Commonwealth of Pennsylvania

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

Number 11-W-00308/3

Draft 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

Table of Contents

A. General Background Information 3

1. History and Overview 3
2. Demonstration Approval 17
3. Description of the Demonstration 17
4. Population Impacted 24

B. SUD Evaluation Questions and Hypothesis 24

1. Targets for Improvement 25
2. Logic Model, Research Questions and Hypotheses 26

C. Methodology 30

1. Evaluation Design 30
2. Target and Comparison Populations 32
3. Evaluation Period 33
4. Evaluation Measures and Data Sources 34
5. Summary Design Tables for the Evaluation of the Demonstration 42
6. Analytic Methods 58

D. Methodological Limitations 61

1. Data Availability and Quality 61
2. Descriptive Nature of the Findings and Implications for Causal Interpretation 63
3. Assumptions in ITS Analyses 63
4. 1115 as a Policy Bundle 63
5. COVID-19 Pandemic and Medicaid Unwinding 63
6. Bias in Qualitative Interview and Focus Group Data 64
7. Bias in Survey Data 64

E. Attachments 65

1. Independent Evaluator 65
2. Evaluation Budget 68
3. Timeline and Major Deliverables in Waiver Period 2 71

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.

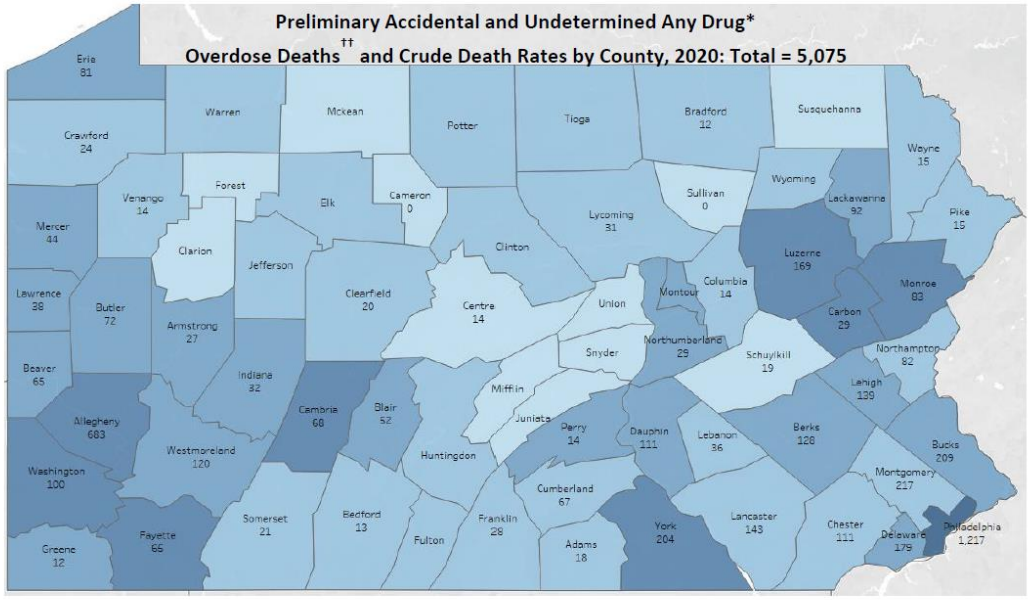
The Commonwealth has utilized the Demonstration authority to align its SUD service array with the ASAM, third edition criteria. The Commonwealth of Pennsylvania Department of Human Resources (DHS or Department) has made progress on implementation of the SUD component of the 1115 Demonstration waiver.

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.

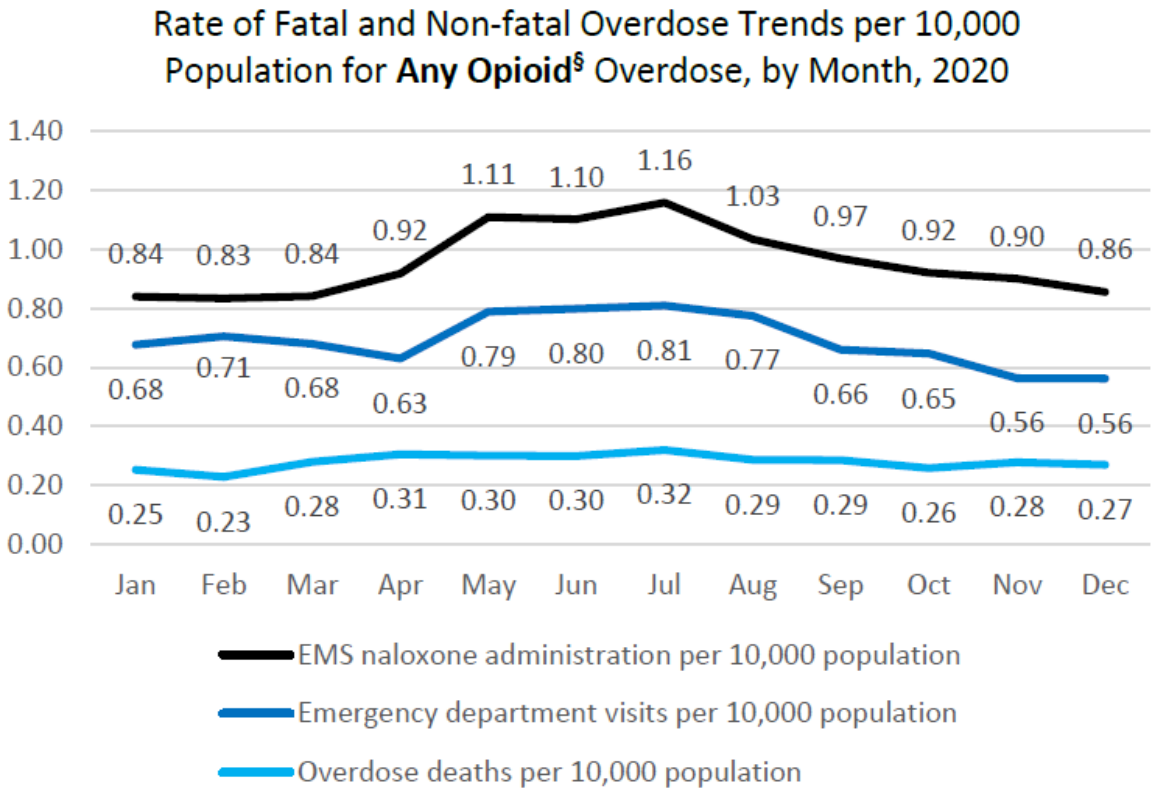
[1] Pennsylvania Department of Health. Fatal and Non-fatal Drug Overdoses in Pennsylvania, 2020. Retrieved from https://www.health.pa.gov/topics/Documents/Programs/PDMP/Pennsylvania%20Overdose%20Data%20Brief%202020.pdf, accessed on October 29, 2021. The trend continued in 2022, when Statewide, there 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.

pennsylvania
DEPARTMENT OF HEALTH



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.

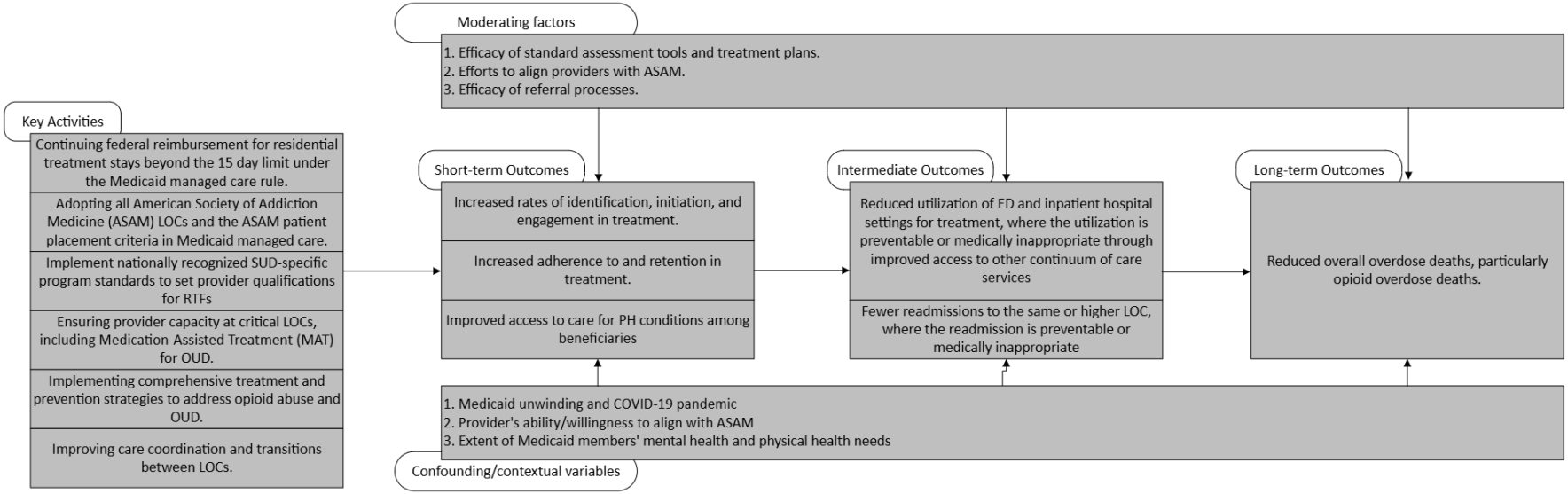
DHS/OMHSAS Objectives	Targets for Improvement
1. Increased rates of identification, initiation, and engagement in treatment;	• Annual increase of 1% in each alcohol or other drug (AOD) Initiation and Engagement of Alcohol and other Drug Dependence Treatment (IET) measure (National Committee for Quality 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]

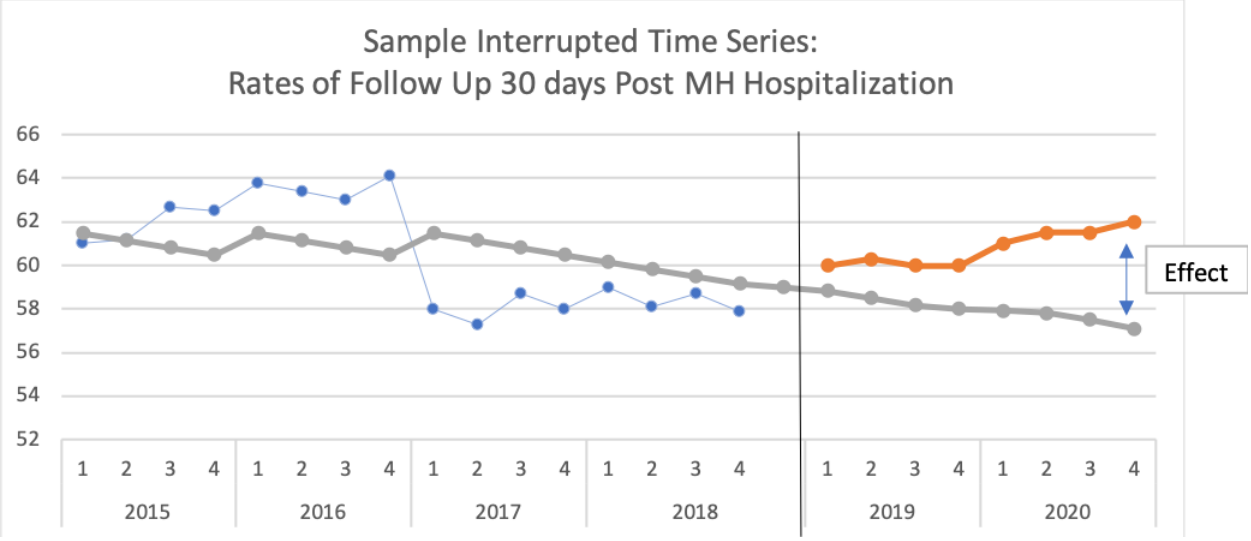
The more historical data points available, the better these predictions will be. The Commonwealth considered options for a contemporary comparison group to support more rigorous analytical methods such as difference-in-differences. Since the Demonstration will target managed care members, a comparison 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
Laurie Klanchar	Project Lead	laurie.klanchar@mercer.com
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.

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.

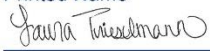
Because we have established these clear guidelines regarding our consulting engagements, we rarely encounter potential conflicts of interest.

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.

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