following during the year: • Hospice • Cancer diagnosis • Sickle Cell Disease diagnosis • Palliative care	Claims/ encounters	Year	Descriptive time series analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Annual decrease of 1% in concurrent use of prescribed opioids and benzodiazepines (PQA).

Primary Driver/Goal 4: Reduced utilization of EDs and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.							
Continuity of pharmacotherapy for OUD	United States Code (USC), NQF #3175 CMS Metric #22	Beneficiaries aged 18 years and older with OUD who have at least 180 days of continuous treatment without a gap of more than seven days	Medicaid managed care enrollees aged 18 years and older who had a diagnosis of OUD	Claims/ encounters	Year	Descriptive time series analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Annual increase of 1% in continuity of pharmacotherapy for OUD (RAND, NQF #3175).

Primary Driver/Goal 5: Fewer readmissions to the same or higher LOC where the readmission is preventable or medically inappropriate.							
Hypothesis 8: The 1115 SUD Demonstration will reduce readmissions for individuals in Pennsylvania Medicaid managed care.							
Research question 9.1: Will improvements in treatment and prevention strategies in Medicaid managed care reduce readmissions for individuals in Pennsylvania Medicaid managed care?							
Measure	**Steward**	**Numerator**	**Denominator**	**Data Source**	**Measurement Period**	**Analytic Method**	**Target**
Follow-up after ED visit for mental illness	NCQA, NQF #2605, Medicaid Adult Core set CMS Metric #17(2)	Medicaid managed care enrollees aged 18 years and older who received follow-up within: (1) 30 days of the ED visit and (2) 7 days of the ED visit	Medicaid managed care enrollees aged 18 years and older with an ED visit with a principal diagnosis of mental illness or intentional self-harm	Claims/ encounters	Year	Descriptive time series analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Increase of 1% in the rate of follow-up

Primary Driver/Goal 5: Fewer readmissions to the same or higher LOC where the readmission is preventable or medically inappropriate.							
Follow-up after ED visit for AOD	NCQA, NQF #2605, Medicaid Adult Core set CMS Metric #17(1)	Medicaid managed care enrollees aged 18 years and older who received follow-up within: (1) 30 days of the ED visit and (2) 7 days of the ED visit	Medicaid managed care enrollees aged 18 years and older with an ED visit with a principal diagnosis of AOD abuse or dependence	Claims/ encounters	Year	Descriptive time series analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Increase of 1% in the rate of follow-up
Readmissions among beneficiaries with SUD	CMS Metric #25	The count of 30-day readmissions	Count of Index Hospital Stays	Claims/ encounters	Year	Descriptive time series analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Decrease in 1% of readmissions among beneficiaries with SUD.
Inpatient stays for SUD per 1,000 Medicaid beneficiaries	CMS Metric #24	Number of inpatient discharges related to a SUD	Beneficiaries enrolled in Medicaid managed care for at least 1-month (30 consecutive days) during the measurement period	Claims/ encounters	Month	Descriptive time series analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Annual decrease of 1.5% in inpatient stays for adult Medicaid managed care beneficiaries with SUD.

Primary Driver/Goal 6: Improved access to care for PH conditions among beneficiaries.							
Hypothesis 9: The 1115 SUD Demonstration will improve access to care for PH conditions.							
Research question 10.1: Has the Demonstration impacted access to care for individuals with SUD in Medicaid managed care?							
Measure	**Steward**	**Numerator**	**Denominator**	**Data Source**	**Measurement Period**	**Analytic Method(s)**	**Target**
Access to preventive/ambulatory health services for adult Medicaid managed care beneficiaries with SUD	NCQA CMS Metric #32	Medicaid managed care enrollees aged 18 years and older who had an ambulatory or preventive care visit	Medicaid managed care enrollees aged 18 years and older who had a SUD diagnosis	Claims/ encounters	Year	Descriptive time series analysis Pre/post hypothesis testing (e.g., t-test, z-test, etc.)	Annual increase of 1.5% in utilization of preventive/ambulatory visits for adult Medicaid managed care beneficiaries with SUD.

Performance measures for cost. Note: There are no hypotheses regarding these metrics.

Pennsylvania will add the following measures of cost:

- Total Medicaid SUD spending in Medicaid managed care during the measurement period
- Total Medicaid SUD spending on residential treatment within IMDs in Medicaid managed care during the measurement period
- Costs by source of care for high-cost individuals with SUD in Medicaid managed care during the measurement period

The spending will be compared to prior to the implementation of the waiver.

Measure	Steward	Numerator	Denominator	Data Source	Measurement Period	Reporting Frequency	Target
Proportion of Medicaid SUD spending in Medicaid managed care during the measurement period	Commonwealth CMS Metric #28	Portion of the Medicaid managed care rate spent on SUD	Total Medicaid managed care rates	Capitation Rate Documentation and Number of Capitation Rates Paid	Year	Interim and final evaluation reports	Maintenance of SUD spending in capitation rates.

Measure	Steward	Numerator	Denominator	Data Source	Measurement Period	Reporting Frequency	Target
Proportion of Medicaid SUD spending on residential treatment within IMDs in Medicaid managed care during the measurement period	Commonwealth CMS Metric #29	Portion of the Medicaid managed care rate spent on IMDs	Total Medicaid managed care rates	Capitation Rate Documentation and Number of Capitation Rates Paid	Year	Interim and final evaluation reports	Maintenance of IMD spending in capitation rates.
Proportion of Medicaid SUD spending by source of care for high-cost individuals with SUD in Medicaid managed care during the measurement period	Commonwealth	Portion of the Medicaid managed care rates spent on different categories of care for individuals with SUD	Total Medicaid managed care rates	Capitation Rate Documentation and Number of Capitation Rates Paid	Year	Interim and final evaluation reports	Proportion of spending on different service categories in capitation rates for high-cost individuals with SUD.

Cost data will be analyzed using descriptive time series analysis. This will show the changes in cost over time, from the pre- to post-period. Changes over time will be analyzed to determine whether costs increase, decrease, or remain consistent.

6. Analytic Methods

Multiple analytic techniques will be used, depending on the type of data for the measure.

Qualitative Analysis

TA will be used to analyze and present findings from qualitative data sources. These include data gathered from document reviews, key informant interviews, etc., as discussed previously. Standardized interview guides will be developed based on the driver diagrams and the implementation plan and will leverage aspects of the "Consolidated Framework for Implementation Research."[6] Mercer will develop a code book based on the standardized interview guides to analyze the interview transcripts. TA of qualitative data will allow Mercer to draw conclusions from a diverse range of experiences and viewpoints. Qualitative analysis will be used to organize documentation, including key informant interview transcripts. Analysis will identify common themes across interviews and documents. These data will be summarized to describe the activities undertaken for each project intervention, including highlighting specific successes and challenges.

ITS

ITS analyses will be used if sufficient pre-treatment and post-treatment data are available.[7] Specific outcome measure(s) will be collected for multiple time periods both before and after start of intervention. Segmented regression analysis will be used to statistically measure the changes in level and slope in the post-period compared to the pre-period. The ITS design uses historical data to forecast the counterfactual of the post-period, that is to say, what would happen if the Demonstration did not occur. We propose using basic time series linear modeling to forecast these counterfactual rates for the post-period.[8]

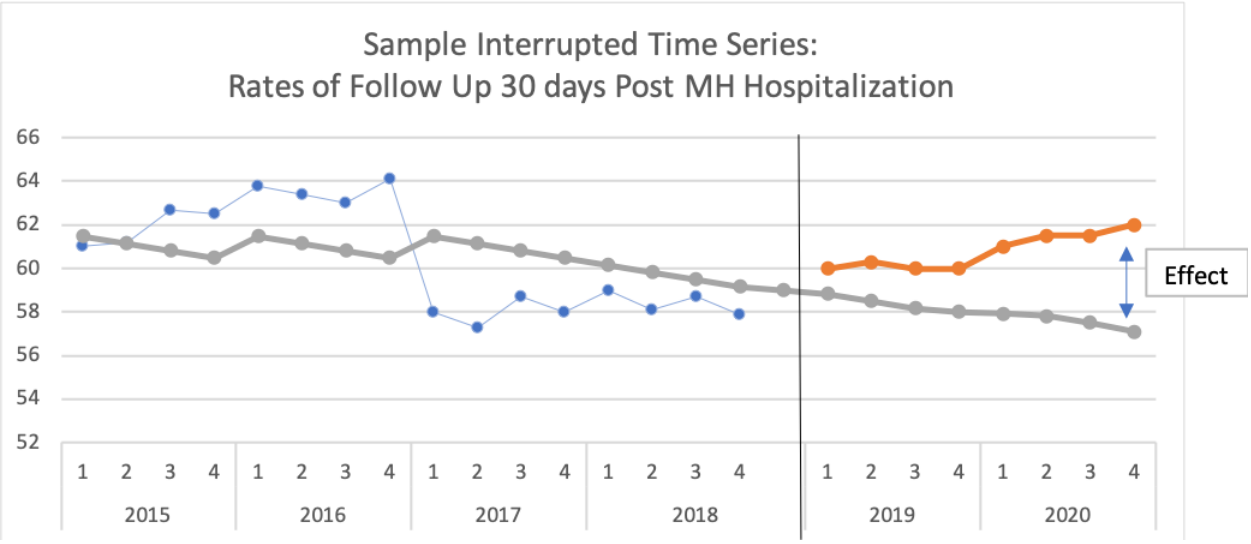
The more historical data points available, the better these predictions will be. The Commonwealth considered options for a contemporary comparison group to support more rigorous analytical methods such as difference-in-differences. Since the Demonstration will target managed care members, a comparison group made up of FFS members was considered. However, many of the Demonstration changes take place at the provider level and will, therefore, also impact FFS members, thus contaminating the comparison group. ITS models are commonly used in situations in which a contemporary comparison group is not available.[9]

[6] Center for Clinical Management Research. 2024. https://cfirguide.org/
[7] Bernal JL, Cummins S, Gasparrini A. Interrupted time series regression for the evaluation of public health interventions: a tutorial (2017 Feb.). International Journal of Epidemiology 46(1): 348-355.
[8] E Kontopantelis E. (2015). Regression based quasi-experimental approach when randomisation is not an option: interrupted time series analysis. British Medical Journal (BMJ). Retrieved from https://www.bmj.com/content/350/bmj.h2750
[9] Ibid.

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

This can be represented graphically as follows:

(SAMPLE data only) Rates of Follow-Up Post MH Hospitalization



$$Y_t = \beta_0 + \beta_1 Post_t + \beta_2 Time_t + \beta_3 (Post_t \times Time_t) + \varepsilon_{i,t}$$

The equation above depicts an ITS regression where Y_t representing the outcome measure of interest at time *t*. $Post_t$ is a binary indicator that is equal to 1 for observations in the post-period, and equal to 0 for observations pre-period. $Time_t$ is a continuous variable for time and captures underlying trends in the outcome over time. $Post_t \times Time_t$ is an interaction term that allows for differential time trends between the pre- and post-periods. Finally, ε_t represents unobservable factors that may affect the outcome. To assess differences between subpopulations analyses will be stratified.

Descriptive Analyses and Hypothesis Testing

Descriptive statistics, including frequency distributions and time series (presentation of rates over time), will be used to summarize and analyze data patterns and identify trends. Patterns and trends identified will help inform qualitative data collection efforts such as focus groups/interviews. While descriptive trends cannot support causal interpretation of the SUD Demonstration's impacts, they can provide valuable insights into changes over time that are correlated with the Demonstration and help inform more rigorous future evaluation efforts when additional data are available.

Mercer will also leverage hypothesis testing (e.g., t-test, z-test, ANOVA, etc.) to assess whether differences between groups and across time are statistically significant at the 95% level. The choice of the statistical test, as noted earlier, depends on the nature of the outcome measure being assessed. The final Interim and Summative Evaluation Reports will document how the evaluator selected the appropriate statistical test. The appropriate statistical tests will also be utilized to assess differences in outcome measures by subpopulations of interest via stratified analyses. To assess differences between subpopulations, analyses will be stratified by the relevant subpopulation categories.

Sensitivity Checks

Sensitivity analyses will also be conducted to test robustness of the model. For instance, we will adjust the definition of the pre- and post-period cutoff to accommodate situations where annual metrics in CY2022 encompass data from both the pre-period and post-period. This can be done in two ways. One check will assign CY2022 to the pre-period given that the new approval period started on October 1, 2022, meaning the majority of CY2022 was part of the pre-period. A separate check could drop consideration of CY2022 data and compare pre-period data (CY2021) to CY2023 and after.

National Benchmarks

We will also attempt to seek out national and other state data for benchmarking that will allow us to determine whether Pennsylvania is performing in a similar fashion to other Demonstration states, non-Demonstration states, or national benchmarks overall.

D. Methodological Limitations

This section highlights key limitations of the evaluation that should be considered when interpreting its findings. Mercer, the evaluator, will strive to address these limitations through methodological approaches when feasible. However, when this is not possible, the evaluation will clearly document the limitations, explain their implications, and offer recommendations for future evaluations.

1. Data Availability and Quality

Implications of Limited Pre-Data

The first limitation to consider relates to data availability and quality. Originally, the evaluator considered including data back to 2015, however, due to the data quality issue noted above, this is not possible for this evaluation. Pre-2021 data raised data quality concerns due to a significant, unexplained shift in outcomes observed around January 2021 across multiple measures.[10] To prevent confusing potential data quality issues with actual program impacts, the evaluator chose to exclude all data from before 2021. Excluding pre-2021 data limits the availability of a longer pre-trend period, which is ideal for analyses like ITS.

Implications of Using the Renewal Date as the Pre- Versus Post-Period Cut-off

Upon further review of the Commonwealth's implementation progress, the evaluator observed that significant adoption of ASAM by SUD providers did not occur until 2022. Pennsylvania's providers were slow to adopt ASAM for several reasons, including challenges related to the COVID-19 pandemic, litigation between providers and the Commonwealth, and administrative burdens. Therefore, using 2022 as the cutoff between pre- and post-implementation periods may be more methodologically appropriate, as the program's implementation after that time more closely reflected its intended design. While this evaluation will use October 1, 2022—the approval date for the current period—as the primary cut-off date to distinguish the pre- versus post-period, sensitivity checks as described above, will also adjust this date to assess how sensitive the results are to the choice of cut-off.

Additionally, several of the SUD program components were already existing in the Commonwealth before approval of the 1115 authority in July of 2018. For example, Pennsylvania was paying for IMD services before the Demonstration through in lieu of services authority. Furthermore, the Commonwealth had begun implementing PDMP, prescribing guidelines, HIE, and increasing access to naloxone prior to the Demonstration. While there were some advances to the PDMP, such as new clinical alerts being sent in 2018, the real innovation from 1115 was ASAM alignment, which was not fully implemented until after the COVID-19 pandemic, and was further delayed by litigation.

Using the approval date of the current approval period as the cutoff between pre- and post-periods means that the pre-period in this evaluation does not reflect a true "pre-1115" state, but rather a phase in which some program elements were already in place. Consequently, the findings are more indicative

[10] Many of the metrics calculated by PeopleStat for the waiver were new to OMHSAS during the early years of the Demonstration. As familiarity with these metrics has grown, we believe the calculation methods have been refined, leading to more accurate measurements. In 2023, the Commonwealth identified data quality concerns, prompting a process to re-run the data retrospectively back to January 2021.

of “renewal effects” rather than the “total program effects.” One significant component that was delayed until 2022 was ASAM alignment. As a result, this evaluation is more likely to capture the impacts of ASAM adoption among SUD providers in the Commonwealth rather than the full effects of the 1115 Demonstration. The evaluator believes these insights on ASAM adoption remain valuable and offer important insight for developing guidance and program design for future SUD programs both in the Commonwealth and on a national scale, especially as providers begin adopting the 4th edition of ASAM. Another implication of using this cutoff is that the true program impact may be underestimated as some effects are already reflected in the pre-period. Nevertheless, any positive findings would indicate that the program continues to generate benefits even during a mature stage of implementation. Furthermore, to the extent the design produces more conservative estimates, findings can be interpreted as a lower-bound of the program’s overall benefit.

Implications of Using Aggregated Data

Another important point about the data is that it is only available to the evaluator in aggregated form. Mercer considered using individual member-level data to enable more precise estimates and adjustments for confounding factors. However, because the data is processed across multiple BH-MCOs and MCOs within Pennsylvania, and each state agency has slightly different coding schemes for their respective managed care organizations, the most consistent and reliable format for the evaluator to receive the data is in this aggregated form. There are also differences in procedure code usage between OMAP and OMHSAS which can lead to variations in how services are coded. To address this, the Commonwealth has internal processes in place to ensure that data are coded and captured accurately and consistently before being provided to the evaluator. Additionally, since the data is stored on the Commonwealth’s servers and processed independently by the Commonwealth rather than the evaluator, it undergoes an extra layer of review by both the Commonwealth and its quality assurance team. While we recognize that this approach limits the ability of ITS models to capture individual-level variation and reduces statistical power, it ensures greater consistency, data security, and quality control across the evaluation. Nonetheless, the evaluator believes that the results will still provide meaningful population-level outcomes associated with the SUD Demonstration. Furthermore, the evaluator will also utilize qualitative data gathered from focus groups to contextualize the quantitative findings to provide a more comprehensive understanding of Pennsylvania’s Demonstration impacts.

Vital Statistics Data Are at the State Level

The evaluator will use Vital Statistics Data from the Commonwealth to assess the impact of the SUD Demonstration on overdose death rates. However, as mentioned earlier in the Vital Statistics Data description, the Commonwealth cannot identify Medicaid-specific individuals within this data. Therefore, analyses cannot be limited to the Medicaid population, and the results reflect population-level outcomes across the entire Commonwealth. Although this limitation restricts our ability to attribute changes solely to the SUD Demonstration, it still provides valuable information on the overall progress toward a key goal of the Demonstration—reducing overdose deaths—by highlighting broader population-level trends that can inform future policy and program improvements.

Efforts to Support Future Evaluations

After discussions between the Commonwealth and CMS regarding data availability concerns, the Commonwealth discussed the feasibility of obtaining individual-level data and pre-2021 data to enhance future program evaluations.

2. Descriptive Nature of the Findings and Implications for Causal Interpretation

Due to the lack of an appropriate comparison group for the target population, this evaluation plan relies heavily on descriptive time series analysis and qualitative data, and in instances where feasible, ITS analyses. While these analytical approaches can still produce meaningful findings about how the 1115 program is related to outcomes measures of interest, they generally preclude causal interpretation. For ITS, causal interpretation is justified when specific conditions are met, such as a stable pre-trend that would likely have continued if the policy intervention had not occurred. Additional details about ITS analysis and its limitations are described in the "Assumptions in ITS Analyses" section below.

3. Assumptions in ITS Analyses

ITS analysis relies on several key assumptions to support valid causal inferences.[11] One primary assumption is that the pre-period trend is stable and would have continued unchanged if the intervention had not occurred. ITS also assumes that no other concurrent events or interventions coincide with the timing of the cut-off utilized, which could otherwise confound the observed effects (note: implications of Medicaid unwinding are discussed in a later section). Additionally, ITS typically requires sufficient data points before and after the intervention to accurately estimate trends, and limited data can reduce the robustness of the analysis. Evaluators will need to work closely with OMHSAS and its data teams to gather as many data points as possible and discuss limitations within the evaluation findings if enough points cannot be collected.

4. 1115 as a Program Bundle

Since the 1115 Demonstration encompasses a bundle of program initiatives, this evaluation can only show what occurred following its implementation. However, it will be challenging to determine why these changes happened. In other words, directly attributing post-waiver changes to specific activities within the waiver—except for ASAM adoption, as noted above—will be difficult. To gain a better understanding of the mechanisms driving the observed outcomes, qualitative data from interviews and focus groups with key stakeholders will be used to identify the pathways through which outcomes shifted.

5. COVID-19 Pandemic and Medicaid Unwinding

The COVID-19 pandemic, which began in early 2020, brought fundamental changes to healthcare delivery, utilization, and Medicaid enrollment patterns. Pennsylvania faced several pandemic-related challenges while implementing its SUD Demonstration. Although the evaluator considered adjusting the

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

models to account for pandemic effects, previously noted data limitations prevented the inclusion of data from the years most heavily impacted by the pandemic.

The Medicaid unwinding process, following the COVID-19 pandemic, caused shifts in enrollment and service utilization that are unrelated to the program intervention. These shifts can confound the observed trends, making it difficult to isolate the true effects of the intervention. To address the impacts of Medicaid unwinding, ITS analyses will include an "unwinding" indicator to isolate the effects of unwinding separately. Qualitative analyses will also assess the impacts of unwinding through focus groups/interviews to better understand findings in the context of this policy shock.

6. Bias in Qualitative Interview and Focus Group Data

Although Mercer will use qualitative data collected from key informant interviews and focus groups to understand policy and implementation changes that may impact the quantitative findings, qualitative research methods have their own set of methodological limitations. Qualitative research focuses on a specific group of individuals' experiences with a policy or policy change and therefore has limited generalizability. Qualitative data is also subject to bias and reflects the individual informant's perspective and experience of the program. Mercer will attempt to limit the impact of this by collecting data from a variety of sources and the use of standardized interview protocols.

7. Bias in Survey Data

Member Satisfaction Surveys that the Commonwealth administers can be subject to several types of bias that may affect the accuracy and reliability of their results. For example, response bias can occur if members with particularly positive or negative experiences are more likely to respond, skewing the overall satisfaction ratings. Recall bias may also influence responses, as members might not accurately remember or report their experiences. Additionally, the way questions are worded, or the survey's structure can introduce bias by leading respondents toward certain answers or limiting the range of responses. These biases will be carefully considered when interpreting survey findings.

E. Attachments

1. Independent Evaluator

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

- To enhance program oversight and compliance with Commonwealth and federal requirements
- To advance the BH data management
- To develop strategies with federal, Commonwealth, and local partners for cross-system coordination
- To improve health outcomes through quality of care

Below are some of the qualifications, as expressed in the RFP:

Desired Qualifications:

- Experience working with federal programs and/or Demonstration waivers
- Experience with evaluating effectiveness of complex, multi-partnered programs
- Familiarity with CMS federal standards and policies for program evaluation
- Familiarity with nationally recognized data sources
- Analytical skills and experience with statistical testing methods

Based on these criteria, Mercer was selected as the technical assistance vendor. One of the scopes of work in the technical assistance work plan is the waiver evaluation. Mercer will develop the evaluation design, calculate the results of the study, evaluate the results for conclusions, and write the interim and summative evaluation reports.

Mercer has over 25 years in assisting state governments with the design, implementation, and evaluation of publicly sponsored health care programs. Mercer currently has over 25 states under contract and has worked with over 35 different states in total. It has assisted states such as Arizona, Connecticut, Missouri, and New Jersey in performing independent evaluations of their Medicaid programs; many of which include 1115 Demonstration waiver evaluation experience. Mercer also has unique knowledge of the Commonwealth of Pennsylvania, where they conduct rate setting activities for both PH and BH and provide ongoing technical assistance. Many projects include the collection and analysis of eligibility, enrollment, encounter and financial data, and production of year-over-year comparisons. Given its previous work with the Commonwealth's programs, the Mercer team is well-equipped to work effectively as the external evaluator for the Demonstration project. The table below includes contact information for the lead coordinators from Mercer for the evaluation:

NAME	POSITION	EMAIL ADDRESS
Laura Trieselmann	Engagement Leader	laura.trieselmann@mercer.com
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Barbara Anger, CPC	Certified Professional Coder	barbara.anger@mercer.com
Ashley Wieser	Project Manager	ashley.wieser@mercer.com
Kevin Tolmich	Technical Resource	kevin.tolmich@mercer.com
Tonya Aultman-Bettridge, PhD	Evaluator	taultman-bettridge@triwestgroup.net
Siqing McDonnell	Evaluator	siqing.mcdonnell@mercer.com
Brenda Jackson, MPP	Specialty Sector — policy	brenda.d.jackson@mercer.com
Stacy Smith	Specialty Sector — clinical	stacy.smith@mercer.com

Conflict of Interest Statement

DHS has taken steps to ensure that Mercer is free of any conflict of interest and will remain free from any such conflicts during the contract term. DHS considers it a conflict if Mercer currently 1) provides services to any MCOs or health care provider doing business in Pennsylvania under the MA program or 2) provides direct services to individuals in DHS-administered programs included within the scope of the technical assistance contract. If DHS discovers a conflict during the contract term, DHS may terminate the contract pursuant to the provisions in the contract. The attached Conflict of Interest statement and attestation are current for this scope of work.

Mercer

Government Human Services Consulting

Conflict of Interest

For purposes of disclosure, Mercer Health & Benefits LLC's parent company, Mercer (US) Inc. is a wholly owned subsidiary of Marsh & McLennan Companies (MMC). Mercer Health & Benefits LLC (Mercer H&B) is the legal entity that has entered into the Technical Assistance contract with DHS. Mercer's Government Human Services Consulting practice (GHSC), a specialty consulting group within Mercer H&B, performs the work under this contract.

Being a large services organization, there is the potential for situations where the interests of one client may conflict with the interests of another. Relationships may exist within other Mercer (US) business outside of Mercer H&B, however GHSC does not typically communicate with other Mercer (US) operating companies or business units. Other than ownership by a common parent, GHSC has no operational relationship with those business units. As a practical matter, there is no occasion for someone on a GHSC team to work on common projects with anyone within other Mercer (US) Inc. operating companies or, indeed, to have any communications with them at all.

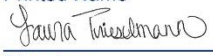
Because we have established these clear guidelines regarding our consulting engagements, we rarely encounter potential conflicts of interest.

If potential conflicts should arise, GHSC will disclose the potential conflict to all parties and present solutions to avoid any conflict of interest to the mutual satisfaction of all parties. Solutions may include establishing appropriate safeguards such as keeping separate teams, restricting access to files, and establishing process firewalls to avoid any conflict of interest. If a client does not approve of the relationship or conflict mitigation steps, the engagement will not be accepted. We have collectively turned down a multitude of potential assignments over the years to avoid a conflict of interest.

GHSC will also work closely with all subcontractors in vetting any potential or perceived conflicts of interest. All subcontractors must confirm that they do not have any interest, either direct or indirect, which would conflict in the performance of this contract. Should a potential or perceived conflict of interest be identified GHSC will collaborate with the associated parties to mitigate any risk, up to and including, declining to subcontract with any firms that is determined to be a conflict in the performance with this contract. To the extent GHSC needs to implement a conflict mitigation plan with any of its valued subcontractors, it will do so consistent with corporate business policies and processes.

GHSC, through our contract with DHS, has assured that it presently has no interest and will not acquire any interest, direct or indirect, which would conflict in any manner with the performance of its services under this engagement. Management of potential conflicts of interest is extremely important to GHSC and the entire Mercer organization. Under no circumstances will GHSC ever use client information, leverage existing or potential client relationships, or take any action in a way that puts the interests of GHSC or our clients above the interest of another client.

Laura Trieselmann, Principal
Printed Name



Signature

February 7, 2024
Date

Services provided by Mercer Health & Benefits LLC.

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2. Evaluation Budget

Waiver Period

The evaluation budget for the second waiver period (DY6–DY10) is expected to be similar to the evaluation budget for the first waiver period (DY1–DY5) with a few key changes:

- First, the first waiver period for year 5 (DY5) had a budget for just 1-quarter because of the timing of the SUD amendment. For the second waiver period, all DYs reflect a full 4 quarters of cost.
- Second, the same activities are required in the second waiver period as in the first waiver period. The Commonwealth must submit an evaluation design, mid-point assessment, interim evaluation, summative evaluation, and calculate performance metrics for all of those reports.
- Third, the Demonstration extension period budget accounts for cost changes related to inflation and salary increases by not decreasing the amount of FTE associated with the maintenance of the on-going Demonstration. As the Commonwealth staff gain more experience with the SUD Demonstration, it is anticipated that the time associated with the Demonstration by State staff will slightly decrease even though the amount of salary associated with the remaining time increases due to inflation. We have assumed that inflation will offset the reduced time spent on the evaluation resulting in the same financial resource commitment from the Commonwealth for their staff. As a result, we have taken the same percentage of salary and benefits associated with Commonwealth staff over the life of the Demonstration.

	DY6 10/1/2022-9/30/2023	DY7 10/1/2023-9/30/2024	DY8 10/1/2024-9/30/2025	DY9 10/1/2025-9/30/2026	DY10 10/1/2026-9/30/2027	Final Evaluation 12/31/2029	Total Evaluation Cost for First Waiver Period
STAFF COSTS							
OMHSAS (see the break-down in the table below)	$54,346	$54,346	$54,346	$54,346	$54,346	$54,346	$326,076
STATE SYSTEM PARTNERS							
PeopleStat	$19,500	$19,500	$19,500	$19,500	$19,500	$19,500	$117,000
DDAP	$80,000	$80,000	$80,000	$80,000	$80,000	$80,000	$480,000
INDEPENDENT EVALUATOR/CONTRACTOR							
Mercer	$203,502	$55,000	$85,000	$115,000	$115,000	$285,000	$858,502
TOTAL	$357,348	$208,846	$238,846	$268,846	$268,846	$438,846	$1,781,578

		DY6		DY7		DY8		DY9		DY10		Final Evaluation		Total OMHSAS Staff Cost
		10/1/2022–9/30/2023		10/1/2023–9/30/2024		10/1/2024–9/30/2025		10/1/2025–9/30/2026		10/1/2026–9/30/2027		12/31/2029		
OMHSAS Staff	**% of Salary over time for 1115 Evaluation**	**Annual Salary plus Benefits**	**% of Salary plus Benefits**	**Annual Salary plus Benefits**	**% of Salary plus Benefits**	**Annual Salary plus Benefits**	**% of Salary plus Benefits**	**Annual Salary plus Benefits**	**% of Salary plus Benefits**	**Quarter Year Salary plus Benefits**	**% of Salary plus Benefits**	**Annual Salary plus Benefits**	**% of Salary plus Benefits**	
Division Director, Program Management and Planning	12%	$119,343	$14,321	$119,343	$14,321	$119,343	$14,321	$119,343	$14,321	$119,343	$14,321	$119,343	$14,321	$85,926
Director, Bureau of Program Management and Planning	5%	$155,463	$7,773	$155,463	$7,773	$155,463	$7,773	$155,463	$7,773	$155,463	$7,773	$155,463	$7,773	$46,638
Community and Hospital Operations Representative	7%	$119,343	$8,354	$119,343	$8,354	$119,343	$8,354	$119,343	$8,354	$119,343	$8,354	$119,343	$8,354	$50,124
Director Area Operations	5%	$155,463	$7,773	$155,463	$7,773	$155,463	$7,773	$155,463	$7,773	$155,463	$7,773	$155,463	$7,773	$46,638
Quality Management Director	5%	$136,196	$6,810	$136,196	$6,810	$136,196	$6,810	$136,196	$6,810	$136,196	$6,810	$136,196	$6,810	$40,860
Director Bureau of Quality Management and Data Review	2%	$145,514	$2,910	$145,514	$2,910	$145,514	$2,910	$145,514	$2,910	$145,514	$2,910	$145,514	$2,910	$17,460

		DY6		DY7		DY8		DY9		DY10		Final Evaluation		Total OMHSAS Staff Cost
		10/1/2022–9/30/2023		10/1/2023–9/30/2024		10/1/2024–9/30/2025		10/1/2025–9/30/2026		10/1/2026–9/30/2027		12/31/2029		
OMHSAS Staff	**% of Salary over time for 1115 Evaluation**	**Annual Salary plus Benefits**	**% of Salary plus Benefits**	**Annual Salary plus Benefits**	**% of Salary plus Benefits**	**Annual Salary plus Benefits**	**% of Salary plus Benefits**	**Annual Salary plus Benefits**	**% of Salary plus Benefits**	**Quarter Year Salary plus Benefits**	**% of Salary plus Benefits**	**Annual Salary plus Benefits**	**% of Salary plus Benefits**	
Division Director OMHSAS Bureau of Quality Management and Data Review	3%	$124,753	$3,743	$124,753	$3,743	$124,753	$3,743	$124,753	$3,743	$124,753	$3,743	$124,753	$3,743	$22,458
Quality Assurance/Risk Management Director	2%	$133,089	$2,662	$133,089	$2,662	$133,089	$2,662	$133,089	$2,662	$133,089	$2,662	$133,089	$2,662	$15,972
TOTAL		**$1,089,164**	**$54,346**	**$1,089,164**	**$54,346**	**$1,089,164**	**$54,346**	**$1,089,164**	**$54,346**	**$1,089,164**	**$54,346**	**$1,089,164**	**$54,346**	**$326,076**

3. Timeline and Major Deliverables in Waiver Period 2

The table below highlights key milestones, evaluation milestones, and activities for the SUD waiver and the dates for completion:

Deliverable	STC reference	Date
Submit evaluation design plan to CMS	11.3	180 days after renewal March 31, 2023
Final evaluation design — due 60 days after CMS comments are received	11.4	60 days post comments
Publish final evaluation design on Commonwealth website — 30 days after CMS approval	11.4	30 days after CMS approval
Mid-point assessment due	5.4	60 days from September 30, 2025
Draft interim report due	11.7	September 30, 2026, or with the renewal application
Final interim report — due 60 days after CMS comments are received	11.7	60 days post comments
Publish final interim report on Commonwealth website — 30 days after CMS approval is received	11.7	30 days after CMS approval
Draft summative evaluation report — due 18 months following Demonstration	11.8	March 31, 2029
Final summative evaluation report — due 60 days after CMS comments are received	11.8	60 days post comments
Publish final summative evaluation report on Commonwealth website — 30 days after CMS approval is received	11.8	30 days after CMS approval

Attachment E

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

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

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

Milestone Criteria	Current State	Future State	Summary of Actions Needed
Coverage of outpatient services	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	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	has developed an application guidance for PA's current substance use system. While PA will begin to utilize The ASAM Criteria's for admission determination of level of care on July 1, 2018, other details of aligning PA's SUD system of care (services, hours of service, staff credentials, etc.) with the ASAM Criteria will be an ongoing process beyond July 2018 and is expected to be completed within 24 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	Already provided	None needed. Service already provided

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	• Emergency medical services available • Referral to detox, if clinically necessary • Specialized professional/medical consultation, and testing such as HIV and TB tests, and other laboratory work if needed • Biopsychosocial Assessment • Individualized treatment planning, with review at least every 30 days (where treatment is less than 30 days, the review shall occur every 15 days) • Individual therapy • Group therapy (group size: no larger than 12) • Couples therapy and/or family therapy (if appropriate) • Occupational and vocational counseling • Monitoring of medication, as needed • Physical exam • Development of discharge plan and plan for referral into continuum of care **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 planned interventions according to the		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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 care, general health education (esp.	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
	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) **Applicable 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) • Access to occupational and vocational counseling	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
	• 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 coordinated provision of services (non-Medicaid). **Required Staff:** The required Staff in Medically		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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 • Individualized treatment planning, with reviews at least every 30 days	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 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) **Required Staff:** The required Staff in Medically Monitored Long Term Residential treatment include a director and counselor(s), and a		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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, biomedical problems, and emotional/behavioral disorders. • 24-hour physician availability	Already provided	None needed. Service already provided

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	• 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 policies and procedures for identification, treatment, and referral of individuals found to have such		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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 • Emergency medical services available • Referral to medically managed detox, if clinically 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
	• 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 identification, treatment, and referral of individuals found to have such illnesses, in order to protect other		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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) • Family/significant other services, as appropriate (non-Medicaid). **Required Staff:** The required Staff at a medically monitored inpatient detox facility		

Milestone Criteria	Current State	Future State	Summary of Actions Needed
	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
- **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 Criteria	Current State	Future State	Summary of Actions Needed

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[1], 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 affirming this requirement.	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.

[1] "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

			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 residential	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

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, medication monitoring, psychoeducational groups,	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	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) d. Level of care specific P&P	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 demonstration

	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		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 System of Care" that addresses the availability of	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 treated as	DDAP has revised the Treatment Manual to reflect the guidance referenced in the second column.

	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.	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 counseling**	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. Since 2002 till January 2018, 3717 Pennsylvania	Will continue to ensure that access standards are met and required capacity is available.	None needed

and other services); • **Intensive Care in Residential and Inpatient Settings;** • **Medically Supervised Withdrawal Management**	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. Pennsylvania has 250 licensed facilities that provide intensive care in residential and inpatient settings, with a capacity to serve 10,071 individuals. 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	Current State	Future State	Summary of

Criteria			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. Automated approval applies at the pharmacy point of sale for beneficiaries with diagnosis of active cancer, sickle cell crisis, neonatal abstinence	Will continue to ensure the efficacy of the opioid prescribing guidelines.	None needed at this time.

	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	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	This order will be reviewed and updated as needed, if there is	None needed at this time.

reversal	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	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.	
Implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs	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 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	The seven education modules discussed in the previous column under *PDMP and Opioid Prescriber Education Initiative*	The Commonwealth will continue to monitor practices and needs and take steps as needed.

	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 **Ensuring all authorized users can assign delegates** To ease the burden on the licensed medical professionals such as the prescribers and dispensers, PA PDMP allowed the authorized users to assign delegates that can run the patient searches on behalf of them. This is a very important feature especially when providers are busy addressing patient health concerns. This feature has overall improved the clinical workflows for the providers. **Interstate data sharing capability**	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	

	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	Current State		Summary of

Criteria			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 and chronic) and behavioral health care, as well as social services, housing, educational systems, and employment opportunities as necessary to facilitate wellness and	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 CCBHCs to submit data on three identified goals (30+ measures). This data is reviewed on a quarterly basis and	The Commonwealth will review data from CCBHCs.

	recovery of the whole person.	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 F SUD Monitoring Protocol

Table: Substance Use Disorder Demonstration Planned Metrics

Standard information on CMS-provided metrics											Baseline, annual goals, and demonstration target			Alignment with CMS-provided technical specifications manual		Phased-in metrics reporting		
#	Metric name	Metric description	Milestone or reporting issue	Metric type	Reporting category	Data source	Measurement period	Reporting frequency	Reporting priority	State will report	Baseline period (MM/DD/YYYY-MM/DD/YYYY)	Annual goal	Overall demonstration target	Attest that planned reporting matches the CMS-provided technical specifications manual	Explanation of any deviations from the CMS-provided technical specifications manual or other considerations (different	Phased-in metrics reporting State plans to phase in	SUD monitoring report in which metric will be phased in (format	Explanation
EXAMPLE: 1 **(Do not delete or edit this row)**	*EXAMPLE: Assessed for SUD Treatment Needs Using a Standardized Screening Tool*	*EXAMPLE: Number of beneficiaries screened for SUD treatment needs using a standardized screening tool during the measurement period*	*EXAMPLE: Assessment of need and qualification for SUD treatment services*	*EXAMPLE: CMS-constructed*	*EXAMPLE: Other monthly and quarterly metrics*	*EXAMPLE: Medical record review or claims*	*EXAMPLE: Month*	*EXAMPLE: Quarterly*	*EXAMPLE: Recommended*	*EXAMPLE: Y*	*EXAMPLE: 07/01/2018-06/30/2019*	*EXAMPLE: Increase*	*EXAMPLE: Increase*	*EXAMPLE: N*	*EXAMPLE: The Department will use state-defined procedure codes (list specific codes) to calculate this metric.*	*EXAMPLE: Y*	*EXAMPLE: DY2Q1*	*EXAMPLE: This measure requires an update to the Adult Needs and Strengths Assessment tool that reflects an ASAM level of treatment. The work is in the testing phase with anticipated go live in mid to late 2021.*
1	Assessed for SUD Treatment Needs Using a Standardized Screening Tool	Number of beneficiaries screened for SUD treatment needs using a standardized screening tool during the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other monthly and quarterly metrics	Medical record review or	Month	Quarterly	Recommended	N								
2	Medicaid Beneficiaries with Newly Initiated SUD Treatment/Diagnosis	Number of beneficiaries who receive MAT or a SUD-related treatment service with an associated SUD diagnosis during the measurement period but not in the three months before the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Recommended	N								
3	Medicaid Beneficiaries with SUD Diagnosis (monthly)	Number of beneficiaries who receive MAT or a SUD-related treatment service with an associated SUD diagnosis during the measurement period and/or in the 11 months before the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2018-06/30/2019	Increase	Increase	N	Action 1: PeopleStat needs to add the following National Drug Codes (NDC): 00054039168, 00054039268, 00054355344, 00054355563, 00054355663, 00054421825, 00054421925, 00054453825, 00054457025, 00054457125, 00054855324, 00054855424, 00406052710, 00406054034, 00406192303, 00406192403, 00406254001, 00406575501, 00406575562, 00406577101, 00406577162, 00406802003, 00406872510, 00904653061, 13107008801, 13107008901, 42806031801, 47781035503, 47781035703, 66689069430, 66689069479, 66689069579, 66689071116, 66689071216, 66689089840, 67877011601, 68462080001, 68462080101 Action 2: To correctly pull/include the detoxification codes, PeopleStat will need to add the Diagnosis Related Groups (DRGs) 433, 521, 522, and 523. They will need to add the following Office of Mental Health and Substance Abuse Services (OMHSAS) revenue codes (0760, 0761, 0762, 0769, 0949) with provider type 01 and provider specialty 010 Acute Care Hospital; 019 D&A Hospital or 441 D&A Rehab Unit. Because this is not standard and unique coding, PeopleStat will need to look on the encounter category on the Note Segment if the encounter is 02. EDW includes this information. Note: Rehab is 04. Also, because the Office of Medical Assistance Programs (OMAP) uses these revenue codes extensively and consistent with national definitions for both inpatient and outpatient services which are not related to SUD treatment or detoxification (and not consistently with	N		
4	Medicaid Beneficiaries with SUD Diagnosis (annually)	Number of beneficiaries who receive MAT or a SUD-related treatment service with an associated SUD diagnosis during the measurement period and/or in the 12 months before the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other annual metrics	Claims	Year	Annually	Required	Y	07/01/2018-06/30/2019	Increase	Increase	N	same as #3.	N		
5	Medicaid Beneficiaries Treated in an IMD for SUD	Number of beneficiaries with a claim for inpatient/residential treatment for SUD in an IMD during the measurement period.	Milestone 2	CMS-constructed	Other annual metrics	Claims	Year	Annually	Required	Y	07/01/2018-06/30/2019	Increase	Increase	N	Action 1: Using the claims identified in Metric 10, omit the individuals who were not treated in an IMD. Note: Will make all withdrawal management coding changes to this	N		
6	Any SUD Treatment	Number of beneficiaries enrolled in the measurement period receiving any SUD treatment service, facility claim, or pharmacy claim during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2018-06/30/2019	Increase	Increase	N	Action 1: Need to add H2034 for Halfway House which is not in the national dataset. Action 2: Need to use POS 99 for the residential place of service for OMHSAS claims. Action 5: The State will include all H0018 and T2048 residential codes in this performance measure when the individual has an SUD diagnosis. This includes: • H0018 HE – BH ST residential (mental health [MH]) Note: With H0018 HE modifier is MH OP code for adult RTF • H0018 HF – Drug Free Residential • H0018 (no modifier) – (PT/PS for children and youth 52/520) – progmenexception (08 or 11/340) – BHRS not D&A Note: H0018 without modifier is BHRS and CRR code children. • T2048 With HE modifier is MH OP for LTSR • T2048 HF Action 6: Add DRGs 433, 521, 522, 523 are not in the inpatient residential treatment value set for OMHSAS claims only. To correctly pull/include the inpatient treatment codes, PeopleStat will need to add the DRGs (DRGs: 433, 521, 522, 523) and will need to add the following OMHSAS Revenue codes 0760, 0761, 0762, 0769, 0949 with provider type 01 and Provider specialty 010 Acute Care Hospital; 019 D&A Hospital or 441 D&A Rehab Unit. Because this is not standard and unique coding, PeopleStat will need to look on the encounter category on the Note Segment of the encounter is 04. EDW includes this information. Note: Detox is 02.	N		
7	Early Intervention	Number of beneficiaries who used early intervention services (such as procedure codes associated with SBIRT) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2018-06/30/2019	Increase	Increase	Y	Metric #7 Early Intervention PeopleStat will pull this measure using all of the suggested SBIRT Early Intervention national coding. It is expected that overtime with the new PH MCO initiatives the	N		
8	Outpatient Services	Number of beneficiaries who used outpatient services for SUD (such as outpatient recovery or motivational enhancement therapies, step down care, and monitoring for stable patients) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2018-06/30/2019	Increase	Increase	N	Action 1a: Need to remove H2035 from the outpatient data set. Action 1b: Need to ensure that H0014 is always pulled with its modifier H0014 HG. Action 1c: Need to add H0006 and H0006 TF to the OP data set. Action 1d: Need to pull H0004 with only the HF modifier. Note H0004 with different modifiers is used for many BH services like Family based and OP. Action 2: Need to pull T1015 with the modifier HF and UB for outpatient. If the Commonwealth pulls T1015 without the modifier, it will get all RHC/FQHC encounters. Action 3a: OMHSAS data- Need to filter on PT/PS to exclude these revenue codes for the outpatient measure (they are residential and inpatient services in OMHSAS). Note: OMHSAS requires all outpatient claims to be converted to an 837p format so no revenue codes are utilized for outpatient claims in OMHSAS. Action 3b: OMAP needs to include the revenue codes for outpatient services. OMAP uses revenue codes on outpatient hospital institutional claims. • I, A, L claim types are inpatient in OMAP (there are 2400 claims in 2017 that are I not associated with R&B that are outpatient) • O and C is the primary outpatient claims in OMAP Action 4: Ensure that coding in other POS are complete Action 5: To correctly pull/include the Detoxification codes, PeopleStat will need to add the DRGs (DRGs: 433, 521, 522, 523) and will need to add the following OMHSAS Revenue codes 0760, 0761, 0762, 0769, 0949 with provider type 01 and Provider	N		
9	Intensive Outpatient and Partial Hospitalization Services	Number of beneficiaries who used intensive outpatient and/or partial hospitalization services for SUD (such as specialized outpatient SUD therapy or other clinical services) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2018-06/30/2019	Increase	Increase	N	Action 1: Need to add H2035 from the Intensive outpatient data/partial hospitalization set. Action 2: Need to ensure that the programing includes the OMAP MCOs reported claims for 905 (IOP - psychiatric), 906 (Chemical dependency), 912 (BH Partial hospitalization – less intensive) and 913 (BH Partial hospitalization intensive) extensively. Note: 907 is not used – BH Community BH program day treatment Action 3: Need to add codes to POS 52 (Psychiatric Facility partial hospitalization) only used for following codes: H2010, H0038 H0035 with modifiers U7, UB/HA, U7/U2, U2/UA, U7/HB/UA, UB/UA PT/PS 11/113 and 11/114 Action 4: Ensure that coding in other POS are complete Action 5: To correctly pull/include the Detoxification codes, PeopleStat will need to add the DRGs (DRGs: 433, 521, 522, 523) and will need to add the following OMHSAS Revenue codes 0760, 0761, 0762, 0769, 0949 with provider type 01 and Provider specialty 010 Acute Care Hospital; 019 D&A Hospital or 441 D&A Rehab Unit. Because this is not standard and unique coding, PeopleStat will need to look on the encounter category on the Note Segment of the encounter is 02. EDW includes this information. Note: Rehab is 04. Also because OMAP uses these revenue codes extensively and consistent with national definitions for both inpatient and outpatient services which are not related to SUD treatment or detoxification (and not consistently with how OMHSAS uses the codes), PeopleStat	N		
10	Residential and Inpatient Services	Number of beneficiaries who use residential and/or inpatient services for SUD during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2018-06/30/2019	Increase	Increase	N	Action 1: Need to add H2034 for halfway house which is not in the national dataset Action 2: Need to use POS 99 for the residential place of service for OMHSAS claims *Multiple filters might be needed Action 4: Current coding does not permit residential treatment and residential withdrawal management to be identified on claims/encounter data. The State will adopt different provider level coding to distinguish these services or to distinguish (e.g., a modifier) when withdrawal management is delivered. This change will be implemented at a date to be named in the future. This measure is expected to decrease slightly when WM is separated. Note: the ALOS of IMDs will potentially decrease. Action 5: The State will include all H0018 and T2048 residential codes in this performance measure when the individual has an SUD diagnosis. This includes: • H0018 HE – BH ST residential (MH) Note: With H0018 HE modifier is MH OP code for adult RTF • H0018 HF – Drug Free Residential • H0018 (no modifier) – (PT/PS for children and youth 52/520) – progmenexception (08 or 11/340) – BHRS not D&A Note: H0018 without modifier is BHRS and CRR code Children. • T2048 With HE modifier is MH OP for LTSR • T2048 HF Action 6: Add DRGs 433, 521, 522, 523 are not in the inpatient residential treatment value set for OMHSAS claims only. To correctly pull/include the inpatient treatment codes, PeopleStat will need to	N		
11	Withdrawal Management	Number of beneficiaries who use withdrawal management services (such as outpatient, inpatient, or residential) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2018-06/30/2019	Increase	Increase	N	Action 1: Need to ensure that H0014 is always pulled with its modifier H0014 HG. Action 2: Current coding does not permit residential treatment and residential withdrawal management to be identified on claims/encounter data. The State will adopt different provider level coding to distinguish these services or to distinguish (e.g., a modifier) when withdrawal management is delivered. This change will be implemented at a date to be named in the future. This measure is expected to increase slightly when WM is separated. Note: the ALOS of IMDs will potentially decrease. Action 3: To correctly pull/exclude the Detoxification codes, PeopleStat will need to add the DRGs (DRGs: 433, 521, 522, 523) and will need to add the following OMHSAS Revenue codes 0760, 0761, 0762, 0769, 0949 with provider type 01 and Provider specialty 010 Acute Care Hospital; 019 D&A Hospital or 441 D&A Rehab Unit. Because this is not standard and unique coding, PeopleStat will need to look on the encounter category on the Note Segment of the encounter is 02. EDW includes this information. Note: Rehab is 04. Also because OMAP uses these revenue codes extensively and consistent with national definitions for both inpatient and outpatient services which are not related to SUD treatment or detoxification (and not consistently with how OMHSAS uses the codes), PeopleStat	N		
12	Medication-Assisted Treatment	Number of beneficiaries who have a claim for MAT for SUD during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2018-06/30/2019	Increase	Increase	N	Action 2: Need to program utilization for H0020 for PT/PS 11/129 in both the MAT and the OP measures (#8 and #12) Action 3: Need to Program utilization for T1015HG in both MAT and OP (#8 and #12) Action 4a: Need to program utilization for H0020 UB for PT/PS 08/084 in both the MAT and the OP measures (#8 and #12) Action 4b: Current coding does not permit identification of MAT provision on claims/encounter data. The State will adopt different provider level coding to distinguish specifically when MAT is delivered. This change will be implemented at a date to be named in the future. This measure is expected to decrease slightly when MAT is specifically reported. Action 5: PeopleStat needs to add the following NDCs: 00054039168, 00054039268, 00054355344, 00054355563, 00054355663, 00054421825, 00054421925, 00054453825, 00054457025, 00054457125, 00054855324, 00054855424, 00406052710, 00406054034, 00406192303, 00406192403, 00406254001, 00406575501, 00406575562, 00406577101, 00406577162, 00406802003, 00406872510, 00904653061, 13107008801, 13107008901, 42806031801, 47781035503, 47781035703, 66689069430, 66689069479, 66689069579, 66689071116, 66689071216, 66689089840, 67877011601, 68462080001, 68462080101 Issue 1: OMHSAS utilizes HCPCS codes to determine when an individual has obtained MAT including: • J0571	N		
13	SUD Provider Availability	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period	Milestone 4	CMS-constructed	Other annual metrics	Provider enrollment database;	Year	Annually	Required	Y	07/01/2018-06/30/2019	Consistent	Consistent	Y	For Metric #13 the providers were identified as those enrolled in Medicaid at any time during the measurement period. Therefore in this metric that is an annual measure, this would include all providers	N		
14	SUD Provider Availability - MAT	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period and who meet the standards to provide buprenorphine or methadone as part of MAT	Milestone 4	CMS-constructed	Other annual metrics	Provider enrollment database; Claims; SAMHSA	Year	Annually	Required	Y	07/01/2018-06/30/2019	Consistent	Consistent	Y	For Metric #14 the list providers were identified as those enrolled in Medicaid at any time during the measurement period. Therefore in this metric that is an annual measure, this would include all providers enrolled for at least one day during the measurement period. For Metric #14 the providers were counted by their 9 digit Master	N		
15	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET-AD) [NCQA; NQF #0004; Medicaid Adult Core Set; Adjusted HEDIS measure]	Percentage of beneficiaries age 18 and older with a new episode of alcohol or other drug (AOD) abuse or dependence who received the following: • Initiation of AOD Treatment—percentage of beneficiaries who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or medication treatment within 14 days of the diagnosis • Engagement of AOD Treatment—percentage of beneficiaries who initiated treatment and who were engaged in ongoing AOD treatment within 34 days of the initiation visit The following diagnosis cohorts are reported for each rate: (1) Alcohol abuse or dependence, (2) Opioid abuse or dependence, (3) Other drug abuse or dependence, and (4) Total AOD abuse or dependence. A total of 8 separate rates are reported for this measure.	Milestone 6	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	01/01/2018-12/31/2018	Increase	Increase	N	Action: Pennsylvania Hospice coding will need to be determined. Action: Deviations listed in Metrics #3, #4, and #6 are likely applicable to this measure and are anticipated to be applied in programming. The State will use accepted claims and encounters which will include MCO paid and MCO denied claims. The State will not include suspended, pended claims. Issue: • The Commonwealth will use the following hierarchy to exclude beneficiaries receiving hospice services: o Procedure codes (Q5001-Q5009 or T2042-T2046) OR o Procedure code modifier (GV) OR o Bill Type (81 or 82) OR	Y	DY6Q4	The Commonwealth has not yet programmed Metric #15 under the Demonstration and plans to report this metric initially with the other CY2022 metrics due to be reported 12/29/2003.
16	SUB-3 Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge [Joint Commission]	SUB-3: Patients who are identified with alcohol or drug use disorder who receive or refuse at discharge a prescription for FDA-approved medications for alcohol or drug use disorder, OR who receive or refuse a referral for addictions treatment. SUB-3a: Patients who are identified with alcohol or drug use disorder who receive a prescription for FDA-approved medications for alcohol or drug use disorder OR a referral for addictions treatment.	Milestone 6	Established quality measure	Annual metrics that are established quality measures	Medical record review or claims	Year	Annually	Recommended	N								
17(1)	Follow-up after Emergency Department Visit for Alcohol or Other Drug Dependence (FUA-AD) [NCQA; NQF #3488; Medicaid Adult Core Set; Adjusted HEDIS measure]d	Percentage of ED visits for beneficiaries age 18 and older with a principal diagnosis of AOD abuse or dependence who had a follow-up visit for AOD abuse or dependence. Two rates are reported: - Percentage of ED visits for which the beneficiary received follow-up within 30 days of the ED visit (31 total days). - Percentage of ED visits for which the beneficiary received follow-up within 7 days of the ED visit (8 total days).	Milestone 6	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	01/01/2018-12/31/2018	Increase	Increase	N	The data in this measure is related to metric #15 and #6 with the exception of the following value sets: • Ambulatory Surgical Center POS • Electroconvulsive Therapy, • Intentional Self-Harm, • Mental Health Diagnosis, • Mental Illness, • Telehealth POS.	N		
17(2)	Follow-up after Emergency Department Visit for Mental Illness (FUM-AD) [NCQA; NQF #3489; Medicaid Adult Core Set; Adjusted HEDIS measure]e	Percentage of ED visits for beneficiaries age 18 and older with a principal diagnosis of mental illness or intentional self-harm and who had a follow-up visit for mental illness. Two rates are reported: - Percentage of ED visits for mental illness for which the beneficiary received follow-up within 30 days of the ED visit (31 total days) - Percentage of ED visits for mental illness for which the beneficiary received follow-up within 7 days of the ED visit (8 total days).	Milestone 6	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	01/01/2018-12/31/2018	Increase	Increase	N	The data in this measure is related to metric #15 and #6 with the exception of the following value sets: • Ambulatory Surgical Center POS • Electroconvulsive Therapy, • Intentional Self-Harm, • Mental Health Diagnosis, • Mental Illness, • Telehealth POS,	N		
18	Use of Opioids at High Dosage in Persons Without Cancer (OHD-AD) [PQA, NQF #2940; Medicaid Adult Core Set]	Percentage of beneficiaries age 18 and older who received prescriptions for opioids with an average daily dosage greater than or equal to 90 morphine milligram equivalents (MME) over a period of 90 days or more. Beneficiaries with a cancer diagnosis, sickle cell disease diagnosis, or in hospice are excluded.	Milestone 5	Established quality measure	Annual metrics that are established quality measures	Claims	Year	Annually	Required	Y	01/01/2018-12/31/2018	Decrease	Decrease	N	Action: Deviations listed in Metrics #3, #4, and #6 are likely applicable to this measure and are anticipated to be applied in programming. Action: • The Commonwealth will use the following hierarchy to exclude beneficiaries receiving hospice services: o Procedure codes (Q5001-Q5009 or T2042-T2046) OR o Procedure code modifier (GV) OR o Bill Type (81 or 82) OR o Provider Type (06). The State will use accepted claims and encounters which will include MCO paid and MCO denied claims. The State will not include suspended, pended claims.	N		
19	Use of Opioids from Multiple Providers in Persons without Cancer (OMP) [PQA; NQF #2950]	The percentage of individuals ≥18 years of age who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies within ≤180 days.	Milestone 5	Established quality measure	Annual metrics that are established quality	Claims	Year	Annually	Recommended	N								
20	Use of Opioids at High Dosage and from Multiple Providers in Persons Without Cancer (OHDMP) [PQA, NQF #2951]	The percentage of individuals ≥18 years of age who received prescriptions for opioids with an average daily dosage of ≥90 morphine milligram equivalents (MME) AND who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies.	Milestone 5	Established quality measure	Annual metrics that are established quality	Claims	Year	Annually	Recommended	N								
21	Concurrent Use of Opioids and Benzodiazepines (COB-AD) [PQA, NQF #3389; Medicaid Adult Core Set]	Percentage of beneficiaries age 18 and older with concurrent use of prescription opioids and benzodiazepines. Beneficiaries with a cancer diagnosis, sickle cell disease diagnosis, or in hospice are excluded.	Milestone 5	Established quality measure	Annual metrics that are established quality	Claims	Year	Annually	Required	Y	01/01/2018-12/31/2018	Decrease	Decrease	N	Related to #18 above This is data set is related to Metric #18. The deviations in Metric #18 will apply to this metric The State will use accepted claims and encounters which will include	N		
22	Continuity of Pharmacotherapy for Opioid Use Disorder [USC; NQF #3175]	Percentage of adults 18 years of age and older with pharmacotherapy for OUD who have at least 180 days of continuous treatment	Milestone 1	Established quality measure	Annual metrics that are established quality	Claims	Year	Annually	Required	Y	01/01/2018-12/31/2018	Increase	Increase	N	Action: the Deviations noted in Metric #12 are anticipated. The State will use accepted claims and encounters which will include MCO paid and MCO denied claims. The State will not include suspended, pended claims.	N		
23	Emergency Department Utilization for SUD per 1,000 Medicaid Beneficiaries	Total number of ED visits for SUD per 1,000 beneficiaries in the measurement period	Milestone 5	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2018-06/30/2019	Decrease	Decrease	N	The State will use accepted claims and encounters which will include MCO paid claims. No other deviations.	N		
24	Inpatient Stays for SUD per 1,000 Medicaid Beneficiaries	Total number of inpatient stays per 1,000 beneficiaries in the measurement period	Other SUD-related metrics	CMS-constructed	Other monthly and quarterly metrics	Claims	Month	Quarterly	Required	Y	07/01/2018-06/30/2019	Decrease	Decrease	N	Same deviations for inpatient stays as on Metric #10 Action 6: Add DRGs 433, 521, 522, 523 are not in the inpatient residential treatment value set for OMHSAS claims only. To correctly pull/include the inpatient treatment codes, PeopleStat will need to add the DRGs (DRGs: 433, 521, 522, 523) and will need to add the following OMHSAS Revenue codes 0760, 0761, 0762, 0769, 0949 with provider type 01 and Provider specialty 010 Acute Care Hospital; 019 D&A Hospital or 441 D&A Rehab Unit. Because this is not standard and unique coding, PeopleStat will need to look on the encounter category on the Note Segment of the encounter is 04. EDW includes this information. Note: Detox is 02. Also because OMAP uses these revenue codes extensively and consistent with national definitions for both inpatient and outpatient services which are not related to SUD treatment or detoxification (and not consistently with how OMHSAS uses the codes), PeopleStat will need to ensure that the following revenue codes are excluded for OMAP services: 0760 Specialty services general 0761 specialty services treatment room 0762 specialty services observation hours 0769 specialty services other 949 – Other Therapeutic Services Other Issue: OMAP and OMHSAS differently code. Same deviations for inpatient stays as on Metric #10. Issue 6: DRGs 433, 521, 522, 523 are not in the inpatient residential treatment value set but BH-MCOS use DRGs (unique to BH- MCOs). OMHSAS uses revenue codes	N		
25	Readmissions Among Beneficiaries with SUD	The rate of all-cause readmissions during the measurement period among beneficiaries with SUD	Milestone 6	CMS-constructed	Other annual metrics	Claims	Year	Annually	Required	Y	07/01/2018-06/30/2019	Decrease	Decrease	N	This measure uses extensive data sets related to hospitalizations for a variety of conditions. Deviations related to the inpatient stay data set as outlined in metric #10. Action 6 will be taken into account in	N		
26	Overdose Deaths (count)	Number of overdose deaths during the measurement period among Medicaid beneficiaries living in a geographic area covered by the demonstration. The state is encouraged to report the cause of overdose death as specifically as possible (for example, prescription vs. illicit opioid).	Other SUD-related metrics	CMS-constructed	Other annual metrics	State data on cause of death	Year	Annually	Required	Y	07/01/2018-06/30/2019	Decrease	Decrease	N	Action: Pennsylvania will obtain the most precise overdose death data available from vital statistics for these ICD-10 codes, which does not include Medicaid eligibility. Issue: The ICD-10 codes for underlying cause of death are not in the OMAP inpatient or outpatient data	N		

Attachment F SUD Monitoring Protocol

Table: Substance Use Disorder Demonstration Planned Metrics

1	Overdose Deaths (new)	Rate of overdose deaths during the demonstration period per reporting period (Numerator: Number of deaths due to drug overdose during the demonstration period, as identified in annual death certificate data; Denominator: Total number of beneficiaries in reporting period) Source of data: Vital statistics death data (preferable); or, as a proxy if death certificate data is not available, Medicaid claims data.	Effectiveness ↑	CMS core measure ↑	Other annual claims	State data or Core MAT claims	Yes	Annually	Required	N	01/01/2023-12/31/2023	Increase	Decrease	N	The SUD Core Set – Protocol topic 1.4.B states the data period for calculating this measure is CY 2023. However, the Core Set Technical Specifications Manual states to exclude deaths that occur in July. Should the SUD Core Set be followed for the reporting year or should we use the Federal fiscal year as the reporting period?	N		
2	SUD Prescribing	Total Medicaid SUD prescribing during the measurement period	Other SUD-related	CMS core measure ↑	Other annual claims	Claims	Yes	Annually	Recommended	N										
3	SUD Drug Spending, Per Eligible (PMPM)	Total Medicaid SUD spending, as expressed as combined numerator within PMPM, during the	Other SUD-related	CMS core measure ↑	Other annual claims	Claims	Yes	Annually	Recommended	N										
4	Per Capita SUD Spending	Per capita SUD spending during the measurement period	Other SUD-related	CMS core measure ↑	Other annual claims	Claims	Yes	Annually	Recommended	N										
5	Per Capita SUD Spending, Within MMEs	Per capita SUD spending within MMEs during the measurement period	Other SUD-related	CMS core measure ↑	Other annual claims	Claims	Yes	Annually	Recommended	N										
6	Number of Beneficiaries Identified as Received Services for Substance Use Disorder (SUD) and Who Had an Additional Co-occurring Mental Health Condition	The percentage of Medicaid beneficiaries with SUD who had an additional co-occurring mental health condition during the measurement period.	Other SUD-related (SDOH)	Recommended (SDOH) measure	Annual vital or claims data	Claims	Yes	Annually	Required	N	01/01/2023-12/31/2023	Increase	Increase	N	This measure may overlap with data also related to MMEs/MAT. Is this acceptable? Also, the state will have a standard definition of co-occurring mental health conditions for this measure. However, the state may not include 'unspecified' as listed as a code.	N				
7	Number of Beneficiaries Identified as SUD Treatment Provider Who Received Training on Mental Health Conditions	Number of providers identified during the measurement period that are referred to SUD treatment	Other SUD-related	CMS core measure ↑	Annual provider survey	Unknown at this time	Unknown at this time	Quarterly	Recommended	N										
8	Number of providers referred to SUD treatment	Number of providers identified during the measurement period that are referred to SUD treatment	Other SUD-related	CMS core measure ↑	Annual provider survey	Unknown at this time	Unknown at this time	Quarterly	Recommended	N										
9	Number of Providers Referred to SUD Treatment	Number of providers identified during the measurement period that are referred to SUD treatment	Other SUD-related	CMS core measure ↑	Annual provider survey	Unknown at this time	Unknown at this time	Quarterly	Recommended	N										
10	Follow-up Care Post-Opioid Use Disorder (OUD) Treatment	Percentage of beneficiaries with a history of medication-assisted treatment for opioid use disorder (MAT-OUD) who received follow-up care within 30 days of discharge from the MAT-OUD episode.	Effectiveness ↑	CMS core measure ↑	Other annual claims	Claims	Yes	Annually	Required	N	01/01/2023-12/31/2023	Optimize	Numerator/Denominator	N	Follow-up Measure 1 For Medicaid, in April 2021, the Centers for Medicare & Medicaid Services (the CMS) finalized the Med-Core set of CMS' Medicare-Medicaid Alignment Initiative. The Med-Core set of measures is a subset of the Core Set and includes measures that are aligned with Medicare programs. The Med-Core set of measures is voluntary for states to report. The Core Set Technical Specifications Manual for the Adult Core Set Measures states that the measure is reported by individuals enrolled in managed care. Is this the same for the SUD Core Set?	N				
11	POMP: Identifying Co-occurring Opioid Use and Pain Complaints in Primary Care	POMP: Proportion Co-prescribed Opioid Prescriptions (Numerator) for CY - Base Year(PY-1) Co-prescribed Opioid Prescriptions (Denominator)	Research SP	Process-specific	Other monthly reports/portals	POMP reports	Month	Quarterly	Required	Y	01/01/2023-12/31/2023	Increase	Increase							
12	POMP: Identifying Co-occurring Opioid Use and Pain Complaints in Primary Care	POMP: Number of POMP-Licensed Users for QE - Base Year(PY-1) Existing Licensed Users (Baseline)	Research SP	Process-specific	Other monthly reports/portals	POMP reports	Month	Quarterly	Required	Y	01/01/2023-12/31/2023	Increase	Increase							
13	Post-Overdose Prescription Fills	Medicaid beneficiaries that receive Naloxone from the beneficiary, the MPI project QE, Base Year(PY-1)	Research SP	Process-specific	Other monthly reports/portals	Claims	Month	Quarterly	Required	Y	01/01/2023-12/31/2023	Increase	Increase							
14	[illegible]	Opioid prescriptions collected in the POMP	POMP: Number of opioid prescriptions submitted to the POMP QE - Base Year(PY-1) Existing number of active Access Accounts (Eligible Individuals) with NOT	Research SP	Process-specific	Other monthly reports/portals	POMP reports	Month	Quarterly	State-specific	Y	07/01/2023-06/30/2024	Maintain	Maintain						

Attachment F SUD Monitoring Protocol

Table: Substance Use Disorder Demonstration Planned Metrics

Standard informati

[a] There are no CMS-provided metrics related to milestone 3

[b] If the state is not reporting a required metric (i.e., column K = " N"), enter explanation in corresponding row in column P.

[c] The state should use column P to outline calculation methods for specific metrics as explained in Version 4.0 of the Medicaid Section 1115 Substance Use Disorder Demonstrations Monitoring Protocol Instructions

[d] Rates 1 and 2 reported for Metric #17(1) correspond to rates 2 and 3 for Metric #17 from Version 1.1 of the the Medicaid Section 1115 Substance Use Disorder Demonstrations: Technical Specifications for Monitoring Metrics

[e] Rates 1 and 2 reported for Metric #17(2) correspond to rates 1 and 2 for Metric #17 from Version 1.1 of the the Medicaid Section 1115 Substance Use Disorder Demonstrations: Technical Specifications for Monitoring Metrics

[f] While grievances and appeals metrics are recommended for reporting, the state is required, per 42 CFR 431.428(a)5, to provide updates on the results of beneficiary satisfaction surveys, if conducted during the reporting year, including updates on grievances and appeals from beneficiaries, in in its annual (Q4) monitoring report.

Attachment F SUD Monitoring Protocol

Medicaid Section 1115 Substance Use Disorder Demonstration Monitoring Protocol Workbook – SUD planned subpops

Medicaid Section 1115 SUD Demonstrations Protocol (Part A) - Planned Subpopulations (Vers

State	Pennsylvania
Demonstration Name	Medicaid Coverage for Former Foster Care Youth from a D

Table: Substance Use Disorder Demonstration Planned Subpopulations

Planned subpopulation reporting						Alignment with CMS-provided technical specifications manual			
						Subpopulations		Relevant metrics	
Subpopulation category	Subpopulations	Reporting priority	Relevant metrics	Subpopulation type	State will report (Y/N)	Attest that planned subpopulation reporting within each category matches the description in the CMS-provided technical specifications manual (Y/N)	If the planned reporting of subpopulations does not match (i.e., column G = "N"), list the subpopulations state plans to report (Format comma separated)[a,b,c]	Attest that metrics reporting for subpopulation category matches CMS-provided technical specifications manual (Y/N)	If the planned reporting of relevant metrics does not match (i.e., column I = "N"), list the metrics for which state plans to report for each subpopulation category (Format metric number, comma separated)
EXAMPLE: *Age group* ***(Do not delete or edit this row)***	*EXAMPLE:* *Children <18, adults 18–64, and older adults 65+*	*EXAMPLE:* *Required*	*EXAMPLE:* *Metrics #1-3, 6-12, 23, 24, 26, 27*	*EXAMPLE:* *CMS-provided*	*EXAMPLE:* *Y*	*EXAMPLE:* *N*	*EXAMPLE:* *Children/Young adults 12-21, Adults 21-65*	*EXAMPLE:* *N*	*EXAMPLE:* *1, 2, 3*
Age group	Children <18, adults 18–64, and older adults 65+	Required	Metrics #1-3, 6-12, 23, 24, 26, 27	CMS-provided	Y	Y		Y	
Dual–eligible status	Dual-eligible (Medicare-Medicaid eligible), Medicaid only	Required	Metrics #1-3, 6-12	CMS-provided	Y	Y	Data on beneficiaries is collected by Pennsylvania by each month/year they have Medicare coverage. Therefore the time period is reflective of the measurement period and the month/year Medicare eligibility. Dual Eligibles: Uses field from the Enterprise Data Warehouse (EDW) table RCPT_INFO called mdcare_code to determine if the Medicaid recipient is enrolled in Medicare. If the field is A,B,C, or D then the recipient is considered Dual Enrolled.	Y	
Pregnancy status	Pregnant, Not pregnant	Required	Metrics #1-3, 6-12	CMS-provided	Y	Y	Pregnancy Uses field from the Enterprise Data Warehouse (EDW) table T_ENC_FACT to pull claims that have a procedure code (cde_proc) listed below keeping only recipients within the range for which the report is being run. '59400' - Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy and/or forceps) and postpartum care '59409' - Vaginal delivery only (with or without episiotomy and/or forceps) '59410' - Vaginal delivery only (with or without episiotomy and/or forceps) '59510' - Cesarean Delivery Procedures '59514' - Cesarean delivery only '59515' - Cesarean delivery only '59610' - Delivery Procedures After Previous Cesarean Delivery '59612' - Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps) '59614' - Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps) '59618' - Delivery Procedures After Previous Cesarean Delivery	Y	
Criminal justice status	Criminally involved, Not criminally involved	Required	Metrics #1-3, 6-12	CMS-provided	N		The State will not report on the criminal justice subpopulation.		
OUD population	Opioid diagnosis	Recommended	Metrics #2-12, 23, 24, 26, 27, 36	CMS-provided	N				
[Insert row(s) for any state-specific subpopulation(s)]									

Table: Substance Use Disorder Demonstration Planned Subpopulations

Planned subpopulation reporting

[a] If the state is not reporting a required subpopulation category (i.e., column F = "N"), enter explanation in corresponding row in column H.

[b] If the state is reporting on the Dual-eligible status, Pregnancy status, Criminal justice status, and OUD population subpopulation categories, the state should use column H to outline its subpopulation identification approach as explained in Version 4.0 of the Medicaid Section 1115 Substance Use Disorder Demonstrations Monitoring Protocol Instructions.

[c] If the state is planning to phase in the reporting of any of the subpopulation categories, the state should (1) select N in column G and (2) provide an explanation and the

Attachment F SUD Monitoring Protocol

State: Pennsylvania
Demonstration Name: Medicaid Continuous Pre-Release Treatment for Youth Ages 12 through 20 and Medicaid Work and Child Incentives 1115 Demo

Instructions:

(1) In the reporting periods (open cells) of Table 2, use the prompt in column A to enter the requested information in the corresponding row of column B. All monitoring report submissions must include the information requested in the open cells of Table 2. Please refer to the Monitoring Report Instructions for more information on what to include in each section. Please refer to the SUD demonstration reporting schedule in Table 1. All cells in the open table must be completed in order to enter text in the cells that are in the standard reporting schedule or be automatically auto-populated.

(2) Review the states reporting schedule in the SUD demonstration reporting schedule table (Table 1). For each of the reporting categories listed in columns C, when "Y or N is entered in column D, the corresponding reporting period will be open in the corresponding row in Table 2. For each reporting period in which a reporting date was noted in the standard reporting schedule for any quarter and/or reporting category (i.e., column D = "Y"), the state should describe these deviations, as related to the standard schedule, in column E. For example, if the state is not required to report on a specific metric for the SUD demonstration period, with delay relative to column A or consistent the standard schedule (column A), with other columns, and noted the adding and should say by/delayed by the state.

Table 1. Substance Use Disorder Demonstration Reporting Periods Input Table

	Data Entry
	Demonstration Reporting Periods
Date of first SUD demonstration year reporting period	1/1/2022
Date of 30th quarter of the demonstration (i.e., 12 years 6 months = 72 + 6 = 78 quarters)	6/30/2041
Identify earliest SUD demonstration reporting period (corresponding with the first reporting period in which the state is electing demonstration flexibilities. This is usually the first SUD reporting period in the demonstration)	1/1/2022
Date SUD demonstration started in 1900 [2]	01-Jan-2022
Identify the month/day/year of when the SUD DSRIP reporting period ends (i.e., 6 months after the end date of the quarter in which the state elects to start monitoring the SUD demonstration)	7/1/2022
	10/1/2022
	1/1/2023
	4/1/2023
	7/1/2023
	10/1/2023

Table 2. Substance Use Disorder Demonstration Reporting Schedule

SUD reporting quarter start date (MM/DD/YYYY)	SUD reporting quarter end date (MM/DD/YYYY)	Monitoring report data submission due date (MM/DD/YYYY)	Monitor-online SUD reporting period, if applicable, due SUD monitoring report submission date (MM/DD/YYYY)	SUD reporting period (Annual, Quarterly, or Monthly)	Reporting Category	Has state reporting category, measurement period for which documentation is expected to be reported, and associated reporting schedule changed (e.g., different reporting period, different reporting frequency) (Y/N)	Reason(s) for changes identified in Column G	Explanation for deviations identified in Column H	Proposed deviations to reporting period dates or reporting schedule for approval (e.g., different reporting frequency)
1/1/2022	3/31/2022	6/30/2022	7/1/2022	Quarterly	Emergency department utilization	Y			
					Other monthly and quarterly metrics	Y		Reporting is continued per previous demonstration reporting schedule. Pennsylvania DHT has only 3 months run-out for claims/encounters for data collection. On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	4Q2022
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	Y		Y is aligns with the baseline period from the previous demonstration period. Pennsylvania will report other annual metrics on a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	CY21-2021 - 06/30/2023
4/1/2022	6/30/2022	9/30/2022	10/1/2022	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		Reporting is continued per previous demonstration reporting schedule. Pennsylvania DHT has only 3 months run-out for claims/encounters for data collection. On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	1Q2022
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	N			
7/1/2022	9/30/2022	12/31/2022	1/1/2023	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	2Q2022
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	N			
10/1/2022	12/31/2022	3/31/2023	4/1/2023	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	3Q2022
					Annual metrics that are availability/quality metrics	Y	1/1/2023		
					Other annual metrics	N			
1/1/2023	3/31/2023	6/30/2023	7/1/2023	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	4Q2022
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	Y		Y is aligns with the baseline period from the previous demonstration period. Pennsylvania will report other annual metrics on a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	CY22-2022 - 06/30/2023
4/1/2023	6/30/2023	9/30/2023	10/1/2023	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	1Q2023
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	N			
7/1/2023	9/30/2023	12/31/2023	1/1/2024	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	2Q2023
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	Y		Y is aligns with the baseline period from the previous demonstration period. Pennsylvania will report other annual metrics on a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	CY23-2023 - 06/30/2023
10/1/2023	12/31/2023	3/31/2024	4/1/2024	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	3Q2023
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	N			
1/1/2024	3/31/2024	6/30/2024	7/1/2024	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	4Q2023
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	Y		Y is aligns with the baseline period from the previous demonstration period. Pennsylvania will report other annual metrics on a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	CY24-2024 - 06/30/2023
4/1/2024	6/30/2024	9/30/2024	10/1/2024	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	1Q2024
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	N			
7/1/2024	9/30/2024	12/31/2024	1/1/2025	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	2Q2024
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	Y		Y is aligns with the baseline period from the previous demonstration period. Pennsylvania will report other annual metrics on a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	CY25-2025 - 06/30/2026
10/1/2024	12/31/2024	3/31/2025	4/1/2025	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	3Q2024
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	N			
1/1/2025	3/31/2025	6/30/2025	7/1/2025	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	4Q2024
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	Y		Y is aligns with the baseline period from the previous demonstration period. Pennsylvania will report other annual metrics on a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	CY26-2026 - 06/30/2026
4/1/2025	6/30/2025	9/30/2025	10/1/2025	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	1Q2025
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	N			
7/1/2025	9/30/2025	12/31/2025	1/1/2026	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	2Q2025
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	N			
10/1/2025	12/31/2025	3/31/2026	4/1/2026	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	3Q2025
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	N			
1/1/2026	3/31/2026	6/30/2026	7/1/2026	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	4Q2025
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	Y		Y is aligns with the baseline period from the previous demonstration period. Pennsylvania will report other annual metrics on a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	CY27-2027 - 06/30/2026
4/1/2026	6/30/2026	9/30/2026	10/1/2026	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	1Q2026
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	N			
7/1/2026	9/30/2026	12/31/2026	1/1/2027	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	2Q2026
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	N			
10/1/2026	12/31/2026	3/31/2027	4/1/2027	Quarterly	Emergency department utilization	N			
					Other monthly and quarterly metrics	Y		On September 26, 2023 Pennsylvania will report other annual metrics as a fully data-refreshed basis. To ensure complete data, CMS may approve a revision to Pennsylvania will have 6 months from the end of the measurement period to report	3Q2026
					Annual metrics that are availability/quality metrics	N			
					Other annual metrics	N			

[1] SUD demonstration start date: For a new demonstration – CMS utilizes the start date of the demonstration as the global terms & conditions (STCs) are issued. For example, if the state's STCs for the initial SUD demonstration approval were finalized on January 1, 2018, but the state elected to delay implementation of the demonstration's effective January 1, 2019. On December 31, 2018, the state should complete Section 2 – B.9 to the Monitoring Protocol and enter January 1, 2019 in the first cell of the "SUD demonstration start date" column. CMS may approve a section 1115 demonstration with an effective date that is in the future. For example, CMS may approve an extension request on December 31, 2018 for a demonstration that was originally approved with an effective date of January 1, 2019. In this example, the state should enter January 1, 2019 in the first cell of the "SUD demonstration start date" column. For an existing demonstration, the start date is the first day of the first month the state elected to start monitoring the SUD demonstration. For example, if a state's effective date is March or January 15, 2016, but the state elected to delay "SUD DSRIP" to the end date is Table 1 of the "SUD reporting schedule" tab. Please see Appendix A for more information on determining demonstration quarter timing.

[2] The auto-populated reporting schedule in Table 2 outlines the date the state is expected to report for each demonstration year and quarter. However, states are not expected to begin reporting any metrics data until after monitoring protocol approval. The state should see Section B of the Monitoring Report Instructions for more information on retrospective reporting of data following protocol approval.

Medicaid Section 1115 Substance Use Disorder Demonstrations
Monitoring Protocol Template

Note: PRA Disclosure Statement to be added here

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

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

State	
Demonstration name	
Approval period for section 1115 demonstration	*Enter the current approval period for the section 1115 demonstration as listed in the current special terms and conditions (STC), including the start date and end date (MM/DD/YYYY – MM/DD/YYYY).* *Start Date:* 10/01/2022 *End Date:* 09/30/2027
SUD demonstration start date[a]	*Enter the start date for the section 1115 SUD demonstration or SUD component if part of a broader demonstration (MM/DD/YYYY).* 10/01/2022
Implementation date of SUD demonstration, if different from SUD demonstration start date[b]	*Enter SUD demonstration implementation date (MM/DD/YYYY).* 07/01/2018
SUD (or if broader demonstration, then SUD-related) demonstration goals and objectives	*Enter summary of the SUD (or if broader demonstration, then SUD-related) demonstration goals and objectives.* Under this demonstration, the State expects to achieve the following: Objective 1. Increase rates of identification, initiation, and engagement in treatment. Objective 2. Increase adherence to and retention in treatment. Objective 3. Reduce overdose deaths, particularly those due to opioids. Objective 4. Reduce utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services. Objective 5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate. Objective 6. Improve access to care for physical health conditions among beneficiaries.

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

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

2. Acknowledgement of narrative reporting requirements

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

3. Acknowledgement of budget neutrality reporting requirements

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

4. Retrospective reporting

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

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

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

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

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

☐ The state will report retrospectively for any Qs prior to monitoring protocol approval as described above, in the state's second monitoring report submission that contains metrics after monitoring protocol approval.

☒ The state proposes an alternative plan to report retrospectively for any Qs prior to monitoring protocol approval: *Insert narrative description of proposed alternative plan for retrospective reporting. Regardless of the proposed plan, retrospective reporting should include retrospective metrics data and a general assessment of metric trends for the period. The state should provide justification for its proposed alternative plan.*

Not applicable; monitoring protocol applies to a demonstration extension period

Attachment G

CENTERS FOR MEDICARE & MEDICAID SERVICES

Expenditure Authority

NUMBER: **11-W-00308/3**

TITLE: **Pennsylvania Medicaid Coverage Former Foster Care Youth from a Different State & SUD**

AWARDEE: **Pennsylvania Department of Human Services**

Title XIX Expenditure Authority

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by the Commonwealth of Pennsylvania for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period of this demonstration, be regarded as expenditures under the state's title XIX plan. The following expenditure authority must only be implemented consistent with the approved Special Terms and Conditions (STCs) and shall enable the Commonwealth of Pennsylvania to implement the section 1115 demonstration amendment. All other requirements of the Medicaid program, including current and future CMS guidance for continuous eligibility, as expressed in law, regulation, and policy statements must apply to these expenditures, unless identified as not applicable below.

Continuous Eligibility. Expenditures for continued state plan benefits for individuals who have been determined eligible as specified in Table 1 of STC 1.2, who are not otherwise excluded under STC 1.3 for the applicable continuous eligibility period, and who would otherwise lose coverage during an eligibility redetermination, except as noted in STC 1.4**.**

SPECIAL TERMS AND CONDITIONS

1. Eligibility and Enrollment

1.1 Continuous Eligibility: Eligible populations, identified in STC 1.2, will receive continuous eligibility through the demonstration. The state is authorized to provide continuous eligibility for the populations for the durations specified in Table 1 below, regardless of the delivery system through which these populations receive Medicaid benefits.

a. For individuals who qualify for continuous eligibility, the continuous eligibility period begins on the effective date of the individual's eligibility under 42 CFR 435.915, the effective date of the most recent redetermination, or the date of their release from a state correctional institution.
b. Because individuals are continuously eligible regardless of changes in circumstances, the state does not need to conduct renewals or redeterminations of eligibility

consistent with 42 CFR 435.916 and 435.919 for individuals who qualify for continuous eligibility until the end of the individual's continuous eligibility period, except in the limited circumstances of a beneficiary meeting one of the exceptions outlined in STC 1.4**.**

c. At the end of the continuous eligibility periods, the Commonwealth of Pennsylvania must conduct a renewal of Medicaid eligibility and consider eligibility on all bases consistent with 42 CFR 435.916(d)(1) prior to terminating coverage. Individuals determined eligible on another basis at the end of the continuous eligibility period will be moved to the appropriate group at that time. Individuals determined eligible on another basis resulting in a reduction of Medicaid eligibility or services or increase in cost sharing or premiums will be provided advance notice of termination in accordance with 42 CR 435.917 and 42 CFR 431, Subpart E. Individuals determined ineligible for Medicaid on all bases will be provided advance notice of termination in accordance with 42 CR 435.917 and 42 CFR 431, Subpart E and assessed for potential eligibility for other insurance affordability program in accordance with 42 CFR 435.916(d)(2).

1.2 Populations and Duration: The state is authorized to provide continuous eligibility for the following populations for the associated durations.

a. Children up to age six. Except as provided in STC 1.4**,** individuals age zero through the end of the month of their sixth birthday, who enroll in Medicaid shall qualify for continuous eligibility until the end of the month in which their sixth birthday falls.

b. Formerly Incarcerated. Except as provided in STC 1.4, the state is authorized to provide 12 months of continuous eligibility for individuals aged 19 – 65 who are released from a state correctional institution and meet one or more of the following criteria for high risk:

   i. Have one or more substance use disorders,
   ii. Have serious mental illness,
   iii. Eligible for Medicaid funded 1915(c) home and community-based services administered by the Office of Long-Term Living or Office of Developmental Programs,
   iv. With one or more chronic health conditions,
   v. Are pregnant or in the 12-month postpartum period, or
   vi. With Autism Spectrum Disorder.

   The period of continuous eligibility shall begin at the date of their release and will extend through the end of the 12th month following release.

Table 1: Eligible Populations and Associated Duration for Continuous Eligibility (CE)	
Population	**Duration of CE**
Children up to age 6	Until the end of the month of their 6th birthday
Beneficiaries leaving incarceration (aged 19 - 65) and meet one or more of the following criteria for high risk:	Up to 12 months following their release from a state correctional facility

• Have one or more substance use disorders, • Have serious mental illness, • Eligible for Medicaid funded 1915(c) home and community-based services administered by the Office of Long-Term Living or Office of Developmental Programs, • With one or more chronic health conditions, • Are pregnant or in the 12-month postpartum period, or • With Autism Spectrum Disorder.	

1.3 Eligibility Exclusions: The following adults and children are excluded from receiving continuous eligibility:

a. Have only established Medicaid eligibility as medically needy (as set forth in section 1902(a)(10)(C) of the Act),
b. Have been determined presumptively eligible for Medicaid but have not yet received an eligibility determination based on a regular application, or
c. Upon the adult and child's renewal are determined to only be eligible for Medicaid based on transitional medical assistance (as set forth in section 1925 of the Act).

1.4 Exceptions to Continuous Eligibility: Notwithstanding STC 1.2, if any of the following circumstances occur during an individual's designated continuous eligibility period, the individual's Medicaid eligibility shall be redetermined or terminated:

a. The beneficiary attains the age limit of the continuous eligibility period or eligibility group (if applicable);
b. The beneficiary is no longer a Commonwealth of Pennsylvania resident;
c. The beneficiary or their representative requests termination of eligibility;
d. The beneficiary dies;
e. The agency determines that eligibility was erroneously granted at the most recent determination, redetermination, or renewal of eligibility because of agency error or fraud, abuse, or perjury attributed to the individual.

1.5 Beneficiary-Reported Information and Periodic Data Checks:

a. The state must have procedures designed to ensure that beneficiaries can make timely and accurate reports of any change in circumstances that may affect their continuous eligibility as outlined STC 1.4 (such as a change in state residency) and are able to report other information relevant to the state's implementation or monitoring and evaluation of this demonstration, such as changes in income. The beneficiary must be

able to report this information through any of the modes of submission available at application (online, in person, by telephone, or by mail).

b. For individuals who qualify for a continuous eligibility period that exceeds 12 months, the state must continue to attempt to verify residency at least once every 12 months. The state should follow its typical processes that it would otherwise use to verify continued residency at renewal if continuous eligibility was not available for these individuals.
c. Additionally, at least once every 12 months, the state must follow its typical processes to attempt to confirm the individual is not deceased, consistent with the data sources outlined in the state's verification plan(s) and/or confirmed by the household per 42 CFR 435.952(d)**.** The state must redetermine eligibility if the state receives information that indicates a change in state residency or that the individual is deceased, verifying the change consistent with 42 CFR 435.919 and in accordance with 42 CFR 435.940 through 435.960 and the state's verification plan developed under 42 CFR 435.945(j)**.**
d. Because individuals are receiving continuous eligibility beyond their eligibility period, the state does not need to complete the individual's annual renewal or act on changes in circumstances that would otherwise affect eligibility, except as detailed in STC 1.4, until the end of the individual's continuous eligibility period. Additionally, if the state obtains information about changes that may affect eligibility (e.g., change in income), they are not permitted to use the information related to the change to end the continuous eligibility period early and terminate coverage, unless the change relates to one or more of the exceptions detailed in STC 1.4.

1.6 Annual Updates to Beneficiary Contact Information: For all continuous eligibility periods longer than 12 months, the state must have procedures and processes in place to accept and update beneficiary contact information and must attempt to update beneficiary contact information on an annual basis, which may include examining data sources annually and partnering with managed care organizations to encourage beneficiaries to update their contact information. The state is reminded that updated contact information obtained from third-party sources with an in-state address is not an indication of a change affecting continuous eligibility. Contact information with an out-of-state or no forwarding address indicates a potential change in circumstance with respect to state residency, but without additional follow up by the state per 42 CFR 435.952(d), the receipt of this third-party data is not sufficient to make a definitive determination that beneficiaries no longer meet state residency requirements.

1.7 Annual Reminders of Continued Eligibility: The state must have procedures and processes in place to provide individuals who qualify for a continuous eligibility period that exceeds 12 months an annual reminder of continued eligibility. The annual reminder of continued eligibility must:

a. Be written in plain language;

b. Be accessible to persons who are limited English proficient and individuals with disabilities, consistent with 42 CFR 435.905(b); and
c. If provided in electronic format, comply with requirements for electronic notices in 42 CFR 435.918.

The annual reminder of continued eligibility must, at a minimum, include:

d. An explanation of the individual's continued eligibility, including the end date of the continuous eligibility period;
e. The circumstances under which the individual must report, and procedures for reporting, any changes that may affect the individual's continuous eligibility;
f. Basic information on the level of benefits and services available as described at 42 CFR 435.917(b)(1)(iv); and
g. If the beneficiary's eligibility is based on having household income at or below the applicable MAGI standard, the content regarding non-MAGI eligibility described at 42 CFR 435.917(c).

1.8 Cost Sharing within Continuous Eligibility: Individuals receiving continuous eligibility enrolled in this demonstration may be subject to cost sharing responsibilities, such as monthly premiums and co-payments, to the extent allowable under title XIX requirements or as approved under current section 1115 demonstration authority**.** However, beneficiaries may not be disenrolled from this demonstration for failure to pay a premium during the individual's continuous eligibility period approved in the demonstration.

2. Monitoring and Reporting Requirements

2.1 Performance Metrics: For the continuous eligibility policy, monitoring metrics must support tracking enrollment and ex parte renewals. The state must describe successes and challenges related to activities to annually update beneficiary contact information, provide beneficiaries reminders of continued eligibility, verify beneficiary residency, and confirm that the beneficiary is not deceased, for all beneficiaries who qualify for a continuous eligibility period that exceeds 12 months.

3. Evaluation of the Demonstration

3.1 Evaluation Questions and Hypotheses:

a. For the continuous eligibility policy, the state must evaluate the impact of the policy on all relevant populations, appropriately tailored for the specific time span of eligibility. Evaluation hypotheses must focus on, but may not be limited to, enrollment continuity, utilization of age-appropriate preventive care, inpatient admissions and avoidable emergency care, and health disparities.

4. General Financial Requirements

4.1 Medicaid Expenditure Groups. Medicaid Expenditure Groups (MEG) are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject

to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The Master MEG Chart table provides a master list of MEGs defined for this demonstration.

BN – budget neutrality; MEG – Medicaid expenditure group; WOW – without waiver; WW – with waiver

Table 2: Master MEG Chart					
MEG	**Which BN Test Applies?**	**WOW Per Capita**	**WOW Aggregate**	**WW**	**Brief Description**
CE – Children TANF/MAGI	**Hypo**	X		X	All expenditures for continued benefits for children who have been determined eligible for the continuous eligibility period who would otherwise lose coverage during an eligibility determination.
CE – Children SSI/HH and Other Disabled	**Hypo**	X		X	All expenditures for continued benefits for children who have been determined eligible for the continuous eligibility period who would otherwise lose coverage during an eligibility determination.
CE - Formerly incarcerated TANF/MAGI	**Hypo**	X		X	All expenditures for continued benefits for beneficiaries leaving incarceration who meet criteria for high risk during the Continuous Eligibility period and who would otherwise lose coverage during an eligibility determination.

BN – budget neutrality; MEG – Medicaid expenditure group; WOW – without waiver; WW – with waiver

4.2 Reporting Expenditures and Member Months. The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11- W-00308/3). For the CE MEG, 2.6 percent for adults or 0.11 percent for children of expenditures are allocated to the CE MEG. Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by Demonstration Year (DY) according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

a. Member Months. As part of the Quarterly and Annual Monitoring Reports, the state must report the actual number of "eligible member months" and expenditures for all

demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below, with the exception of the Continuous Eligibility (CE) MEGs. The term "eligible member months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months each contribute two eligible member months per person, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.

For the Children CE MEGs, this percentage will be 0.11 percent. For Formerly Incarcerated CE MEGs, this percentage will be 2.6 percent. For example, the actual member months and expenditures for formerly incarcerated individuals in the corresponding MEGs will be reduced by 2.6 percent and the equivalent member months and expenditures will be reported on the CE - Formerly Incarcerated MEG so that the total calculated member months and expenditures between the two MEGs are equal to the actual member months and expenditures for the group.

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

Table 3: MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	CMS-64.9 or 64.10 Line(s) to Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
CE – Children Age 0 to 6 TANF/MAGI	Children who are eligible via CE, equaling 0.11% of total Medicaid expenditures for Children 0-6	Follow 64.9 Base Category of Service Definition	Date of service	MAP	Y 0.11% of total member months for children aged 0-6	11/14/2024	9/30/2027
CE – Children Age 0 to 6 SSI/HH and Other Disabled	Children who are eligible via CE, equaling 0.11% of total Medicaid expenditures	Follow 64.9 Base Category of Service Definition	Date of service	MAP	Y 0.11% of total member months for children aged 0-6	11/14/2024	9/30/2027

	for Children 0-6						
CE Formerly Incarcerated At Risk	Formerly incarcerated individuals who are eligible via CE, equaling 2.6% of total Medicaid expenditure for formerly incarcerated individuals	Follow 64.9 Base Category of Service Definition	Date of service	MAP	Y 2.6% of total member months for formerly incarcerated all adults	11/14/2024	9/30/2027

4.3 Calculating the Federal Medical Assistance Percentage (FMAP) for Continuous Eligibility for the Adult Group: Because not all "newly eligible" individuals in the Adult Group as defined in 42 CFR 433.204(a)(1) would be eligible for the entire continuous eligibility period if the state conducted redeterminations, CMS has determined that 97.4 percent of expenditures for individuals defined in 42 CFR 433.204(a)(1) will be matched at the "newly eligible" FMAP rate as defined in 42 CFR 433.10(c)(6) and 2.6 percent will be matched at the state's regular title XIX FMAP rate**.**

4.4 State Reporting for the Continuous Eligibility FMAP Adjustment: 97.4 percent of expenditures for "newly eligible" individuals in the Adult Group as defined in 42 CFR 433.204(a)(1) shall be claimed at the "newly eligible" FMAP rate as defined in 42 CFR 433.10(c)(6), unless otherwise adjusted as described in STC 4.2 above. The state must make adjustments on the applicable CMS-64 waiver forms to claim the remaining 2.6 percent or other applicable percentage of expenditures for individuals defined in 42 CFR 433.204(a)(1) at the state's regular title XIX FMAP rate.

4.5 Budget Neutrality Monitoring Tool: The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the Performance Metrics Database and Analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing the demonstration's actual expenditures to the budget neutrality expenditure limits described in Section 5. CMS will provide technical assistance, upon request.[1]

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

4.6 Budget Neutrality Mid-Course Correction Adjustment Request. No more than once per demonstration year, the state may request that CMS make an adjustment to its budget neutrality agreement based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

a. **Contents of Request and Process**. In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 4.6.c. If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. Within 120 days of acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 3.6. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

b. **Types of Allowable Changes.** Adjustments will be made only for actual costs as reported in expenditure data. CMS will not approve mid-demonstration adjustments for anticipated factors not yet reflected in such expenditure data. Examples of the types of mid-course adjustments that CMS might approve include the following:

    i. Provider rate increases that are anticipated to further strengthen access to care;

    ii. CMS or State technical errors in the original budget neutrality formulation applied retrospectively, including, but not limited to the following: mathematical errors, such as not aging data correctly; or unintended omission of certain applicable costs of services for individual MEGs;

    iii. Changes in federal statute or regulations, not directly associated with Medicaid, which impact expenditures;

    iv. State legislated or regulatory change to Medicaid that significantly affects the costs of medical assistance;

    v. When not already accounted for under Emergency Medicaid 1115 demonstrations, cost impacts from public health emergencies;

    vi. High cost innovative medical treatments that states are required to cover; or,

    vii. Corrections to coverage/service estimates where there is no prior state experience (e.g., SUD) or small populations where expenditures may vary widely.

c. **Budget Neutrality Update.** The state must submit an updated budget neutrality analysis with its adjustment request, which includes the following elements:

i. Projected without waiver and with waiver expenditures, estimated member months, and annual limits for each DY through the end of the approval period; and,

ii. Description of the rationale for the mid-course correction, including an explanation of why the request is based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or is due to a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

5. Monitoring Budget Neutrality for the Demonstration

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

5.2 Hypothetical Budget Neutrality. When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), or when a WOW spending baseline for certain WW expenditures is difficult to estimate due to variable and volatile cost data resulting in anomalous trend rates, CMS considers these expenditures to be "hypothetical," such that the expenditures are treated as if the state could have received FFP for them absent the demonstration. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the expenditures on those services. When evaluating budget neutrality, however, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures; that is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this

demonstration approval. If the state's WW hypothetical spending exceeds the Hypothetical Budget Neutrality Test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending through savings elsewhere in the demonstration or to refund the FFP to CMS.

5.3 Hypothetical Budget Neutrality Test 2: Continuous Eligibility: The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test **2**. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditure in excess of the limit from Hypothetical Budget Neutrality Test **2** are counted as WW expenditures under the Main Budget Neutrality Test.

Table 4: Hypothetical Budget Neutrality Test 2

MEG	PC or AGG	WOW Only, WW Only, or Both	Base Year	Trend Rate	DY06 10/1/22-9/30/23	DY07 10/1/23-9/30/24	DY08 10/1/24-9/30/25	DY09 10/1/25-9/30/26	DY10 10/1/26-9/30/27
CE – Children Age 0 to 6 TANF/MAGI	PC	Both	$473.92	4.8%	$0	$0	$496.67	$520.51	$545.49
CE – Children Age 0 to 6 SSI/HH and Other Disabled	PC	Both	$794.65	4.8%	$0	$0	$832.80	$872.77	$914.66
CE - Formerly incarcerated At Risk	PC	Both	$717.11	5%	$0	$0	$752.97	$790.62	$830.15

BN – budget neutrality; MEG – Medicaid expenditure group; WOW – without waiver; WW – with waiver