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

State Demonstrations Group

September 12, 2023

Valerie A. Arkoosh, MD, MPH
Acting Secretary
Pennsylvania Department of Human Services
P.O. Box 2675
Harrisburg, PA 17120

Dear Acting Secretary Arkoosh:

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Interim Evaluation Report, which is required by the Special Terms and Conditions (STCs), specifically STC 42 "Interim Evaluation Report" of the section 1115 demonstration, "Pennsylvania Medicaid Coverage for Former Foster Care Youth from a Different State and Substance Use Disorder (SUD) Demonstration" (Project No: 11-W-00308/3). The demonstration was approved on October 1, 2017, and was effective through September 30, 2022. This Interim Evaluation Report covers the period from July 2018 through March 2021. CMS determined that the Interim Evaluation Report, submitted on March 31, 2022, and revised on August 29, 2023, is in alignment with the CMS-approved Evaluation Design and the requirements set forth in the STCs, and therefore, approves the state's Interim Evaluation Report.

Despite limited data and service disruptions due to the COVID-19 public health emergency (PHE), the state continued to make progress towards its demonstration goals. The state utilized rigorous evaluation methods when possible, including interrupted time series estimates that account for the effect of the PHE. During the period of analysis, the number of SUD beneficiaries receiving early intervention and outpatient services increased. Additionally, the state was able to provide continuous health insurance for 12 months to approximately 40 percent of the former foster care youth beneficiary population and increase the rates of those receiving appropriate medication management for asthma and those on persistent medication with annual monitoring. We look forward to further analysis about the demonstration activities, particularly for metrics which were not included in this report.

In accordance with STC 45, the approved Evaluation Report may now be posted to the state's Medicaid website within 30 days. CMS will also post the Interim Evaluation Report on Medicaid.gov.

We look forward to our continued partnership on the Pennsylvania Medicaid Coverage for Former Foster Care Youth from a Different State and SUD Demonstration section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Paula M. Kazi -S

Digitally signed by Paula M. Kazi -S
Date: 2023.09.12 16:46:54 -04'00'

Paula Kazi
Acting Director
Division of Demonstration Monitoring and Evaluation

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

Mercer

Government Human Services Consulting

Pennsylvania Former Foster Care Youth Substance Use Disorder 1115 Waiver

Number 11-W-00308/3

Interim Evaluation Report

Commonwealth of Pennsylvania

Revised March 9, 2023

Revised August 29, 2023

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Section 1
Executive Summary

History and Overview of the Demonstration

The Affordable Care Act (ACA) created a new mandatory Medicaid eligibility group 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 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.

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 former foster care 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 (SPA) 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 expected 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.

FFCY Modified Evaluation Design

In the Modified Evaluation Design submitted by Pennsylvania to CMS on June 26, 2018, the following goals for the Demonstration were identified.

Goal 1: Ensure access to Medicaid services for former foster care individuals between the ages of 18 years and 26 years who previously resided in another state.

Evaluation Questions

1. Does the Demonstration provide continuous health insurance coverage?

    A. *Hypothesis*: Beneficiaries will be continuously enrolled for 12 months. The data source will be PA's Medicaid eligibility system where current and historical enrollment data is captured. The eligibility system captures both former foster care status and in which state the individual aged out. Individuals indicated to have aged out of foster care in another state will be pulled and enrollment data will be analyzed for each 12-month Demonstration Year.

    B. *Measure*: Number of beneficiaries continuously enrolled.

    Data sources and methods of analysis: Data source is PA's Medicaid eligibility system which houses current and historical eligibility information. Method of analysis is to review and count number of individuals who were enrolled as out-of-state former foster care for 12 months.

2. How did beneficiaries utilize health services?

    A. *Hypothesis*: Beneficiaries will access health services. To measure, beneficiaries identified as being in the former foster care out-of-state group will have claims data pulled and reviewed from PA's claims management system to determine if specific services have been received in each Demonstration Year. The services measured are ambulatory care visits, emergency department (ED) visits, inpatient stays, and behavioral health (BH) encounters.

    B. *Measure*: Number of beneficiaries who had an ambulatory care visit.

    C. *Measure:* Number of beneficiaries who had an ED visit.

    D. *Measure: Number of beneficiaries who had an inpatient visit.*

    E. *Measure:* Number of beneficiaries who had a BH encounter.

    F. *Data sources and methods of analysis:* Data sources are PA's Medicaid eligibility system and PA's claims management system. The Medicaid eligibility system will be used to identify individuals enrolled as out-of-state former foster care in the Demonstration Year. These individuals will be cross-referenced with PA's claims management system to determine which individuals received services identified during the Demonstration Year. These instances will be counted and a percentage derived.

The Demonstration was found to provide continuous health insurance for 12 months for approximately 40% of the 38 youth enrolled in the program each year. This resulted in access to health care for all 38 of the enrollees. Annually, 69% of youth received at least one ambulatory care visit. Overtime, the number of youth with at least one ED visit fluctuated from 26% to 43% with the average number of youth with an ED visit at 36% annually. The number of youth with an inpatient visit was on average 5% annually (ranging from 0% to 11%). The number of youth with a BH encounter was on average 21% annually.

The Demonstration was found to improve or maintain health outcomes for the target population. For example, on average, there was appropriate follow-up after hospitalization (FUH) 43% of the time for the target population. Sixty-seven percent of the population with asthma had appropriate medication management for asthma in Demonstration Year 1 (DY1) increasing to 100% of the population with asthma in DY2–DY4. Sixty-seven percent of the populations on persistent medication had appropriate medication monitoring in DY1 increasing to 100% of the population on persistent medication having appropriate monitoring in DY4. Twenty-one percent of the population had an annual preventive visit in each of the DYs. Eighteen percent of the beneficiaries eligible to have a cervical cancer screening received a screening.

Goal 2: Improve or maintain health outcomes for the target population.

Evaluation Questions

1. What do health outcomes look like for beneficiaries?

    A. *Hypothesis*: With access to healthcare for the out-of-state former foster care group, health outcomes will improve over time. To measure, claims data from the claims data management system will be evaluated to see if follow-up care, maintenance care, and preventative care are being utilized.

    B. *Measure:* Number of beneficiaries with appropriate follow-up care for hospitalizations.

    C. *Measure*: Number of beneficiaries with appropriate medication management for asthma.

    D. *Measure*: Number of beneficiaries on persistent medication with annual monitoring.

    E. *Measure*: Number of beneficiaries with an annual preventive visit.

    F. *Measure: Number of beneficiaries eligible with a cervical cancer screening.*

    G. *Data sources and methods of analysis:* Data sources are PA's Medicaid eligibility system and PA's claims management system. The Medicaid eligibility system will be used to identify individuals enrolled as out-of-state former foster care in the Demonstration Year. These individuals will be cross-referenced with PA's claims management system to determine which individuals received services identified during the Demonstration Year. These instances will be counted and a percentage derived.

History and Overview of the Substance Use Disorder Amendment

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, Former 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 changes to the Medicaid 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 Disease (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 Substance Use Disorder (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 Amendment 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 will continue through September 30, 2022 (four years and three months). The draft Interim Evaluation was originally submitted to CMS as part of the Commonwealth's renewal application on March 30, 2022.

Description of the SUD Demonstration Amendment

The purpose of the Section 1115 Demonstration waiver amendment 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. Reduce overdose deaths, particularly those due to opioids.
2. Reduce utilization of ED and inpatient hospital settings.
3. Reduce readmissions to the same or higher LOC.

The Commonwealth believes that these three 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.

SUD Evaluation Questions and Hypotheses

Evaluation questions and hypotheses to be addressed in the SUD portion of the Interim Evaluation were derived from and organized based on the Driver Diagrams approved in the Evaluation Design. The overall aims of the project are to: 1) reduce overdose deaths, particularly those due to opioids, 2) reduce utilization of ED and inpatient hospital settings, and 3) reduce readmissions to the same or higher LOC. To accomplish these goals, the Demonstration includes several key activities (called primary drivers) including increasing access to care, ensuring high quality of care across the entire treatment continuum and increasing treatment program retention, and improving care transition across the continuum of SUD services. Six secondary drivers support the three primary drivers for this change. These secondary drivers become the milestones in the Commonwealth's implementation plan:

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

SUD Evaluation Design

The evaluation of the Pennsylvania 1115 waiver utilizes a mixed-methods evaluation design with three main goals:

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.

A combination of qualitative and quantitative approaches is used throughout the evaluation. Qualitative methods include key informant interviews with the Office of Mental Health and Substance Abuse Services (OMHSAS) and provider staff regarding waiver activities, document reviews of agreements, policy guides and manuals, and summaries of Consumer and Family Satisfaction Team (CFST) surveys conducted between 2019 and 2021. Quantitative methods include descriptive statistics showing change over time in both counts and rates for specific metrics and interrupted time series (ITS) analysis to assess the degree to which the timing of waiver interventions affect changes across specific outcome metrics.

Qualitative analysis has been used to identify and describe the SUD delivery system and the changes/maintenance through the Demonstration for Medicaid enrollees in the eligible population. Each of the milestones are discussed and documented in this Interim Evaluation Report. We identify key elements that Pennsylvania intended to modify through the Demonstration and measure the effects of those changes. Using a combination of case study methods, including document review, telephone interviews, surveys, and face-to-face meetings, we will have conducted a descriptive analysis of the key Pennsylvania Demonstration features.

Methodological Limitations

There are three primary limitations to the evaluation methodology presented here. The first involves issues of data quality and data sources that either 1) are not sufficient to conduct the analysis proposed here (i.e., not enough historical data for needed prior time periods), and 2) contain errors. The second limitation is related to the design itself. Since this evaluation plan relies heavily on descriptive, time series analysis and qualitative data, this report is able to demonstrate what happened after the Demonstration was implemented. However, it is difficult to isolate why changes occurred. In other words, it will be difficult to directly attribute changes after waiver implementation to the activities undertaken as part of the waiver. Each of these limitations is discussed in greater detail within this section. Contextual complications related to the Coronavirus Disease 2019 (COVID-19) public health emergency also make data trend interpretation extremely difficult.

SUD Findings

Milestone 1

There were some delays in providers reaching alignment by July 1, 2021. COVID-19 required changes to planned trainings and a web-based system was developed. In addition, there was some uncertainty and concern on the part of providers around the resources required to reach full alignment. In June 2021, OMHSAS and the Department of Drug and Alcohol Programs (DDAP) agreed to allow providers to apply for extensions for complete implementation. During focus groups conducted during August 2021 and September 2021, OMHSAS and DDAP stakeholders expressed confidence that the majority of concerns have been resolved. There was confidence that providers will be able to comply with all criteria for the LOC they provide in the near future.

Some specific LOCs are still a challenge for providers. Stakeholders acknowledged that this was a significant change in terms of the number of hours of service and staffing ratios. One specific example is ASAM 2.1 because there is not a separately licensed IOP LOC in the Commonwealth. The requirements for this level might be difficult for many providers to meet and many providers may choose not to continue to provide this LOC. DDAP considers WM at inpatient ASAM 3.7-WM and ASAM 4.0-WM to be substantially aligned, but WM at the ambulatory LOCs such as ASAM 1.0-WM and ASAM 2.0-WM are still being assessed for alignment with the ASAM Criteria.

The ITS analysis found:

- Significant increases in the number of members with an SUD diagnosis.
- Initial statistically significant increases in the number of any SUD services, followed by declines at the onset of the pandemic.
- Decreases in the number of members receiving IOP and PHP services.
- Increases in the number of individuals receiving early intervention services.
- Increases in the number of individuals receiving outpatient services.
- An initial decline in residential services, followed by small, statistically significant increases, then significant declines during the pandemic.
- Increases in MAT services.

Milestone 2

OMHSAS required Primary Contractors/Behavioral Health-Managed Care Organizations (PCs/BH-MCOs) to use ASAM patient placement criteria for Medicaid utilization review and admission prior authorization to Residential Facilities on January 1, 2019. DDAP issued guidance to the counties to use ASAM admission criteria as of May 1, 2018. DDAP began requiring ASAM Criteria for treatment plans, continued stay, and discharge criteria as of May 2019.

Some stakeholders report that use of the ASAM for admission criteria is consistent across providers, but many reported a perspective that it is not regularly being used in treatment plans, continued stay, and discharge criteria. OMHSAS and DDAP are working together to develop a protocol and tool that will monitor, among other compliance requirements, the degree to which ASAM Criteria are being used in continued stays and discharge decisions. Once this protocol is in use, more statements that are definitive can be made about use of ASAM placement criteria.

To date, approximately 12,750 individuals have been trained. DDAP has two options to complete required ASAM training, a two-day live classroom offering and a series of on-demand modules. From 2018 through June 2019, over 7,500 individuals were trained in the in-person two-day skill building training. The live classroom course was reformatted for a virtual experience. Approximately 400 students attended virtual ASAM Criteria training in 2020. Since the inception of the ASAM Criteria, over 9,800 Pennsylvania provider staff have been trained in the two-day classroom course. Nine hundred and seventy-two Pennsylvania-based organizations ordered subscriptions to the on-demand, online modules for approximately 2,150 potential users.

Milestone 3

The metrics reported reflect a decline in the delivery of services by unique providers because the Commonwealth only counts enrolled providers who delivered care in FFS, which was affected by the pandemic from January 2020 through June 2020. The actual number of enrolled providers providing SUD services has not declined to the same extent.

Milestone 4

The Commonwealth has not done a capacity review since development of the waiver application.

Once the alignment of provider standards to ASAM is completed, OMHSAS and DDAP believe there will be sufficient outpatient and IOP capacity as well as capacity at most of the residential ASAM LOCs. Without a formal assessment, complete up to date numbers for all available providers is difficult to document. However, both OMHSAS and DDAP stakeholders report they believe that there have been more MAT licenses granted since implementation and are certain that overall treatment capacity has increased for both ambulatory and residential.

Milestone 5

Since the Midpoint Assessment, OMHSAS and DDAP have had challenges implementing residential and residential-WM provider alignment with ASAM. As mentioned previously, the size of the system transformation effort has been the primary challenge. Providers requested more time than the Commonwealth had originally planned to make the transition. However, providers are now making strides in alignment and there is more confidence, as compared to reporting during the Midpoint Assessment, that provider alignment will be accomplished by July 1, 2022.

No descriptive analyses of trends in metrics for Milestone 5 and Milestone 6 are available at this time due to limited data points. Currently, only data for Calendar Year (CY) 2019 are available due to delays in technical specifications for these metrics. The CY 2020 data are still being programmed according to new specifications. This metric will be included in the Final Evaluation Report.

Milestone 6

DDAP continues efforts to improve and increase case management services provided by single county authorities (SCAs), making some funding available through block grants to help strengthen existing case management services. Stakeholders expressed a desire DDAP to go beyond just tracking members through LOCs. Instead, they are encouraging and supporting case management that emphasizes a community-based and individualized approach. ASAM requirements are being integrated into case management expectations.

SUD Evaluation Conclusions

The findings reported here are consistent with a Demonstration that is still in the midst of implementation efforts. Somewhat sharp increases in diagnosis and more gradual increases in access to some levels of SUD care reflect full implementation of ASAM Criteria for assessing treatment needs and making appropriate placements. However, it is hard to explain a very high single month jump of individuals diagnosed during the first implementation month. More gradual increases observed over time after implementation, however, are consistent with early implementation of the ASAM assessment criteria. It is also important to note that the original intent of the waiver was to maintain access to key SUD services that would have been eliminated due to CMS rule changes. Original research hypotheses only anticipated small changes across the entire array of services.

An important theme in discussing Demonstration implementation with key stakeholders is that change takes time. DDAP may have under estimated how disruptive providers viewed the changes. However, initial concerns are beginning to lessen with greater communication, technical assistance, and allowing more time for alignment activities.

Interpretations, and Policy Implications and Interactions with Other State SUD Initiatives

The SUD 1115 Demonstration has been a key tool in Governor Wolf's Administration's campaign to address SUDs. Throughout the 15 SUD PHEs, the Commonwealth has utilized multiple interventions to address all aspects of OUD. OMHSAS has found DDAP and its SCAs to be good partners in implementing the 1115 Demonstration.

Section 8 of this report includes a retrospective description of specific steps to combat SUD taken by the administration.

SUD Lessons Learned and Recommendations

Based on the Commonwealth's experience with the 1115 SUD Demonstration to this point the following lessons have been learned and will be described: 1) placement criteria matters, 2) the pandemic disrupted service patterns, and 3) change management disrupted service patterns before improving access to care. The Commonwealth has two closely related recommendations at this time: 1) a measured approach to change may create less provider abrasion and 2) acceptance of change takes time. Important considerations for this kind of Demonstration project include:

1. **Placement criteria matters** — good placement criteria promotes good treatment planning, combining modality matching (for all pertinent problems and priorities identified in the assessment) with placement matching (which identifies the least intensive LOC that can safely and effectively provide the resources that will meet the patient's needs).

2. **The COVID-19 pandemic disrupted service patterns** — it shifted service delivery from residential and congregate settings to individual telehealth care overnight. The evaluation highlighted changes to utilization and LOCs due to restricted physical movement and migration to virtual appointments. Increased need for services also was highlighted as the number of overdose deaths in 2020 rose to almost peak 2017 rates.
3. **Change management disrupted service patterns before improving access to care** — the changes required for aligning ASAM appear to have slightly decreased utilization in 2018, potentially related to mandatory training. While this lost utilization was small, it was statistically significant. The training also appears to have resulted in a number of individuals being served at lower LOCs (e.g., outpatient rather than IOP or PHP).

At this point in the Demonstration, the Commonwealth has one primary recommendation. The Commonwealth recommends a measured, dare we say slower, approach to change which is easier on the provider organizations and more likely to produce lasting results. Change does not happen overnight and lasting change may take many years to implement.

Section 2

Former Foster Care Individuals Evaluation

Medicaid Coverage for Former Foster Care Youth 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 former foster care 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 Modified Evaluation Design would apply to the five DYs of the 1115 Demonstration waiver:

- 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

Based on the criteria outlined in the Modified Evaluation Design, the goals identified were measured (to date) as follows.

Goal 1: Ensure access to Medicaid services for former foster care individuals between the ages of 18 years and 26 years who previously resided in another state.

Evaluation Questions

1. Does the Demonstration provide continuous health insurance coverage?
   A. *Hypothesis:* Beneficiaries will be continuously enrolled for 12 months.
   B. *Measure*: Number of beneficiaries continuously enrolled.

DY	Number of Beneficiaries Continuously Enrolled	Total Number of Enrollees	Percentage
DY1	16.00	39.00	41%

DY	Number of Beneficiaries Continuously Enrolled	Total Number of Enrollees	Percentage
DY2	18.00	42.00	43%
DY3	14.00	28.00	50%
DY4	12.00	42.00	29%
Average	**15.00**	**37.75**	**40%**

2. How did beneficiaries utilize health services?

   A. *Hypothesis:* Beneficiaries will access health services.

   B. *Measure:* Number of beneficiaries who had an ambulatory care visit.

DY	Number of Beneficiaries with Ambulatory Care Visit	Total Number of Enrollees	Percentage
DY1	27.00	39.00	69%
DY2	29.00	42.00	69%
DY3	20.00	28.00	71%
DY4	28.00	42.00	67%
Average	**26.00**	**37.75**	**69%**

   C. *Measure:* Number of beneficiaries who had an ED visit.

DY	Number of Beneficiaries with ED Visit	Total Number of Enrollees	Percentage
DY1	14.00	39.00	35%
DY2	17.00	42.00	40%
DY3	12.00	28.00	43%
DY4	11.00	42.00	26%
Average	**13.50**	**37.75**	**36%**

   D. *Measure:* Number of beneficiaries who had an inpatient visit.

DY	Number of Beneficiaries with Inpatient Visit	Total Number of Enrollees	Percentage
DY1	2.00	39.00	5%
DY2	0.00	42.00	0%
DY3	3.00	28.00	11%
DY4	2.00	42.00	5%
Average	**1.75**	**37.75**	**5%**

E. *Measure:* Number of beneficiaries who had a BH encounter.

DY	Number of Beneficiaries with BH Encounter	Total Number of Enrollees	Percentage
DY1	9.00	39.00	23%
DY2	6.00	42.00	14%
DY3	6.00	28.00	21%
DY4	10.00	42.00	24%
Average	**7.75**	**37.75**	**21%**

Goal 2: Improve or maintain health outcomes for the target population.

Evaluation Questions

1. What do health outcomes look like for beneficiaries?

A. *Measure:* Number of beneficiaries with appropriate follow-up care for hospitalizations.

DY	Number of Beneficiaries with Follow-Up Care	Number of Beneficiaries with Hospitalizations	Percentage
DY1	1.00	2.00	50%
DY2	0.00	0.00	0%
DY3	0.00	3.00	0%
DY4	1.00	2.00	50%
Average	**0.50**	**1.75**	**43%**

B. *Measure:* Number of beneficiaries with appropriate medication management for asthma.

DY	Number of Beneficiaries with Asthma Medication Management	Number of Beneficiaries on Asthma Medication	Percentage
DY1	2.00	3.00	67%
DY2	2.00	2.00	100%
DY3	1.00	1.00	100%
DY4	2.00	2.00	100%
Average	**1.75**	**2.00**	**88%**

C. *Measure:* Number of beneficiaries on persistent medication with annual monitoring.

DY	Number of Beneficiaries with Annual Monitoring	Number of Beneficiaries on Persistent Medications	Percentage
DY1	6.00	9.00	67%
DY2	6.00	7.00	86%
DY3	8.00	9.00	89%
DY4	7.00	7.00	100%
Average	**6.75**	**8.00**	**84%**

D. *Measure:* Number of beneficiaries with an annual preventive visit.

DY	Number of Beneficiaries with Annual Preventive Visit	Total Number of Enrollees	Percentage
DY1	7.00	39.00	18%
DY2	11.00	42.00	26%
DY3	8.00	28.00	29%
DY4	5.00	42.00	12%
Average	**7.75**	**37.75**	**21%**

E. *Measure: Number of beneficiaries eligible with a cervical cancer screening.*

DY	Number of Beneficiaries Who Received Cervical Cancer Screening	Number of Beneficiaries Eligible for Cervical Cancer Screenings	Percentage
DY1	2.00	19.00	11%
DY2	5.00	20.00	25%
DY3	2.00	14.00	14%
DY4	4.00	20.00	20%
Average	**3.25**	**18.25**	**18%**

Section 3
General Background Information

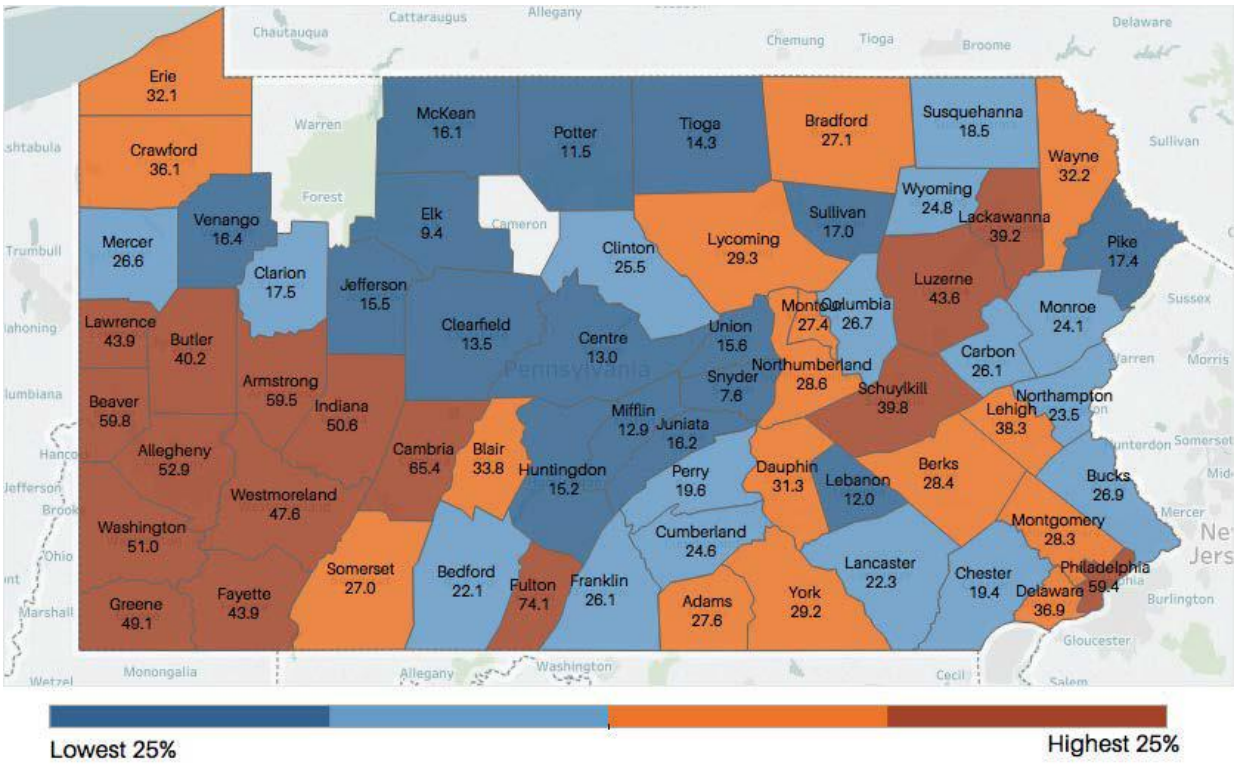
History and Overview of the SUD Amendment

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 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.[1] The opioid disaster declaration was renewed 14 times through August 25, 2021. In 2017, more than 5,403 Pennsylvanians[2] lost their lives to drug-related overdose, which averages to almost 15 drug-related deaths each day. This was a significant increase from the approximately 3,500 overdose fatalities in 2015, and over double from the nearly 2,500 deaths in 2014. The Pennsylvania drug-related overdose death rate in 2016 was 36.50 per 100,000 people, a substantial increase from the death rate of 2015.[3] This death rate was significantly higher than the national average of 16.30 per 100,000. Pennsylvania's Prescription Drug Monitoring Program (PDMP) reports that the number of ED visits related to an opioid overdose has increased by 82% from the third quarter of 2016 to the third quarter of 2017. While Pennsylvania is a very large and diverse state, there is no area of the Commonwealth not affected by this epidemic. The map below shows the rate of drug-related overdose deaths per 100,000 people in Pennsylvania counties in 2016.

[1] Governor Wolf Declares Heroin and Opioid Epidemic a Statewide Disaster Emergency. 2018. Retrieved from https://www.governor.pa.gov/governor-wolf-declares-heroin-and-opioid-epidemic-a-statewide-disaster-emergency.

[2] Pennsylvania lawmakers allow opioid emergency to lapse. August 25, 2021. Retrieved from https://apnews.com/article/health-pennsylvania-coronavirus-pandemic-opioids-017df3ad9649f3e68e98c75707040984.

[3] Analysis of Overdose Deaths in Pennsylvania, 2016. July 1, 2017. Retrieved from Analysis of Overdose Deaths in Pennsylvania, 2016.



The Pennsylvania Health Care Cost Containment Council (PHC4), which is an independent Commonwealth agency charged with collecting, analyzing, and reporting on health care in the Commonwealth, examined hospital admissions between 2000 and 2014 for Pennsylvania residents ages 15 and older (excluding overdoses treated in EDs or overdose deaths that occurred outside the hospital setting). The findings showed a 225% increase in the number of hospitalizations for overdose of pain medication and a 162% increase in the number of hospitalizations for overdose of heroin during that period. While there were higher numbers of hospital admissions for these types of overdoses among urban county residents, the percentage increases were larger for rural county residents. For rural county residents, there was a 285% increase between 2000 and 2014 in the number of hospitalizations for pain medication and a 315% increase for heroin, whereas for urban counties, the percentage increases were 208% and 143%, respectively.[4]

[4] Hospitalizations for Opioid Overdose — 2016 to 2017. June 2018. Retrieved from https://www.phc4.org/reports/researchbriefs/overdoses/17/docs/researchbrief_overdoses2017.pdf.

In June 2018, PHC4 released their updated findings for 2017 that contained the following highlights.[5]

Heroin

- The hospital admission rate for heroin overdose in 2017 peaked at 536 in the second quarter, but as a whole, the year saw an increase of 12.7%, which was the lowest percentage increase since 2011.
- The in-hospital mortality rate for these patients in 2014 was 7.5%, increased to 9.3% in 2016 and was up to 9.6% in 2017.

Pain Medication

- There were 1,747 hospital admissions for overdose of pain medication in 2017.
- The in-hospital mortality rate for these patients was 2.9% in 2016 and rose to 5.0% in 2017.
- In 2017, 84% of opioid-related deaths involved fentanyl or a fentanyl analog.[6]

Pennsylvania recognized the importance of a full continuum of treatment services, including residential services that are provided in a cost-effective manner and for a LOS that is governed by appropriate clinical guidelines to address the crisis described above. This Demonstration was determined to be critical to continue the federal funding needed to support the continuation of medically necessary services and SUD treatment in RTFs that meet the definition of IMDs, for individuals 21–64 years of age, regardless of the LOS.

Prior to the Demonstration application, CMS approved these residential services as cost-effective alternatives to State Plan Services (in lieu of services) in HealthChoices, Pennsylvania's Medicaid mandatory Managed Care Program. However, the requirements in the Medicaid Managed Care rule allow states to receive federal funding, for individuals 21–64 years old, in a RTF that is an IMD only if the LOS is no longer than 15 days. Pennsylvania estimated that this rule change would impact nearly 160 SUD service providers encompassed within the definition of IMD, affecting about 12,240 individuals statewide. Pennsylvania recognized the importance of these services in the continuum of care, and believes that this Demonstration is critical in ensuring that the Commonwealth is able to sustain the availability of these services to the impacted population.

Residential treatment services provide a structured recovery environment in combination with high-intensity clinical services. Individuals in residential settings receive daily clinical services to stabilize symptoms; a range of cognitive, behavioral, and other therapies to develop recovery skills in a protected environment; and recovery support services to assist in developing a social network supportive of recovery. Dependence on substances is a complex disease that affects multiple brain circuits, and effective treatment must incorporate an array

[5] Hospitalizations for Opioid Overdose — 2016. Retrieved from http://www.phc4.org/reports/researchbriefs/overdoses/16/docs/researchbrief_overdose2016.pdf.

[6] Substance Use Prevention and Harm Reduction. Retrieved from https://public.tableau.com/profile/pdph#!/vizhome/UnintentionalDrugRelatedDeaths/.

of clinical and psychosocial components provided in a safe environment, as determined by appropriate clinical guidelines.

Residential treatment is a core service in the continuum of care for many individuals with SUD. The National Institute for Drug Abuse identified key principles for effective treatment, which include the ability to remain in treatment services for an adequate period of time. The appropriate duration of treatment depends on the clinical needs of the individual. Research indicates that the majority of individuals need at least 90 days of treatment to significantly reduce or stop using substances.[7] Recovery is a long-term process, and the best outcomes occur with longer durations of treatment across the entire continuum of care based upon clinical needs.

Pennsylvania has provided residential treatment services to individuals based upon a comprehensive assessment and standardized LOC placement criteria to ensure appropriate treatment. Access to residential treatment services has not been based upon an arbitrary LOS but upon the determination of clinical need and medical necessity for this LOC. The loss in federal matching dollars due to the current changes to the Medicaid 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 RTF provides if it meets the definition of an IMD. This severely impacts 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 ASAM Criteria of services including Prevention, Outpatient, IOP, PHP, Residential and Inpatient, WM, and 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 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 D&A Detoxification, Rehabilitation, and Certified Recovery Specialist services are provided under the capitated agreement as "in lieu of services." Federal grants and Commonwealth funds can be utilized for all allowable services.

SUD Demonstration Amendment 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 will continue through September 30, 2022 (four years and three months). This Interim Evaluation was originally submitted to CMS as part of the Commonwealth's renewal application on March 30, 2022.

[7] Principles of Drug Addiction Treatment — A Research-Based Guide. 2012. Retrieved from https://www.drugabuse.gov/sites/default/files/podat_1.pdf.

Description of the Demonstration

The purpose of the Section 1115 Demonstration waiver amendment is to afford continued access to high quality, medically necessary treatment for 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:

- Reduce overdose deaths, particularly those due to opioids.
- Reduce utilization of ED and inpatient hospital settings.
- Reduce readmissions to the same or higher LOC.

The Commonwealth believes that these three 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 participation 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.

Medicaid and Medicaid Managed Care

In the HealthChoices program, BH services (mental health [MH]/SUD services) are administered separately from physical health (PH) managed care. The HealthChoices program, is administered by five BH prepaid inpatient health plans and eight Physical Health-Managed Care Organizations (PH-MCOs) operating under the 1915(b) waiver authority. In addition, on January 1, 2018, the Commonwealth implemented the Community HealthChoices (CHC) program under a concurrent 1915(c) waiver and 1915(b) waiver. CHC is Pennsylvania's managed long-term services and supports initiative. The CHC 1915(b)/1915(c) concurrent waivers allow the Commonwealth to require Medicaid beneficiaries to receive nursing facility, hospice, home- and community-based services, BH, and PH services through MCOs selected by the Commonwealth through a competitive procurement process.

OMHSAS under the Pennsylvania Department of Human Services (DHS) oversees the HealthChoices Behavioral Health (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 State Fiscal Year (SFY) 2019–2020.

Department of Drug and Alcohol Programs

While DDAP is not responsible for Medicaid in Pennsylvania, the below information outlines how DDAP 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's Office. 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 SCAs 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 agreements 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. Residential D&A Detoxification and Rehabilitation and Certified Recovery Specialist Services 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 utilized 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 FY 2014–2015, the SCAs reported providing treatment to 32,417 unique individuals.

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 Criteria for children and adolescents under the age of 21. The Pennsylvania Client Placement Criteria[8] was utilized for adults prior to the beginning of this Demonstration. The transition to ASAM placement criteria for adults began in July 2018 and the transition is continuing.

Alignment of service standards to ASAM national criteria began with the approval of this Demonstration. The expectation was that providers would be substantially aligned by July 1, 2021 and have full compliance by July 1, 2022. On June 29, 2021, Pennsylvania released additional guidance for providers to request six-month waivers of the implementation timeline if they would have difficulty meeting the July 1, 2021 deadline. Under the new guidance, DDAP may grant a specific provider an extension to December 31, 2021 for substantial compliance; however, there are no changes to the expectation of full compliance by July 1, 2022. Over 300 facilities requested extensions.

[8] Pennsylvania's Client Placement Criteria for Adults — Third Edition. 2014. Retrieved from Pennsylvania Client Placement Criteria (pacdaa.org).

OMHSAS-DDAP Coordination

While 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.

Drug Addiction Treatment Act of 2000 and the SUD Delivery System

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 Drug Enforcement Administration (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 gave 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.[9] According to a survey conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), physicians and patients alike reported an average of an 80% reduction in opioid abuse when asked whether buprenorphine was effective in treating addiction. Additionally, responses to the survey indicated that buprenorphine and similar medications increase other indices of recovery.[10]

In early 2023 the Omnibus bill removed the federal requirement for practitioners to submit a Notice of Intent (have a waiver) to prescribe medication, like buprenorphine, for treating OUD after meeting training and education requirements. With this provision, SAMHSA stopped accepting waiver applications.[11] All prescribers of MAT will be required to complete eight hours of substance abuse training and must be licensed and have DEA controlled prescribing authority under state law. There is no restriction on the number of patients a prescriber can treat, Nurse Practitioners and Physician Assistants can also prescribe buprenorphine if permitted under the state's specific scope of practice.

[9] 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.

[10] MAT Legislation, Regulations, and Guidelines. Retrieved from https://www.samhsa.gov/medication-assisted-treatment/legislation-regulations-guidelines.

[11] Removal of DATA Waiver (X-Waiver) Requirement | SAMHSA.

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.

Section 4

Evaluation Questions and Hypotheses

Evaluation questions and hypotheses to be addressed in the interim evaluation were derived from and organized based on the Driver Diagram's approved in the Evaluation Design. The overall aims of the project are to: 1) reduce overdose deaths, particularly those due to opioids, 2) reduce utilization of ED and inpatient hospital settings, and 3) reduce readmissions to the same or higher LOC. To accomplish these goals, the Demonstration includes several key activities (called primary drivers) including increasing access to care, ensuring high quality of care across the entire treatment continuum and increasing treatment program retention, and improving care transition across the continuum of SUD services. Six secondary drivers support the three primary drivers for this change. These secondary drivers become the milestones in the Commonwealth's implementation plan:

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

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

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

Evaluation Hypotheses and Research Questions

Milestone 1: Improve access to critical LOCs for OUD and other SUDs for individuals in Medicaid managed care. Critical LOCs are defined as early intervention, outpatient services, IOP and PHP services, residential and inpatient services, WM, and MAT.
Hypothesis 1: The 1115 SUD Demonstration will increase access to the specified critical LOCs for individuals in Pennsylvania Medicaid managed care compared to prior to the waiver.
Research Question 1: Has access to critical LOCs as defined below improved in Medicaid managed care?
***Analytic Approach*:** ITS; regression analysis for change over time after waiver implementation.
Research Question 2: 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?
Analytic Approach: ITS; regression analysis for change over time after waiver implementation.

Milestone 2: Use of evidence-based, SUD-specific patient placement criteria.
Hypothesis 2: The 1115 SUD Demonstration will lead to use of ASAM placement criteria by all providers by the end of the first year of the Demonstration project.
Research Question 1: Has the use of evidence-based SUD-specific patient placement criteria (ASAM Criteria) been implemented across all LOCs for all patient populations?
Analytic Approach: Qualitative narrative analysis; counts.

Milestone 3: Use of nationally recognized SUD-specific program standards to set provider qualifications for RTFs.
Hypothesis 4: The 1115 SUD Demonstration will establish ASAM Criteria and program standards to set provider qualifications for all Residential Facilities by January 2021.
Research Question 1: Has OMHSAS established ASAM Criteria and program standards to set provider qualifications for all Residential Facilities?
Analytic Approach: Qualitative narrative analysis; counts.

Milestone 4: Improve provider capacity at critical LOCs including MAT for OUD in Medicaid.
Hypothesis 3: The 1115 SUD Demonstration will increase provider capacity as defined below for SUD treatment at critical LOCs for individuals in Pennsylvania Medicaid managed care.
Research Question 1: Has the availability of providers in Medicaid accepting new patients including MAT improved under the Demonstration?
Analytic Approach: Qualitative narrative analysis; counts.

Milestone 5: Improvements in comprehensive treatment and prevention strategies to address opioid abuse and OUD for individuals in Medicaid managed care.
Hypothesis 5: The 1115 SUD Demonstration will improve outcomes for individuals in Pennsylvania Medicaid managed care under the following metrics: • Alcohol or other drug (AOD) Initiation and Engagement of Alcohol and Other Drug Abuse or Dependence Treatment (IET). • Use of opioids at high dosage (HDO). • Use of opioids from multiple providers (UOP). • Concurrent use of opioids and benzodiazepines. • Continuity of pharmacotherapy for OUD. • Follow-up after discharge from the ED for MH or AOD dependence. • Rate of overdose deaths in the Commonwealth. • Access to preventive/ambulatory health services for adult Medicaid managed care beneficiaries with SUD.
Research Question 1: Will improvements in treatment and prevention strategies in Medicaid managed care improve outcomes of individuals with an SUD in Medicaid managed care as demonstrated by: more effective initiation of treatment, decrease use of opioid at HDOs, reduce use of multiple opioids from multiple providers, reduce concurrent use of opioids and benzodiazepines, improve continuity of pharmacotherapy for OUD, decrease overdose deaths, and increase access to preventive/ambulatory services?
***Analytic Approach*:** ITS; regression analysis for change over time after waiver implementation.

Milestone 6: Improved care coordination and transition between LOCs for individuals in Medicaid managed care.
Hypothesis 6: The 1115 SUD Demonstration will improve follow-up after discharge from EDs and decrease readmissions for individuals in Pennsylvania Medicaid managed care with SUD.
Research Question 1: Has the Demonstration impacted access to care for individuals with SUD in Medicaid managed care by linking beneficiaries with community-based services and supports following stays in residential and inpatient treatment facilities and reducing readmission rates for treatment? • Follow-up after discharge from the ED for MH or AOD dependence; follow-up after discharge from the ED for MH within seven days or 30 days: beneficiaries with an outpatient visit, IOP visit, or PHP with a MH practitioner within seven days or 30 days after an ED visit with a principal diagnosis of mental illness/ED visits with a principal diagnosis of mental illness. • Follow-up after discharge from the ED for AOD dependence within seven days or 30 days: beneficiaries with an outpatient visit, IOP visit, or PHP with a MH practitioner within seven days or 30 days after an ED visit with a principal diagnosis of AOD dependence/ED visits with a principal diagnosis of AOD.
***Analytic Approach*:** ITS; regression analysis for change over time after waiver implementation.

The Evaluation Design also includes the following CMS-required metrics 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.

Cost data will be analyzed using descriptive, time series analysis. This will show the changes in cost over time, from the period (at least one year) prior to the Demonstration waiver, and the years following. Changes over time will be analyzed to determine whether costs increase, decrease, or stay the same.

A full list of metrics and analytic method for each can be found in the approved Evaluation Design for this project. This document has been included with this submission.

Section 5
Methodology

Evaluation Design

The evaluation of the Pennsylvania 1115 waiver utilizes a mixed-methods evaluation design with three main goals:

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

A combination of qualitative and quantitative approaches is used throughout the evaluation. Qualitative methods include key informant interviews with OMHSAS and provider staff regarding waiver activities, document reviews of agreements, policy guides and manuals, and summaries of CFST surveys conducted between 2019 and 2021. Quantitative methods include descriptive statistics showing change over time in both counts and rates for specific metrics and ITS analysis to assess the degree to which the timing of waiver interventions affect changes across specific outcome metrics.

Qualitative analysis has been used to identify and describe the SUD delivery system and the changes/maintenance through the Demonstration for Medicaid enrollees in the eligible population. Each of the milestones are discussed and documented in this Interim Evaluation Report. We identify key elements that Pennsylvania intended to modify through the Demonstration and measure the effects of those changes. Using a combination of case study methods, including document review, telephone interviews, surveys, and face-to-face meetings, Mercer conducted a descriptive analysis of the key Pennsylvania Demonstration features.

The evaluation also analyzes how Pennsylvania is carrying out its implementation plan and describes changes made to its initial design throughout the implementation. We identify 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.

During ongoing communication with the Commonwealth, we have collected detailed information on how Pennsylvania has implemented each milestone including how it has structured the ASAM implementation, identified providers at each ASAM level, implemented PDMP and other Health Information Technology (HIT) changes, and structured care coordination between LOCs for beneficiaries enrolled in the Demonstration. This Interim Evaluation Report describes the scope of each of these milestones as implemented by the Commonwealth.

Key informant interviews/focus groups and document reviews were conducted during fall 2020 and again in August 2021 and September 2021. These consisted of focus group discussions with key staff members in the following departments who are directly responsible for SUD 1115 implementation and operations: OMHSAS, DDAP, DHS' PeopleStat Program (The DHS reporting group), Pennsylvania PDMP System, and Pennsylvania eHealth Partnership Program.

PeopleStat has calculated the quantitative performance metrics required by CMS under the Demonstration. PeopleStat acts independently of OMHSAS and the Office of Medical Assistance Programs (OMAP). It has direct access to the data warehouse utilized by the Medicaid agency for encounter data and claims. The data are automatically updated any time a provider submits a claim or encounter data. PeopleStat has calculated all performance metrics using the period of time specified in the CMS technical manual (e.g., monthly, quarterly, or annual) and the approved 1115 Monitoring Protocol.

Target and Comparison Populations

The target population includes 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 SUD Findings section of this report describes trends in the overall population and any noteworthy outcomes for specific subpopulations. Graphs and data tables for each subpopulation, for each metric, is included in Appendix B: Subpopulation Charts.

The comparison population groups in this design will be comprised of the target population, which will serve as its own comparison group longitudinally, where the research question will compare service utilization differences across the Demonstration period.

Evaluation Period

The evaluation period for this Interim Evaluation Report is July 1, 2018 through March 31, 2021.

Interrupted Time Series Analysis Description

The period of time included in the evaluation was July 2015–June 2020. Preliminary data were available from July 2020–March 2021, but these data were excluded as they were known to be incomplete. Revised data for this period will be included in the analysis for the Demonstration's next report. This analysis did not adjust standard errors; we will explore these analyses in the next evaluation period.

General regression models typically follow the form of "*y = B0 + B1X1 + B2X2"*, where *B1X1*, *B2X2*, and so forth, are the predictors being used in the model. In Mercer's analysis, the outcome variable is people served. Our model is: "*peopleServed = (intercept) + demonstration + time + covid + demonstration * time."* This model predicts the effect of the Demonstration on the number of people served while controlling for the effects of time, COVID-19, and allowing for the effect of the Demonstration to vary by time.

The ITS analysis approach we took relies on a precise set of indicator codes being added to the data. This includes the Demonstration variable, which takes a 0 at all times prior to the Demonstration beginning, and a 1 at all times after implementation. Data prior to the Demonstration spanned July 2015 to June 2018, with the Demonstration effective from July 2018 to June 2020. The COVID-19 predictor is similarly constructed, taking a 0 at all times pre-lockdown (defined as beginning in March 2020), and a 1 at all times after.

The model allows us to see both the immediate effect of the Demonstration upon implementation, as well as the ongoing effect over time. An example of this, as reported for Metric #3, reads, "The ITS analysis for Metric #3 across all members revealed an initial increase in individuals (approximately 6,787) with SUD diagnoses upon the Demonstration beginning. This was followed by a slight decrease of approximately four fewer individuals per month. These effects, as well as the effect of COVID-19, were all highly statistically significant ($p < .001$)."

Methodological Limitations

There are three primary limitations to the evaluation methodology presented here. The first involves issues of data quality and data sources that either 1) are not sufficient to conduct the analysis proposed here (i.e., not enough historical data for needed prior time periods), and 2) contain errors. The second limitation is related to the design itself. Since this evaluation plan relies heavily on descriptive, time series analysis, and qualitative data, this report is able to demonstrate what happened after the Demonstration was implemented. However, it is difficult to isolate why changes occurred. In other words, it will be difficult to directly attribute changes after waiver implementation to the activities undertaken as part of the waiver. Each of these limitations is discussed in greater detail within this section. Contextual complications related to the COVID-19 pandemic also make data trend interpretation extremely difficult.

Many of the metrics being computed by PeopleStat for the waiver are new to OMHSAS. CMS previously identified computation/metric errors and over the course of the Demonstration has distributed revised metric specifications, requiring adjustment, and updated programming by PeopleStat. All metrics in this report use latest data submitted to CMS with the required metric definitions and technical specifications for the time period.

Because of some changes that directly affect the data system (i.e., the change from International Classification of Diseases, Ninth Revision [ICD-9] to ICD-10 codes), the historical data needed to forecast the slope of the "counterfactual" trend line (what would have happened without the Demonstration) is somewhat limited. This historical data is an important component of the ITS design, but also supports the descriptive time series analysis.

In addition to historical data, it is possible that the Commonwealth's data systems will additionally have current issues that make data errors more likely. For example, there are differences in the use of procedure codes between OMAP and OMHSAS that could cause services to be coded differently. The approved Monitoring Protocol identified these differences, and to the extent that the metrics were not national standard metrics, adjusted for these differences through programming documented in the Monitoring Protocol. However, there may be some issues that remain in the national metrics (e.g., Healthcare Effectiveness

Data and Information Set [HEDIS®] metrics) where the Commonwealth did not request deviations.

In addition, the evaluation plan primarily relies on encounter data, which will reflect the services delivered by the providers, but not the actual cost to Medicaid, which is the capitation rate paid. In order to account for this, cost metrics are included based on the actuaries' determination of the portion of the Medicaid capitation rate attributed to SUD services. The Commonwealth has attempted to address this concern by calculating the cost metrics using both the actuarial assumptions to develop the Medicaid capitation rate and by separately calculating those metrics using encounter data.

The current system has a runout of 12 months, and will need to account for timing around pulling data to calculate numerators and denominators for the metrics. The runout or latency period is established based on requirements of the PC and its BH-MCO to adjudicate claim and subsequently submit an encounter to the Commonwealth. Claim adjudication and encounter submission may take up to 180 days before the PC and its BH-MCO because of the allowed timeframes for submission and adjudication of claims.

DHS requires the PC or its BH-MCO to submit an encounter, or "pseudo claim," each time a member has an encounter with a provider. All encounters must be Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliant, submitted, and approved in Provider Reimbursement and Operations Management Information System (PROMISe™) (i.e., pass PROMISe edits) within 90 days following the date that the BH-MCO paid/adjudicated the provider's claim or encounter. CMS noted that Commonwealth metrics calculated with three or less months of runout were not credible. As a result, CMS has granted the Commonwealth permission to calculate the performance metrics using exactly six months of runout, using the "DPW Accepted Date" to run the queries "as of" the six-month mark.

In addition, when encounter data is corrected, the new data does not replace the old automatically, meaning that an encounter can be reported multiple times. An important cleaning procedure is used to identify and remove duplicate encounter records. PeopleStat has worked extensively to ensure that duplicate encounter records have been removed. To de-duplicate the data, People State first looks at the claim type for the claim, then use a specific series of fields to rank the records and eliminate all but the first based on a series of fields; that is, if the fields RID and MCO and BEGIN_DATE are used in the sort for the ranking, the first record based on those three fields should be kept. There are six groupings of fields for these sorts based on the type of claim — Inpatient, Outpatient, Professional, Pharmacy, Long-Term Care, and Dental. As noted previously, PeopleStat acts independently of OMHSAS and OMAP. It has direct access to the data warehouse utilized by the Medicaid agency for encounter data and claims. The data are automatically updated any time a provider submits a claim or encounter data. In addition, CMS has validated the metrics against the SUD databook with the Commonwealth making minor changes as identified through an iterative process.

The third limitation is related to the type of design being used. While the ITS design is the strongest available in the absence of a randomized trial or matched control group, there are some threats to the validity of results in the design.[12] The primary threat is that of history, or other changes over time happening during the waiver period. This ITS design is only valid to the extent that the waiver program was the only thing that changed during the evaluation period. Other changes to policies or programs could affect the outcomes being measured here. We have attempted to control this threat by considering other policy and program changes happening concurrent to the waiver period interventions. In addition, we are aware that impacts of the COVID-19 pandemic likely significantly affect the trend seen here. The presentation of findings below notes the dates of other changes and analyzes the degree to which the slope of the trend line changes after implementation of other interventions are made.

A related threat to the validity of this evaluation is external (history). Since OMHSAS has not identified a comparison group (a group of Medicaid managed care members who would be eligible for the waiver interventions but who will not receive them and/or for whom data will not be collected), it is difficult to attribute causality. It is less certain whether the changes observed in outcomes are due entirely to the waiver interventions, rather than some external, outside cause (including other program and policy changes described earlier). This is further complicated that in the pre-Demonstration time period, Medicaid members could have been receiving other SUD services paid for by another source (e.g., state-block grant) that are not counted in our pre-Demonstration Medicaid data. This means that some observed increases in services might be due to changes in payment source rather than an actual increase in the number of members receiving services. This is reflected in our description of findings, below.

However, the ITS design controls for this threat to *some* degree, by linking what would have likely happened (e.g., forecasting the trajectory of counts and rates over time) without any program changes and comparing this forecast to actual changes over time. To strengthen this design as much as possible, we collected as many data points as possible across multiple years preceding waiver changes. This allows for adjustment of seasonal or other cyclical variations in the data. Additionally, the design will examine multiple change points, identifying key areas of major program and policy adjustments, so that with each major milestone accomplishment corresponding changes to metrics can be observed. One potentially confounding factor of this design is that many of the Demonstration activities proposed are not new interventions, but represent programs that would have no longer been funded without the waiver, due to other rule changes. It is very difficult to predict a trend line in that situation (programs being discontinued).

However, even though programmatic changes in this Demonstration are modest, the hypotheses put forth in this document do assume some small improvement over current trends. If the data is not available to forecast negative trends that may happen without these programs, the current model should still be able to show the minor improvements indicated in these hypotheses.

[12] 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.

The ITS analysis also attempts to include a sensitivity analysis to determine the degree to which specific ITS assumptions impact the analysis. Specifically, the degree to which the assumption that trends in time are linear versus non-linear. Additionally, this model assumes that changes will occur directly after the intervention. However, due to known delays in several implementation steps, we expect that for some outcomes, there will be a significant lag between the start of the waiver and observed outcomes. We attempt to limit this threat to validity by triangulating our data. Encounter data trends across multiple time periods will be compared to trends happening at other points in time (other large policy or program or environmental shifts that might influence the slope of the trend in addition to the Demonstration). In addition, key informant interviews will be used to inform the quantitative findings and explain the degree to which individuals are seeing Demonstration impacts.

Another threat to validity in this design may be the ability to measure the outcome rate of interest for the desired period of time both before and after waiver implementation. Evaluators will work closely with OMHSAS and their data teams to assure that complete data is available for each metric and discuss any specific data concerns or considerations on a metric-by-metric basis.

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

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

Qualitative data, while useful in confirming quantitative data and providing rich detail, can be compromised by individual biases or perceptions. Key informant interviews, for example, represent a needed perspective around context for Demonstration activities and outcomes. However, individuals may be limited in their insight or understanding of specific programmatic components, meaning that the data reflects perceptions, rather than objective program realities. This report attempts to address these limitations by collecting data from a variety of different perspectives to help validate individuals' reports. Finally, results have been reviewed with stakeholders to confirm findings.

Table of Evaluation Metrics and Status for Interim Evaluation Reporting

Metric	Milestone/Hypothesis Number	Current Status
Number of individuals enrolled in Medicaid managed care with an SUD diagnosis. (CMS Metric #3)	Milestone 1 Hypothesis 1	Included in initial draft.
Percentage of individuals enrolled in Medicaid managed care with an SUD diagnosis.	Milestone 1 Hypothesis 1	Added to the revised draft.

Metric	Milestone/Hypothesis Number	Current Status
Number and percentage of individuals enrolled in Medicaid managed care using each of the following critical LOCs: early intervention, outpatient services, IOP, and PHP services, residential and inpatient services, WM, and MAT. (CMS Metrics #7–12)	Milestone 1 Hypothesis 1	Numbers were included in the initial draft. Percentages have been added to the revised draft.
Number and percentage of contracts that require utilization review based on ASAM admission, continuing stay, and discharge criteria for all ASAM LOCs.	Milestone 2 Hypothesis 2	Added to the revised draft.
Number of MCOs whose prior authorization and utilization reviews are based on ASAM residential placement criteria.	Milestone 2 Hypothesis 2	Added to the revised draft.
Number of providers trained to use ASAM as assessment tool.	Milestone 2 Hypothesis 2	Provided in narrative of initial draft, and added to table in revised draft.
Medicaid ASAM placement guidelines created for Medicaid-only providers.	Milestone 2 Hypothesis 2	Added to revised draft.
Number and percentage of individuals enrolled in Medicaid managed care treated in an IMD for SUD. (CMS Metric #5)	Milestone 2 Hypothesis 2	Two data points provided in initial draft. Further analysis will be included in summative report as more data become available.
Average LOS for individuals enrolled in Medicaid managed care treated in an IMD for SUD. Move to milestones. (CMS Metric #36)	Milestone 2 Hypothesis 2	Two data points provided in initial draft. Further analysis will be included in summative report as more data become available.
Provider education on ASAM placement guidelines conducted in first 12 months.	Milestone 2 Hypothesis 2	Provided in initial draft.
Maintenance of existing providers.	Milestone 4 Hypothesis 3	Provided in initial draft.
Bed capacity. (CMS Metric #10)	Milestone 4 Hypothesis 3	The Commonwealth is working to pull historical data for this metric. It is not available for the Interim Report, but we report all available data in the Summative Evaluation Report.
The number of new providers accepting Medicaid patients.	Milestone 4 Hypothesis 3	Provided in initial draft.

Metric	Milestone/Hypothesis Number	Current Status
Number and rate of providers reviewed for compliance.	Milestone 3 Hypothesis 4	The compliance review tool was still being finalized as the interim report was being written, so data is unavailable. This data will be reported in the Summative Evaluation Report.
Number and rate of providers in compliance.	Milestone 3 Hypothesis 4	
Initiation of AOD treatment: Initiation of AOD treatment through an inpatient admission, outpatient visit, IOP encounter, or PHP within 14 days of the index episode start date/eligible population. (CMS Metric #15)	Milestone 5 Hypothesis 5	The Commonwealth has not yet programed this metric so that data can be reported. At this time, the Commonwealth is working to either finish programming of the metric or develop either 1) other options to get the data or 2) an alternative metric.
Engagement of AOD treatment: Two or more inpatient admissions, outpatient visits, IOP encounters, or PHPs beginning the day after the initiation encounter through 29 days after the initiation event/eligible population. (CMS Metric #15)	Milestone 5 Hypothesis 5	
Use of opioids at HDO. (CMS Metric #18)	Milestone 5 Hypothesis 5	Reported in initial draft.
Concurrent use of opioids and benzodiazepines: Beneficiaries with concurrent use of prescription opioids and benzodiazepines/beneficiaries. (CMS Metric #21)	Milestone 5 Hypothesis 5	Reported in initial draft.
Continuity of pharmacotherapy for OUD: Beneficiaries with 180 days continuous pharmacotherapy treatment with an OUD medication. (CMS Metric #22)		Reported in initial draft.
Follow-up after discharge from the ED for MH within seven days or 30 days: Beneficiaries with an outpatient visit, IOP visit, or PHP with a MH practitioner within seven days or 30 days after an ED visit with a principal diagnosis of mental illness/ED visits with a principal diagnosis of mental illness. (CMS Metric #17)	Milestone 5 Hypothesis 5 in Evaluation Design Moved to Milestone 6 Hypothesis 6 in Interim Evaluation Report	Reported in initial draft, under Milestone 6.
Follow-up after discharge from the ED for AOD dependence within seven days or 30 days: Beneficiaries with an outpatient visit, IOP visit, or PHP with a MH practitioner within seven days or 30 days after an ED visit with a principal diagnosis of AOD dependence/ED visits with a principal diagnosis of AOD. (CMS Metric #17)	Milestone 5 Hypothesis 5 in Evaluation Design Moved to Milestone 6 Hypothesis 6 in Interim Evaluation Report	Reported in initial draft, under Milestone 6.

Metric	Milestone/Hypothesis Number	Current Status
Rate of overdose deaths in the Commonwealth: Number of overdose deaths/number of deaths. (CMS Metric #26)	Milestone 5 Hypothesis 5	Added to revised draft.
Access to preventive/ambulatory health services for adult Medicaid managed care beneficiaries with SUD: The number of Medicaid beneficiaries with SUD who had an ambulatory or preventive care visit/number of beneficiaries with SUD. (CMS Metric #32)	Milestone 5 Hypothesis 5	Added to revised draft.

Section 6
Results

The following section outlines results from the ITS analysis as well as both quantitative and qualitative descriptive analysis. Conclusions drawn from these finds are presented in the following section (Section 7).

Milestone 1

Milestone 1: Improve access to critical LOCs for OUD and other SUDs for individuals in Medicaid managed care. Critical LOCs are defined as early intervention, outpatient services, IOP and PHP services, residential and inpatient services, WM, and MAT.
Hypothesis 1: The 1115 SUD Demonstration will increase access to the specified critical LOCs for individuals in Pennsylvania Medicaid managed care compared to prior to the waiver.

Has access to critical LOCs as defined in the Demonstration improved in Medicaid managed care?

The Commonwealth completed its crosswalk of ASAM Criteria with the current system of care and providers have begun to use ASAM Criteria for placement decisions and admission to each LOC. However, work continues to align service delivery descriptions and expectations. Training for providers continues and DHS and DDAP have worked together to develop ASAM service descriptions and delivery standards 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 working to ensure that the coding is consistent with any needed changes. The Demonstration will ensure that providers will align delivery with the new ASAM service alignment starting July 1, 2021, with full compliance required by July 1, 2022.

There were some delays in providers reaching alignment by July 1, 2021. COVID-19 required changes to planned trainings and a web-based system was developed. In addition, there was some uncertainty and concern on the part of providers around the resources required to reach full alignment. In June 2021, OMHSAS and DDAP agreed to allow providers to apply for extensions for complete implementation. During focus groups conducted during August 2021 and September 2021, OMHSAS and DDAP stakeholders expressed confidence that the majority of concerns have been resolved. There was confidence that providers will be able to comply with all criteria for the LOC they provide in the near future.

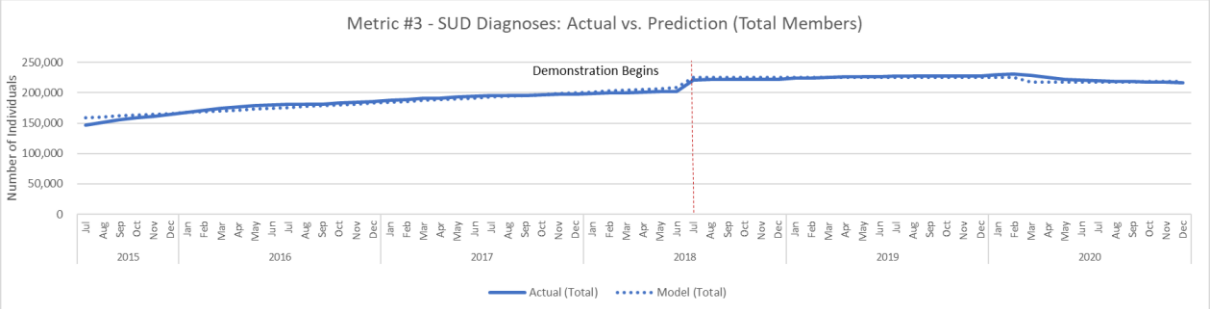
Some specific LOCs are still a challenge for providers. OMHSAS and DDAP stakeholders acknowledged that this was a significant change in terms of the number of hours of service and staffing ratios. One specific example is ASAM 2.1 because there is not a separately licensed IOP LOC in the Commonwealth. The requirements for this level might be difficult for many providers to meet and many providers may choose not to continue to provide this LOC. DDAP considers WM at inpatient ASAM 3.7-WM and ASAM 4.0-WM to be substantially aligned, but WM at the ambulatory LOCs such as ASAM 1-WM and ASAM 2-WM are still being assessed for alignment with the ASAM Criteria. Overall, in the past year, stakeholders report that a great deal of progress has been made in alignment across all providers. DDAP has an alignment self-assessment and facilities checklists available on the website, and to date close to 50 facilities have completed the checklist showing substantial alignment. DDAP is providing technical assistance to all providers for all LOCs to help support their transitions.

To estimate changes in SUD service delivery during the Demonstration, we performed ITS analyses with performance metrics and enrollee data. As noted in the Methodology section of this report, ITS analyses estimate the trends in a variable — such as SUD diagnoses or outpatient services — before and after the start of a program and attempts to measure any resulting trend changes. ITS is especially useful for evaluating population-level time-series health data.[13] It should be noted, however, that there might be other factors impacting change beyond the Demonstration.

The following analyses measure change in utilization and service delivery before and after Demonstration implementation, which began in July 2018. When reviewing the pre-Demonstration data, there are monthly increases and decreases as compared to the trend, but no consistent patterns, so the analyses do not need to control for seasonality. The analyses do control for COVID-19 beginning in March 2020. Analyses of subpopulations appear in Appendix B.

SUD Diagnosis

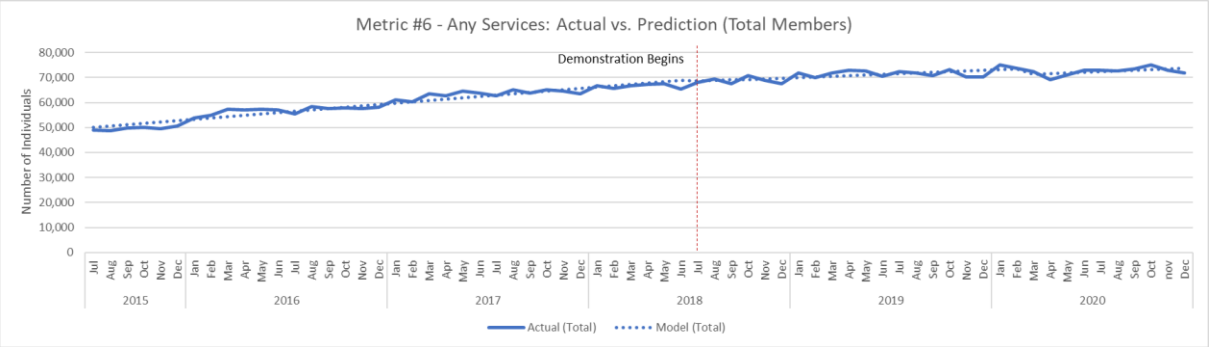
The ITS analysis for Metric #3 across all members revealed an initial increase in individuals (approximately 16,737) with SUD diagnoses upon the Demonstration beginning. This was followed by an additional increase of approximately 40 more individuals per month. The effect of the Demonstration, as well as its effect over time, were statistically significant ($p < .001$). The effect of COVID-19 was also statistically significant ($p < .01$). The one-month initial increase in this metric appears to be very high and potentially due to data issues.



[13] Bernal, J. L., Cummins, S., & Gasparrini, A. (2017). Interrupted time series regression for the evaluation of public health interventions: A tutorial. *International Journal of Epidemiology, 46*(1), 348–355. Retrieved from https://doi.org/10.1093/ije/dyw098.

SUD Any Service

The ITS analysis for Metric #6 across all members revealed an initial decrease in individuals (approximately 331) receiving any SUD services paid by Medicaid upon the Demonstration beginning. This was followed by an increase of approximately 258 more individuals per month. The effects of the Demonstration over time were statistically significant ($p < .001$), as was the effect of COVID-19 ($p < .05$).[14] It is possible that the required new training on ASAM placement criteria in 2018 may account for the initial slight decline in services as practitioners spent two days in non-revenue producing services, followed by a gradual increase in services as implementation moved forward. At the onset of COVID-19 all services declined drastically as personal concern, stay at home orders, and other public health measures drastically reduced in-patient treatment options.



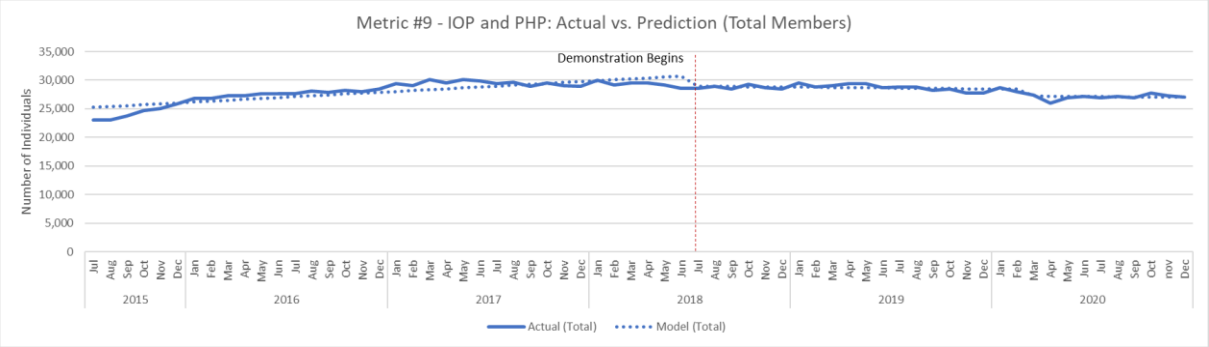
		Percentage of Medicaid Enrollees Percentage of Enrollees with an SUD Diagnosis					
Metric	**Description**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
CMS #3	Percentage of members with an SUD diagnosis	--[15]	7.1%	7.8%	8.3%	8.2%	8.2%
CMS #6	Percentage of members receiving any SUD service	--	2.3%	2.5%	2.6%	2.6%	2.0%

[14] Full ITS Regression analysis results are included in Appendix B of the report.

[15] 2015 member data not available.

Intensive Outpatient Services Partial Hospitalization

The ITS analysis for Metric #9 across all members revealed an initial decrease in individuals (approximately 1,754) receiving IOP and PHP services paid for by Medicaid upon the Demonstration beginning. This was followed by a decline of approximately 27 individuals per month. These effects were all statistically significant ($p < .001$). The effect of COVID-19 was also statistically significant ($p < .05$).



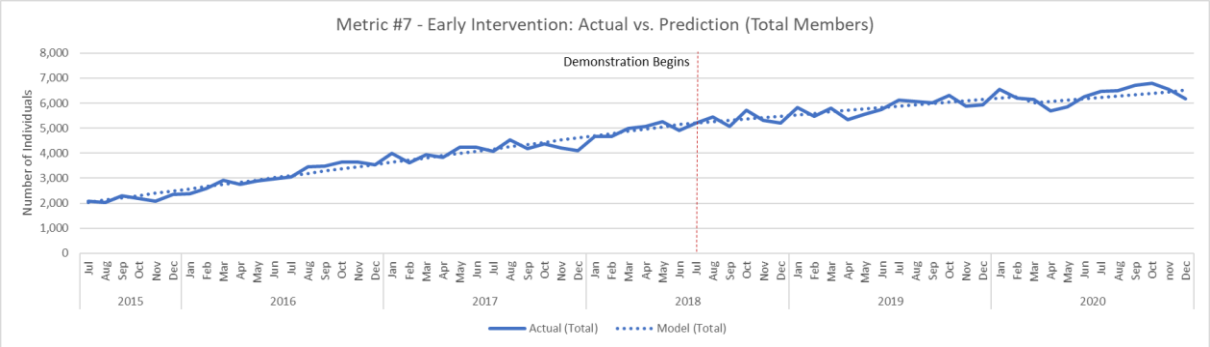
		Percentage of Medicaid Enrollees Percentage of Enrollees with an SUD Diagnosis					
Metric	**Description**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
CMS #9	Percentage of members receiving IOP and PHP services	--[16]	1.1%	1.1%	1.1%	0.3%	0.2%

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?

[16] 2015 member data not available.

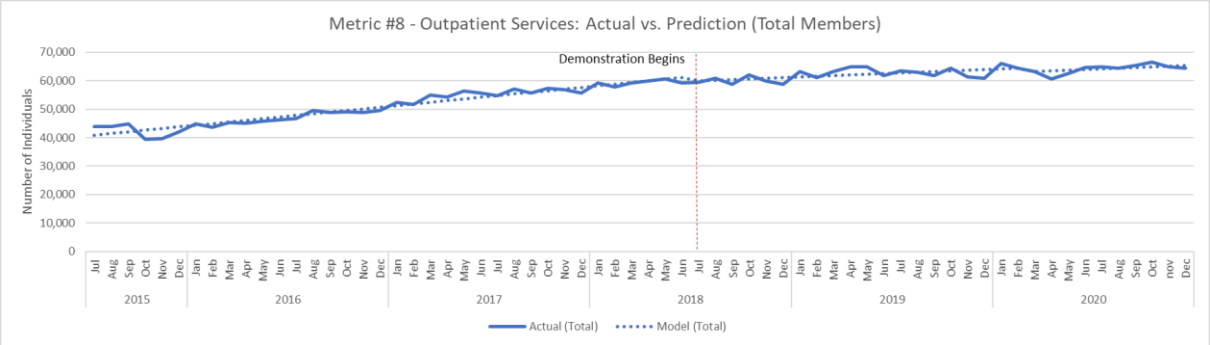
Early Intervention Services

The ITS analysis for Metric #7 across all members revealed a small initial increase in individuals (approximately 71) receiving early intervention Medicaid services upon the Demonstration beginning. This was followed by an increase of approximately 55 more individuals per month. These effects of the Demonstration over time were statistically significant ($p < .001$), while the effect of COVID-19 was not statistically significant. As you can see in the chart below, early intervention services showed a historical trend increase in the 3.5 years prior to the Demonstration. This increase is probably related to the OMAP MCO Screening, Brief Intervention, and Referral to Treatment (SBIRT) adoption starting in 2016 and subsequent performance improvement projects (PIPs). However, the additional increase seen in the ITS analysis shows a greater increase than would have been predicted based on the historical trend.



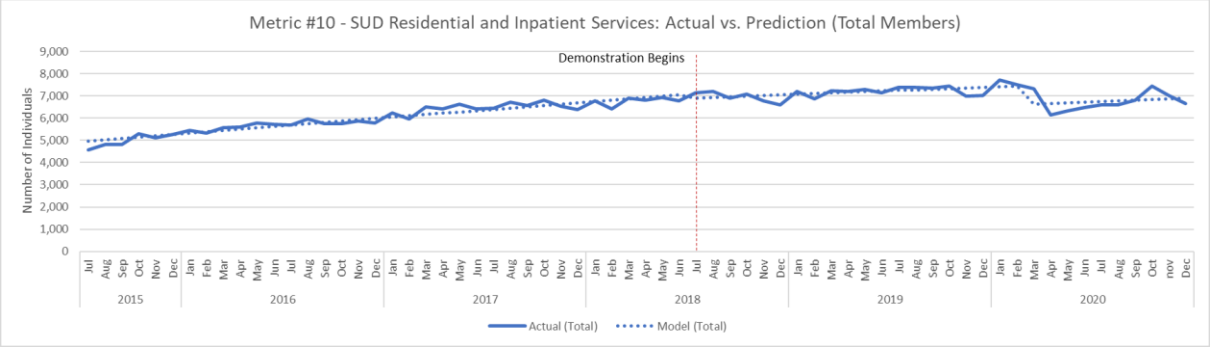
Outpatient Services

The ITS analysis for Metric #8 across all members revealed an initial decrease in individuals (approximately 1,169) receiving Medicaid outpatient services upon the Demonstration beginning. This was followed by an increase of approximately 241 more individuals per month. These effects were statistically significant ($p <.001$), while the effect of COVID-19 was not. As was the case with early intervention services, these increasing trends began well before the Demonstration implementation. Increases between 2016 and 2018 were likely due to the PIPs undertaken by MCOs. However, the ITS model still showed a significant impact over the already observed increases.



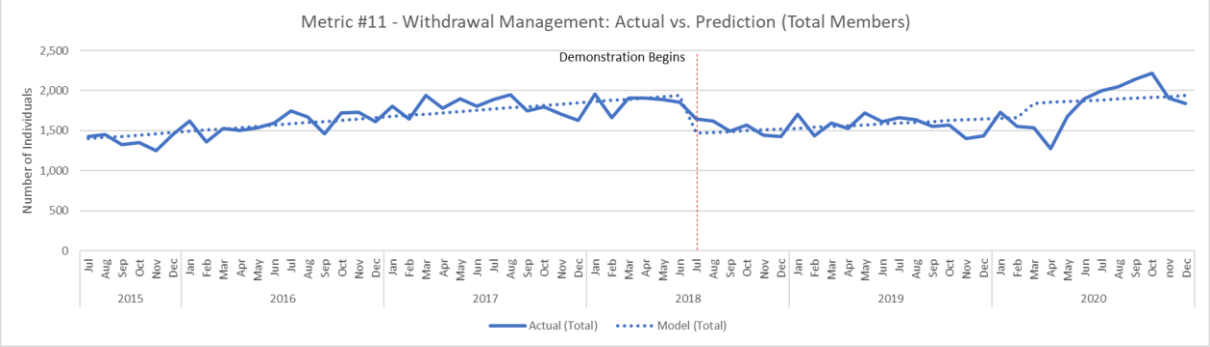
Residential and Inpatient Services

The ITS analysis for Metric #10 across all members revealed an initial decrease in individuals (approximately 162) receiving SUD residential and inpatient services paid for by Medicaid upon the Demonstration beginning. This was followed by an increase of approximately 30 individuals per month. The effects of the Demonstration over time was statically significant ($p < .01$), as was the effect of COVID-19 ($p < .001$). It is possible that the initial decline in services was impacted by required trainings in 2018, where providers were not available for two days during early implementation.



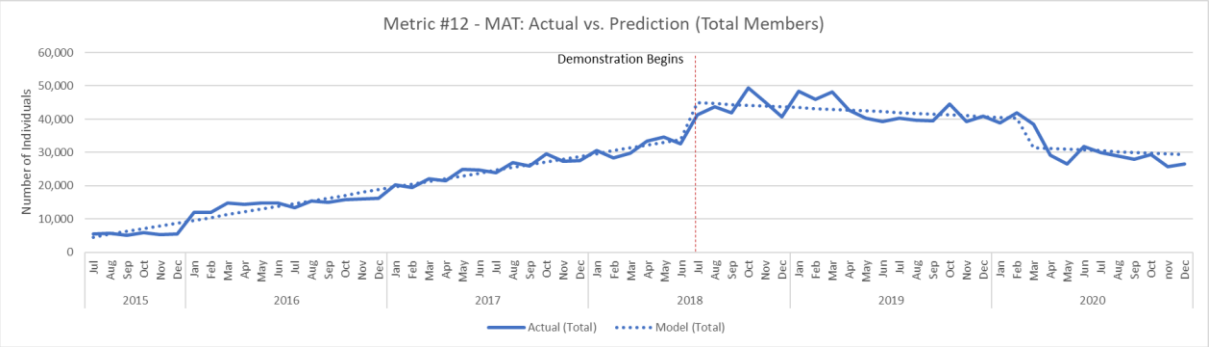
Withdrawal Management

The ITS analysis for Metric #11 across all members revealed an initial decrease in individuals (approximately 472) receiving Medicaid WM services upon the Demonstration beginning. This was followed by an increase of approximately 10 more individuals per month. These effects were not statistically significant.



Medication-Assisted Treatment

The ITS analysis for Metric #12 across all members revealed an initial increase in individuals (approximately 11,078) receiving MAT services paid for by Medicaid upon the Demonstration beginning. The increase post-Demonstration was statistically significant, but likely also influenced heavily by confounding factors. The Commonwealth implemented the Centers of Excellence (COE) and other statewide initiatives to increase MAT usage during the same time period. After the initial increase, there was a decrease of approximately 244 fewer individuals per month. These effects, as well as the effect of COVID-19, were all highly statistically significant (p <.001). The decrease is likely due in part to both the pandemic and Medicare's new coverage of MAT (beginning in 2020), which lead to a significant decrease in MAT billings for the dual-eligible population.



		Percentage of Enrollees with an SUD Diagnosis					
Metric	**Description**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
CMS #7	Percentage receiving IOP and PHP services	--[17]	0.1%	0.2%	0.2%	0.3%	0.2%
CMS #8	Percentage receiving early intervention services	--	1.9%	2.2%	2.2%	2.3%	1.6%
CMS #9	Percentage receiving outpatient services	--	1.1%	1.1%	1.2%	0.3%	0.2%
CMS #10	Percentage receiving residential and inpatient services	--	0.2%	0.3%	0.3%	0.3%	0.2%
CMS #11	Percentage receiving WM services	--	0.1%	0.1%	0.1%	0.1%	0.1%
CMS #12	Percentage receiving MAT	--	0.6%	1.1%	1.5%	1.4%	0.9%

[17] 2015 member data not available.

Consumer Satisfaction — Access to Care

Generally, surveys conducted during 2019, 2020, and 2021 revealed a high level of overall satisfaction with access to care, with more than 85% of respondents responding "yes" to the question "In the past 12 months, were you able to get the help you needed."

CFST	Access to Care Question Proxy	Number Reporting "Yes" 2019–2020	Percentage Reporting "Yes" 2019–2020	Number Reporting "Yes" 2021 (quarter)	Percentage Reporting "Yes" 2021 (quarter)
CFST #1	In the last 12 months, were you able to get the help you needed?	131	98%	49	100%
CFST #2	In the last 12 months, were you able to get the help you needed?	N/A	N/A	536	86%

Milestone 2

Milestone 2: Use of evidence-based, SUD-specific patient placement criteria.
Hypothesis 2: The 1115 SUD Demonstration will lead to use of ASAM placement criteria by all providers by the end of the first year of the Demonstration project.

Has the use of evidence-based SUD-specific patient placement criteria (ASAM Criteria) been implemented across all LOCs for all patient populations?

OMHSAS required PCs/BH-MCOs to use ASAM patient placement criteria for Medicaid utilization review and admission prior authorization to Residential Facilities on January 1, 2019. DDAP issued guidance to the counties to use ASAM admission criteria as of May 1, 2018. DDAP began requiring ASAM Criteria for treatment plans, continued stay, and discharge criteria as of May 2019.

Some stakeholders report that use of the ASAM for admission criteria is consistent across providers, but many reported a perspective that it is not regularly being used in treatment plans, continued stay, and discharge criteria. OMHSAS and DDAP are working together to develop a protocol and tool that will monitor, among other compliance requirements, the degree to which ASAM Criteria are being used in continued stays and discharge decisions. Once this protocol is in use, more statements that are definitive can be made about use of ASAM placement criteria.

Metric Name	Number/Percentage	Description
Number and percentage of contracts that require utilization review based on ASAM admission, continuing stay, and discharge criteria for all ASAM LOCs.	24/24 (100%)	As of July 2020, all contracts have been revised to require utilization review based on ASAM Criteria.

Metric Name	Number/Percentage	Description
Number of MCOs whose prior authorization and utilization reviews are based on ASAM residential placement criteria.	4/4 (100%)	Currently, all MCO's prior authorizations and utilization reviews are based on ASAM residential placement criteria.
Number of providers trained to use ASAM as assessment tool.	12,750	DDAP has two options to complete required ASAM training, a two-day live classroom offering and a series of on-demand modules.
Medicaid ASAM placement guidelines created for Medicaid-only providers.	100%	All residential providers have received ASAM guidance for all LOCs.
Provider education on ASAM placement guidelines conducted in first 12 months.	7,500	From 2018 through June 2019, over 7,500 individuals were trained in the in-person two-day skill building training.

To date, approximately 12,750 individuals have been trained. DDAP has two options to complete required ASAM training, a two-day live classroom offering and a series of on-demand modules. From 2018 through June 2019, over 7,500 individuals were trained in the in-person two-day skill building training. The live classroom course was reformatted for a virtual experience. Approximately 400 students attended virtual ASAM Criteria training in 2020. Since the inception of the ASAM Criteria, over 9,800 Pennsylvania provider staff have been trained in the two-day classroom course. Nine hundred and seventy-two Pennsylvania-based organizations ordered subscriptions to the on-demand, online modules for approximately 2,150 potential users.

Two CMS metrics were identified for the evaluation: IMD placement and LOS. Since only two data points are available regarding IMD placement and LOS, an ITS analysis cannot be done on these metrics. As shown in the table below, the number of individuals placed in an IMD decreased between 2019 and 2021. Additionally, LOS increased by approximately 0.5 days. All agreements have been modified to require utilization review based on ASAM admission, continuing stay, and discharge criteria for all ASAM LOCs. *Note: Metrics #5 and #36 have been moved to Milestone 2 to align with CMS technical specifications 5.0.*

Metric Number	Metric Name	Time Period	Demonstration Denominator	Demonstration Numerator or Count	Demonstration Days
5	Medicaid Beneficiaries Treated in an IMD for SUD	July 1, 2018 through June 30, 2019	-	64,113	-
		July 1, 2019 through June 30, 2020		59,836	
36	Average LOS in IMDs	July 1 2018 through June 30, 2019	36,079	229,696	6.37 days
		July 1, 2019 through June 30, 2020	31,704	216,538	6.83 days

Milestone 4

Milestone 4: Improve provider capacity at critical LOCs including MAT for OUD in Medicaid.

Hypothesis 3: The 1115 SUD Demonstration will increase provider capacity as defined below for SUD treatment at critical LOCs for individuals in Pennsylvania Medicaid managed care.

Has the availability of providers in Medicaid accepting new patients including MAT improved under the Demonstration?

The Commonwealth has not done a capacity review since development of the waiver application.

Once the alignment of provider standards to ASAM is completed, OMHSAS and DDAP believe there will be sufficient outpatient and IOP capacity as well as capacity at most of the residential ASAM LOCs. Without a formal assessment, complete up-to-date numbers for all available providers is difficult to document. However, both OMHSAS and DDAP stakeholders report they believe that there have been more MAT licenses granted since implementation and are certain that overall treatment capacity has increased for both ambulatory and residential.

Workforce issues, as is the case in most other states, continues to be a barrier to overall system capacity. This issue will likely be a point of discussion for the foreseeable future. Providers emphasized that the use of telehealth is a solution to some capacity challenges and that changes to billing and authorization requirements made during the COVID-19 PHE should be maintained after the PHE is over.

The Commonwealth has calculated the required SUD 1115 Demonstration metrics on SUD provider availability.

Metric	Metric Name	Demonstration Count July 1, 2018–June 30, 2019	Demonstration Count July 1, 2019–June 30, 2020
13	SUD Provider Availability	6,274	5,014
14	SUD Provider Availability — MAT	3,753	3,693

The metrics above reflect a decline in the delivery of services by unique providers because the Commonwealth only counts enrolled providers who **delivered** care in FFS, which was affected by the pandemic for time period January 2020 through June 2020. The actual number of enrolled SUD providers has not declined to the same extent. The enrolled SUD providers by provider type and specialty show that enrollment remained steady if the delivery of care is not factored into the analysis.

OMHSAS BH Homes and FFS	Provider Type	Specialty	Description	FY 2018–2019 Provider Count	FY 2019–2020 Provider Count	November 2021 Provider Count
	8	84	Methadone Maintenance (MAT in an OTP)	66	66	64
	8	184	D&A Outpatient (Now ASAM 1.0)	273	273	283
	11	128	D&A IOP (Now ASAM 2.1)	181	181	169
	11	129	D&A PHP (Now ASAM 2.5)	60	60	61
	11	131	D&A Halfway House (Now ASAM 3.1)	34	34	33
	11	132	D&A Medically Monitored Detoxification (Now ASAM 3.7-WM)	44	44	48
	11	133	D&A Medically Monitored Residential, Short-Term (Converting to ASAM 3.5 and 3.7)	83	83	85
	11	134	D&A Medically Monitored Residential, Long-Term	83	83	85
	11	184	Outpatient D&A (Converting to ASAM 3.5 and 3.7)	159	159	163
	Unduplicated Methadone Maintenance Providers			274	274	-
	Unduplicated SUD			373	373	-

All Enrolled Regardless of Program	Provider Type	Specialty	Description	FY 2018–2019 Provider Count	FY 2019–2020 Provider Count
	8	84	Methadone Maintenance (MAT in an OTP)	66	68
	8	184	D&A Outpatient (Now ASAM 1.0)	274	288
	11	128	D&A IOP (Now ASAM 2.1)	181	189
	11	129	D&A PHP (Now ASAM 2.5)	60	65
	11	131	D&A Halfway House (Now ASAM 3.1)	34	34
	11	132	D&A Medically Monitored Detoxification (Now ASAM 3.7-WM)	44	48
	11	133	D&A Medically Monitored Residential, Short-Term (Converting to ASAM 3.5 and 3.7)	83	87
	11	134	D&A Medically Monitored Residential, Long-Term	83	87
	11	184	Outpatient D&A (Converting to ASAM 3.5 and 3.7)	159	170
	Unduplicated Methadone Maintenance Providers			275	289
	Unduplicated SUD			374	393

The number of providers enrolled has remained constant or increased over time. However, as discussed previously the number of providers actually providing services has declined due to the pandemic.

The number of Medicaid enrolled PHP providers is 61. Of those, DDAP data shows that 53 providers are aligned with ASAM Level 2.5 (PHP) already. The number of Medicaid Medically Monitored Detoxification facilities enrolled in Medicaid is 28 of which eight facilities are aligned with ASAM Level 3.7-WM.

Counts of providers do not align with stakeholder perception. Once ASAM alignment is complete, certification reviews will reflect the actual number of beds at each LOC and a complete analysis of capacity can be finalized.

Milestone 3

Milestone 3: Use of nationally recognized SUD-specific program standards to set provider qualifications for RTFs.
Hypothesis 4: The 1115 SUD Demonstration will establish ASAM Criteria and program standards to set provider qualifications for all Residential Facilities by January 2021.

Has OMHSAS established ASAM Criteria and program standards to set provider qualifications for all Residential Facilities?

Since the Midpoint Assessment, OMHSAS and DDAP have had challenges implementing residential and residential-WM provider alignment with ASAM. As mentioned previously, the size of the system transformation effort has been the primary challenge. Providers requested more time than the Commonwealth had originally planned to make the transition. However, stakeholders (OMHSAS and DDAP) report that providers are now making strides in alignment and there is more confidence, as compared to reporting during the Midpoint Assessment, that provider alignment will be accomplished by July 1, 2022.

DDAP has issued specific information about the credentialing requirements and which providers can be grandfathered.

OMHSAS and DDAP are currently working on a monitoring protocol, a tool, and a timeline, anticipating January 2022 start for monitoring activities. Stakeholders expressed confidence that the first monitoring reviews (ASAM Level 3.5) would be complete by summer 2022. An analysis of these reviews will be included in the Summative Evaluation.

Milestone 5

Milestone 5: Improvements in comprehensive treatment and prevention strategies to address opioid abuse and OUD for individuals in Medicaid managed care.
Hypothesis 5: The 1115 SUD Demonstration will improve outcomes for individuals in Pennsylvania Medicaid managed care under the following metrics: • **AOD IET.** • **Use of opioids at high dosage (HDO).** • **Use of opioids from multiple providers (UOP).** • **Concurrent use of opioids and benzodiazepines.** • **Continuity of pharmacotherapy for OUD.** • **Follow-up after discharge from the ED for MH or AOD dependence.** • **Rate of overdose deaths in the Commonwealth.** • **Access to preventive/ambulatory health services for adult Medicaid managed care beneficiaries with SUD.**

Will improvements in treatment and prevention strategies in Medicaid managed care improve outcomes of individuals with an SUD in Medicaid managed care as demonstrated by: More effective initiation of treatment, decrease use of opioid at HDOs, reduce use of multiple opioids from multiple providers, reduce concurrent use of opioids and benzodiazepines, improve continuity of pharmacotherapy for OUD, decrease overdose deaths and increase access to preventive/ambulatory services?

Metric Number	Metric Name	Time Period	Demonstration Denominator	Demonstration Numerator or Count	Demonstration Rate
18	Use of Opioids in HDO in Persons Without Cancer	January 1, 2019 through December 31, 2019	46,035	8,731	18.96
21	Concurrent Use of Benzodiazepines	January 1, 2019 through December 31, 2019	46,036	10,816	23.49
22	Continuity of Pharmacotherapy for OUD	January 1, 2019 through December 31, 2019	23,801	11,307	47.51
26	Overdose Deaths (count)	January 1, 2019 through December 31, 2019	N/A	2,620	N/A
27	Overdose Deaths (rate)	January 1, 2019 through December 31, 2019	3,926,077	2,620	6.67
32	Access to Preventive/ Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD	January 1, 2019 through December 31, 2019	214,042	166,909	77.98

No descriptive analysis of trends in these metrics is available at this time due to limited data points. Currently, only data for CY 2019 are available for Metrics 18, 21, 22, 26, 27, and 32, due to delays in technical specifications for these metrics. The CY 2020 data are still being programmed according to the new specifications. These metrics will be included in the Final Evaluation Report.

Consumer Perceptions — Improved Outcomes

Generally, surveys conducted during 2019, 2020, and 2021 revealed a high level of overall satisfaction with consumer progress in treatment, with between 75% and 90% of respondents reporting overall satisfaction with treatment outcomes and/or the perception that their quality of life or community participation improved after treatment.

Milestone 6

Milestone 6: Improved care coordination and transition between LOCs for individuals in Medicaid managed care.

Hypothesis 6: The 1115 SUD Demonstration will improve follow-up after discharge from EDs and decrease readmissions for individuals in Pennsylvania Medicaid managed care with SUD.

Has the Demonstration impacted access to care for individuals with SUD in Medicaid managed care by linking beneficiaries with community-based services and supports following stays in residential and inpatient treatment facilities and reducing readmission rates for treatment?

DDAP continues efforts to improve and increase case management services provided by SCAs, making some funding available through block grants to help strengthen existing case management services. Stakeholders expressed a desire for DDAP to go beyond just tracking members through LOCs. Instead, they are encouraging and supporting case management that emphasizes a community-based and individualized approach. ASAM requirements are being integrated into case management expectations.

Metric Number	Metric Name	Time Period	Demonstration Denominator	Demonstration Numerator or Count	Demonstration Rate/ Percentage
17 (1)	Follow-up After ED Visit AOD Abuse or Dependence (30 days)	CY 2019	96,090	81,005	84%
17 (1)	Follow-up After ED Visit AOD Abuse or Dependence (seven days)	CY 2019	96,090	27,880	29%
17 (2)	Follow-up After ED Visit Mental Illness (30 days)	CY 2019	179,788	85,091	47%
17 (2)	Follow-up After ED Visit Mental Illness (seven days)	CY 2019	179,788	47,611	27%

No descriptive analysis of trends in these metrics is available at this time due to limited data points. Currently, only data for CY 2019 are available due to delays in technical specifications for these metrics. The CY 2020 data are still being programmed according the new specifications. This measure will be included in the Final Evaluation Report.

Consumer Perceptions — Care Coordination

Generally, surveys conducted during 2019, 2020, and 2021 revealed that the majority of respondents reported being an active participant in their treatment plans and feeling that they are an important part of the treatment process.

CFST	Consumer Reported Outcomes	Number Reporting "Better[18]" 2019–2020	Percentage Reporting "Better" 2019–2020	Number Reporting "Better" 2021 (quarter)	Percentage Reporting "Better" 2021 (quarter)
CFST #1	Treatment has improved my overall quality of life.	121	98%	47	96%
CFST #2	What affect has treatment had on your quality of life?	N/A	N/A	544	87%
CFST #3	Average across 11 outcome items.	N/A	N/A	642	73%

Cost Metrics

Pennsylvania examined spending under the Demonstration to spending prior to the implementation of the waiver.

Spending Metric #1 — Total Medicaid SUD Spending in Medicaid Managed Care

The Total Medicaid SUD spending in Medicaid managed care during the measurement period was compared to spending prior to the implementation of the waiver. This was expressed as the percentage of Medicaid managed care capitation rates spent on SUD during the measurement period. The Demonstration was implemented on July 1, 2018 (the beginning of State Fiscal Year [SFY] 2018–2019). After that date, the percentage of the BH capitated rates increased to over 20% of the rate. However, the percentage of the overall physical and behavioral capitation rates combined spent on SUD decreased after the beginning of the Demonstration to under 4%.

Category	SFY 2015–2016	SFY 2016–2017	SFY 2017–2018	SFY 2018–2019	SFY 2019–2020	SFY 2020–2021
Portion of the Medicaid BH managed care rates spent on SUD during the measurement period.	18.5%	18.9%	19.5%	20.3%	20.7%	20.5%
Portion of the Medicaid managed care rates spent on SUD during the measurement period.	4.1%	4.5%	4.5%	4.1%	3.7%	3.5%

[18] Includes responses of "much better" and "a little or somewhat better."

Spending Metric #2 — Total Medicaid SUD Spending on Residential Treatment Within IMDs in Medicaid Managed Care

The Total Medicaid SUD spending on residential treatment within IMDs in Medicaid managed care during the measurement period was compared to residential treatment within IMDs before the Demonstration. The proportion of the BH capitated rates spend on residential treatment within IMDs increased as a percentage of BH capitated rates.

Category	SFY 2015–2016	SFY 2016–2017	SFY 2017–2018	SFY 2018–2019	SFY 2019–2020	SFY 2020–2021
Portion of the Medicaid BH managed care rates spent on IMDs during the measurement period.	15.7%	15.6%	15.8%	16.3%	16.5%	16.4%
Portion of the Medicaid managed care rates spent on IMDs during the measurement period.	3.5%	3.7%	3.6%	3.3%	2.9%	2.8%

As noted below, the portion of the capitation rates spent on SUD and other BH care has decreased since the beginning of the Demonstration as the portion of the capitation rates spent on PH has increased.

Category	SFY 2015–2016	SFY 2016–2017	SFY 2017–2018	SFY 2018–2019	SFY 2019–2020	SFY 2020–2021
BH — SUD	4.1%	4.5%	4.5%	4.1%	3.7%	3.5%
BH — Other	17.9%	19.2%	18.5%	16.2%	14.1%	13.7%
PH (HC PH and CHC)	54.6%	52.8%	54.0%	60.1%	65.3%	65.9%
Total (All Programs)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Section 7
Conclusions

FFCY

The Demonstration was found to provide continuous health insurance for 12 months for approximately 40% of the 38 youth enrolled in the program each year. This resulted in access to health care for all 38 of the enrollees. Annually, 69% of youth received at least one ambulatory care visit. Over time the number of youth with at least one ED visit fluctuated from 26% to 43% with the average number of youth with an ED visit at 36% annually. The number of youth with an inpatient visit was on average 5% annually (ranging from 0% to 11%). The number of youth with a BH encounter was on average 21% annually.

The Demonstration was found to improve or maintain health outcomes for the target population. For example, on average, there was appropriate follow-up after hospitalization (FUH) 43% of the time for the target population. Sixty-seven percent of the population with asthma had appropriate medication management for asthma in DY1 increasing to 100% of the population with asthma in DY2–DY4. Sixty-seven percent of the populations on persistent medication had appropriate medication monitoring in year DY1 increasing to 100% of the population on persistent medication having appropriate monitoring in DY4. Twenty-one percent of the population had an annual preventive visit in each of the DYs. Eighteen percent of the beneficiaries eligible to have a cervical cancer screening received a screening.

SUD

The findings reported here are consistent with a Demonstration that is still in the midst of implementation efforts. Somewhat sharp increases in diagnosis and more gradual increases in access to some levels of SUD care reflect full implementation of ASAM Criteria for assessing treatment needs and making appropriate placements. However, it is hard to explain a very high single month jump of individuals diagnosed during the first implementation month. More gradual increases observed over time after implementation, however, are consistent with early implementation of the ASAM assessment criteria. It is also important to note that the original intent of the waiver was to maintain access to key SUD services that would have been eliminated due to CMS rule changes. Original research hypotheses only anticipated small changes across the entire array of services.

An important theme in discussing Demonstration implementation with key stakeholders is that change takes time. The Department may have under estimated how disruptive providers viewed the changes. However, initial concerns are beginning to lessen with greater communication, technical assistance, and allowing more time for alignment activities.

Initial data are showing small declines in SUD providers, MAT providers specifically. The new required training on ASAM placement criteria in 2018 may account for the initial slight decline in services as practitioners spent two days in non-revenue producing activities, followed by a gradual increase in services as implementation moved forward. However, it is difficult to determine the degree to which lower numbers are due to the Demonstration or the impacts of COVID-19. Given patterns of lower service utilization directly following the start of the

pandemic, this latter factor seems more likely to be affecting capacity. More data, particularly after the official end of the PHE, will allow for more discussion of the impact of COVID-19 on the Demonstration generally and on provider capacity more specifically. In addition, a monitoring protocol is still under development that will provide vital data around the degree to which providers fully transition to ASAM service definitions alignment.

Increases in early intervention, outpatient services, and MAT are consistent with Demonstration goals to more effectively utilize lower LOCs and evidence-based treatment. Increases in early intervention, outpatient services, and MAT may be related to the OMAP MCO SBIRT adoption prior to the Demonstration and the PIPs PH-MCOs have undertaken. The PIPs are an effort to increase utilization in routine outpatient care related to early detection of SUD and outpatient treatment including MAT. The MAT increase post-Demonstration was potentially related to the Commonwealth implementing the COE and other statewide initiatives to increase MAT usage during the same time period.

After the initial increase, there was a decrease in MAT, likely due in part to both the pandemic and Medicare's new coverage of MAT, which lead to a significant decrease in MAT billings for the dual-eligible population. In addition, new managed care prescriber screening requirements took effect requiring all prescribers to be screened for fraud and abuse and separately enrolled in Medicaid. This initiative might have reduced the number of prescribers of MAT and decreased the amount of prescribing of MAT. Many providers did not provide MAT via telehealth during the pandemic. Therefore, the overall number of providers may have stayed constant, but the number providing any MAT services increased, reflective of those providers not wanting to provide via telehealth when in-person appointments were not possible.

While some placements have increased, providers are still working to realize full alignment with ASAM service delivery criteria, which may be affecting access to two key LOCs. Trends show the number of individuals receiving IOP and PHP has decreased fairly steadily since the beginning of the Demonstration with a dip for the pandemic in May 2020. Note that the Commonwealth's standards for IOP and PHP have been clarified to better align with ASAM standards and this could account for fewer programs reporting that they provide PHP, which is substantially different under ASAM from the historic Commonwealth service description. Since these services are in congregate settings, utilization decreased after the beginning of the pandemic in March 2020. While there has been some increase as the pandemic has gone on, the overall utilization of IOP/PHP has continued to decrease due to ASAM alignment.

The number of individuals receiving residential and inpatient services was fairly steady over time up until the beginning of the pandemic (spring 2020) when there was a drop. Utilization increased again beginning in the fall 2020 through March 2021. The impact of COVID-19 on most of the metrics reported here, particularly large decreases in congregate care settings, are a significant factor in Demonstration progress.

Further, some declines in residential and other services seen immediately following Demonstration implementation could be due to the number of providers attending training in the initial months. More than 7,500 providers attended in-person two-day trainings, which meant they were unable to provide services during that time.

Since most providers are still working to provide the full array of services, aligned with ASAM standards of care, it is premature to discuss member outcomes at this time. This will be more thoroughly examined in the Final Evaluation Report.

Section 8

Interpretations, Policy Implications, and Interactions with Other State Initiatives

The SUD 1115 Demonstration has been a key tool in Governor Wolf's Administration's campaign to address SUDs. Throughout the 15 SUD PHEs, the Commonwealth has utilized multiple interventions to address all aspects of OUD. OMHSAS has found DDAP and its SCAs to be good partners in implementing the 1115 Demonstration.

The following is a retrospective description of specific steps to combat SUD taken by the administration.

- The Commonwealth cooperated with DEA's 19th National Prescription Drug Take-Back Day Initiative on October 24, 2020.
- Governor Wolf launched the nation's first innovative, evidence-based SUD stigma reduction campaign on September 28, 2020. Life Unites Us is an evidence-based approach to stigma reduction of SUD specifically for OUD. The partnership with national non-profit, Shatterproof, is the first of its kind.
- The Wolf administration encouraged participation in overdose awareness day on August 31, 2020 to remember those who have lost their battle with SUD.
- Governor Wolf released an Opioid Command Center Strategic Plan to fight the opioid epidemic on July 6, 2020.
- Governor Wolf announced more than $2 million in grants for employment services for individuals with OUD on July 2, 2020.
- Governor Wolf awarded $1 million in grants to help veterans overcome SUD on March 2, 2020. Governor Wolf awarded $1.5 million in grants for OUD Criminal Justice Diversion Programs on February 18, 2020. On February 11, 2020, the Wolf Administration announced more than $1.2 million in grants to nine county jails to support the county jail-based MAT program to increase OUD services to inmates in prisons and jails across the Commonwealth.
- On February 4, 2020, Governor Wolf proposed regulations to support MH/SUD coverage and consumer rights.
- On January 30, 2020, Governor Wolf announced $5 million in grants from DDAP to help individuals in recovery for OUD and their families. The grants are available for entities to deliver employment support services to individuals in recovery from OUD. On January 8, 2020, Governor Wolf announced that nearly $1 million in grants would be given to higher education institutions for opioid use prevention among college students and to create naloxone training opportunities for post-secondary institutions.

- On December 30, 2019, Governor Wolf announced that the Commonwealth would allocate $5 million in federal funding for loan repayment for health care practitioners providing medical and BH care, and treatment for SUD and OUD in areas where there is high opioid-use and a shortage of health care practitioners.
- On December 3, 2019, Governor Wolf signed the eighth renewal of Pennsylvania's opioid disaster declaration. In January 2018, he signed the first disaster declaration so the Commonwealth could focus resources and break down government siloes to address the burgeoning heroin and opioid epidemic.
- On December 2, 2019, Governor Wolf announced that DDAP would award $2.1 million in federal SAMHSA grants to enhance community recovery supports for individuals with SUD.
- On November 7, 2019, Governor Wolf announced that his administration was awarding $3.4 million in federal SAMHSA grants for support services for pregnant and postpartum women with OUD.
- On October 28, 2019, Governor Wolf announced a new law mandating health care providers prescribing controlled substances do so electronically, unless they meet certain exceptions. Act 96 of 2018 requires the electronic prescribing, which is a deterrent against prescription fraud.
- On October 1, 2019, Governor Wolf kicked off the first Opioid Command Center Opioid Summit: "Think Globally, Act Locally." The summit brought 200 individuals helping their communities fight the opioid crisis, including community organizations, non-profits, schools, health care workers, addiction and recovery specialists, and families affected by the opioid crisis.
- On September 6, 2019, the Governor's Office announced that Pennsylvania would receive more than $75 million in additional federal funding over the next year to support efforts to address the opioid crisis in Pennsylvania. This brings the total in federal funding for the Commonwealth's opioid response to more than $141 million over the past two years.
- DDAP was awarded another $55.9 million by SAMHSA. The grant represents a second year of funding for Pennsylvania through the State Opioid Response grant to continue practices and services that have a demonstrated evidence-based approach to prevention, treatment, recovery, education, and training. The $55.9 million will be used to continue year-one progress of the housing initiative and loan repayment program, as well as provide adequate funding to counties throughout the Commonwealth in support of departmental goals of reducing stigma, intensifying prevention, strengthening treatment systems, and empowering sustained recovery.

- Additionally, the Department of Health (DOH) received a federal grant for more than $8.4 million, expected to repeat each of the next two years, from the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry, to support efforts to address the substance use crisis in Pennsylvania. The funding is to support the Commonwealth in its drug-related overdose surveillance work to get high quality, comprehensive, and timely data on overdose-related morbidity and mortality, and to use that data to assist in prevention and intervention efforts. The funding will go PDMP office to continue the work of the Pennsylvania Overdose Data to Action program, which includes allowing for the collection of data for all drug overdoses. Previously, only data on opioid overdoses was collected. Availability of this funding will improve access to high quality, comprehensive, and timely data on overdose morbidity and mortality. Areas where the funding will help with prevention include:
  - Increased collaboration with county and municipal health departments.
  - Additional naloxone training for first responders.
  - Staffing the program's Patient Advocacy Unit.
  - Provide individualized, one-on-one education to opioid prescribers.
  - Offering continuing medical education to providers on evidence-based approaches to opioid prescribing and addressing SUD.
- The Opioid Command Center, established in January 2018 when Governor Wolf signed the first opioid disaster declaration, meets every week to discuss the opioid crisis. The command center is staffed by personnel from 17 Commonwealth agencies, spearheaded by the DOH and DDAP.
- 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.

Section 9
Lessons Learned and Recommendations

Based on the Commonwealth's experience with the 1115 SUD Demonstration to this point, the following lessons have been learned and will be described: 1) placement criteria matters, 2) the pandemic disrupted service patterns, and 3) change management disrupted service patterns before improving access to care. The Commonwealth has two closely related recommendations at this time: 1) a measured approach to change may create less provider abrasion and 2) acceptance of change takes time.

Placement Criteria Matters

The Commonwealth has already seen results of the implementation of the ASAM assessment criteria being used regularly across the system for treatment planning and placement decisions. They have seen a slight shift in placement of individuals to lower LOCs as providers use ASAM Criteria to develop client treatment plans and BH-MCOs use the placement criteria to ensure that individuals receive the most appropriate resource-intensive services according to ASAM assessments. This shift is supported by research that the consistent use of a multi-dimensional assessment to summarize a person's needs, define severity reliably, and develop a treatment plan that allows clinicians to identify problems, goals, and treatment plan objectives to provide individualized treatment uniformly across the system at the lowest level possible. The ASAM Criteria identify the problem areas most important in formulating an individualized treatment plan and in making subsequent patient placement decisions. Use of ASAM promotes good treatment planning, combining modality matching (for all pertinent problems and priorities identified in the assessment) with placement matching (which identifies the least intensive LOC that can safely and effectively provide the resources that will meet the patient's needs).

The ASAM Criteria is the most widely used and comprehensive set of guidelines for placement, continued stay, transfer, or discharge of patients with addiction and co-occurring conditions. It is a single national set of criteria for providing outcome-oriented and results-based care in the treatment of addiction. Adolescent and adult treatment plans are developed through a multidimensional patient assessment over five broad levels of treatment that are based on the degree of direct medical management provided, the structure, safety, and security provided and the intensity of treatment services provided.

The Pandemic Disrupted Service Patterns

The pandemic shifted service delivery from residential and congregate settings to individual telehealth care overnight. The Interim Evaluation highlighted changes to utilization and LOCs due to restricted physical movement and migration to virtual appointments. Increased need for services also was highlighted as the number of overdose deaths in 2020 rose to almost peak 2017 rates.

Change Management Disrupted Service Patterns Before Improving Access to Care

The changes required for aligning ASAM appear to have slightly decreased utilization in 2018 due to lost productivity potentially caused by mandatory training. While this lost utilization was small, it was statistically significant. The training also appears to have resulted in a number of individuals being served at lower LOCs (e.g., outpatient rather than IOP or PHP).

At this point in the Demonstration, the Commonwealth has one primary recommendation. The Commonwealth recommends a measured, dare we say slower, approach to change which is easier on the provider organizations and more likely to produce lasting results. Change does not happen overnight and lasting change may take many years to implement

Appendix A

Centers for Medicare & Medicaid Services-Approved Evaluation Design

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

State Demonstrations Group

May 22, 2020

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

Dear Ms. Miller:

The Centers for Medicare & Medicaid Services (CMS) has approved the evaluation design for the Substance Use Disorder (SUD) component of Pennsylvania's section 1115 demonstration entitled, "Pennsylvania Medicaid Coverage for Former Foster Care Youth from a Different State and Substance Use Disorder Demonstration" (Project Number 11-W-00308/3), and effective through September 30, 2022. We sincerely appreciate the state's commitment to a rigorous evaluation of your demonstration.

CMS has added the approved evaluation design to the demonstrations Special Terms and Conditions (STC) as part of Attachment E. A copy of the STCs, which includes the new attachment, is enclosed with this letter. The approved evaluation design may now be posted to the state's Medicaid website within thirty days, per 42 CFR 431.424(c). CMS will also post the approved evaluation design as a standalone document, separate from the STCs, on Medicaid.gov.

Please note that an interim evaluation report, consistent with the approved evaluation design is due to CMS one year prior to the expiration of the demonstration, or at the time of the renewal application if the state chooses to extend the demonstration. Likewise, a summative evaluation report, consistent with this approved design, is due to CMS within 18 months of the end of the demonstration period.

Page 2 – Ms. Teresa Miller

We look forward to our continued partnership with you and your staff on the Pennsylvania Medicaid Coverage for Former Foster Care Youth from a Different State and Substance Use Disorder Demonstration. If you have any questions, please contact your CMS project officer, Mr. Felix Milburn. Mr. Milburn may be reached by email at Felix.Milburn@cms.hhs.gov.

Sincerely,

Danielle Daly -S Digitally signed by Danielle Daly -S Date: 2020.05.27 11:06:27 -04'00'

Danielle Daly
Director
Division of Demonstration
Monitoring and Evaluation

Angela D. Garner -S Digitally signed by Angela D. Garner -S Date: 2020.05.29 13:36:25 -04'00'

Angela D. Garner
Director
Division of System Reform
Demonstrations

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

Commonwealth of Pennsylvania

Substance Use Disorder 1115 Waiver

Number 11-W-00308/3

Evaluation Design

Updated January 31, 2020

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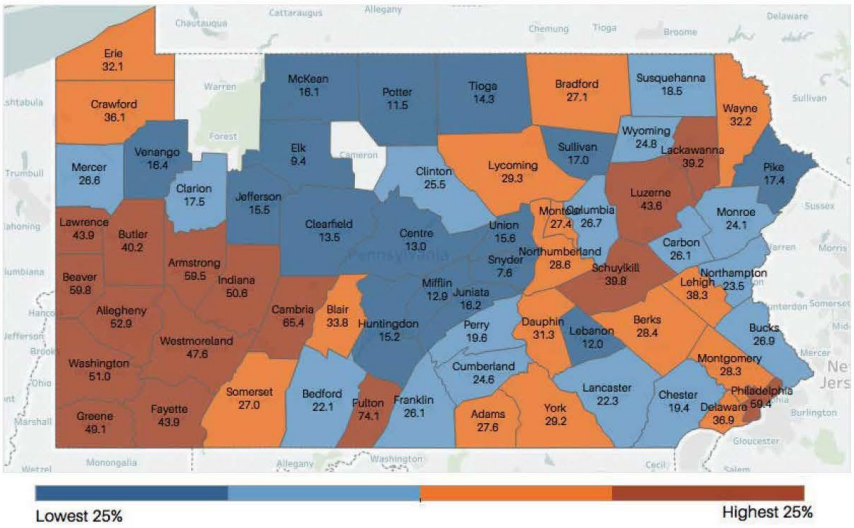
A. General Background Information

1. History and Overview

The Commonwealth of Pennsylvania (Commonwealth or Pennsylvania) is 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 Tom 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 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.[1] In 2016, more than 4,600 Pennsylvanians[2] lost their lives to drug-related overdose which averages to 13 drug-related deaths each day. This is a significant increase from the approximately 3,500 overdose fatalities in 2015, and almost double from the nearly 2,500 deaths in 2014. The Pennsylvania drug-related overdose death rate in 2016 was 36.5 per 100,000 people, a substantial increase from the death rate of 2015. This death rate is significantly higher than the national average of 16.3 per 100,000. Pennsylvania's Prescription Drug Monitoring Program (PDMP) reports that the number of emergency department (ED) visits related to an opioid overdose has increased by 82% from the third quarter of 2016 to the third quarter of 2017. While Pennsylvania is a very large and diverse state, there is no area of the Commonwealth that is not affected by this epidemic. The map below shows the rate of Drug-Related Overdose Deaths per 100,000 people in Pennsylvania Counties in 2016:



[1] Governor Wolf Declares Heroin and Opioid Epidemic a Statewide Disaster Emergency. (2018). Retrieved from https://www.governor.pa.gov/governor-wolf-declares-heroin-and-opioid-epidemic-a-statewide-disaster-emergency

[2] "Analysis of Overdose Deaths in Pennsylvania, 2016." Available at: https://www.dea.gov/docs/DEA-PHL-DIR-034-17%20Analysis%20of%20Overdose%20Deaths%20in%20Pennsylvania%202016.pdf

The Pennsylvania Health Care Cost Containment Council (PHC4), which is an independent Commonwealth agency charged with collecting, analyzing, and reporting on health care in the Commonwealth, examined hospital admissions between 2000 and 2014 for Pennsylvania residents ages 15 and older (excluding overdoses treated in EDs or overdose deaths that occurred outside the hospital setting). The findings showed a 225% increase in the number of hospitalizations for overdose of pain medication and a 162% increase in the number of hospitalizations for overdose of heroin during that period. While there were higher numbers of hospital admissions for these types of overdoses among urban county residents, the percentage increases were larger for rural county residents. For rural county residents, there was a 285% increase between 2000 and 2014 in the number of hospitalizations for pain medication and a 315% increase for heroin, whereas for urban counties, the percentage increases were 208% and 143%, respectively.[3]

In June 2018, PHC4 released their updated findings for 2017 that contained the following highlights[4]:

Heroin

- The hospital admission rate for heroin overdose in 2017 peaked at 536 in the second quarter, but as a whole, the year saw an increase of 12.7% which was the lowest percentage increase since 2011.
- The in-hospital mortality rate for these patients in 2014 was 7.5%, increased to 9.3% in 2016 and was up to 9.6% in 2017.

Pain Medication

- There were 1,747 hospital admissions for overdose of pain medication in 2017.
- The in-hospital mortality rate for these patients was 2.9% in 2016 and rose to 5.0% in 2017.
- In 2017, 84% of opioid-related deaths involved fentanyl or a fentanyl analog.[5]

Pennsylvania recognized the importance of a full continuum of treatment services, including residential services that are provided in a cost-effective manner and for a length of stay (LOS) that is governed by appropriate clinical guidelines to address the crisis described above. This Demonstration is critical to continue the federal funding needed to support the continuation of medically necessary services and substance use disorder (SUD) treatment in residential treatment facilities that meet the definition of Institution for Mental Diseases (IMDs), for individuals 21-64 years of age, regardless of the LOS.

Until recently, the Centers for Medicare & Medicaid Services (CMS) approved these residential services as cost-effective alternatives to State Plan Services (in lieu of services) in HealthChoices, Pennsylvania's Medicaid mandatory Managed Care Program. However, the requirements in the Medicaid Managed Care rule allow states to receive federal funding, for individuals 21-64 years old, in a residential treatment facility that is an IMD only if the LOS is no longer than 15 days. Pennsylvania estimated that this rule change would impact nearly 160 SUD service providers encompassed within the definition of IMD, affecting about 12,240 individuals statewide. Pennsylvania recognized the importance of these

[3] Hospitalizations for Opioid Overdose – 2016 to 2017. (2018). Retrieved from http://www.phc4.org/reports/researchbriefs/overdoses/17/docs/researchbrief_overdoses2017.pdf
[4] Hospitalizations for Opioid Overdose – 2016. Retrieved from http://www.phc4.org/reports/researchbriefs/overdoses/16/docs/researchbrief_overdose2016.pdf
[5] Opioid Program - Profile. Retrieved from https://public.tableau.com/profile/pdph#!/vizhome/UnintentionalDrugRelatedDeaths/

services in the continuum of care, and believes that this Demonstration is critical in ensuring that the Commonwealth is able to sustain the availability of these services to the impacted population.

Residential treatment services provide a structured recovery environment in combination with high-intensity clinical services. Individuals in residential settings receive daily clinical services to stabilize symptoms; a range of cognitive, behavioral, and other therapies to develop recovery skills in a protected environment; and recovery support services to assist in developing a social network supportive of recovery. Dependence on substances is a complex disease that affects multiple brain circuits, and effective treatment must incorporate an array of clinical and psychosocial components provided in a safe environment, as determined by appropriate clinical guidelines.

Residential treatment is a core service in the continuum of care for many individuals with SUD. The National Institute for Drug Abuse identified key principles for effective treatment which include the ability to remain in treatment services for an adequate period of time. The appropriate duration of treatment depends on the clinical needs of the individual. Research indicates that the majority of individuals need at least 90 days of treatment to significantly reduce or stop using substances.[6] Recovery is a long-term process, and the best outcomes occur with longer durations of treatment across the entire continuum of care based upon clinical needs.

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 LOS but upon the determination of clinical need and medical necessity for this LOC. The loss in federal matching dollars due to the current 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 provides if it meets the definition of an IMD. This severely impacts 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 will support the delivery of the complete American Society of Addiction Medicine (ASAM) criteria of services including Prevention, Outpatient, Intensive Outpatient, Partial Hospitalization, residential and inpatient, withdrawal management, and medication assisted treatment 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 and managed care delivery systems, federal grants and state funds. Inpatient, Outpatient, and MAT services are covered services within Pennsylvania's Medicaid state plan. Residential drug and alcohol detoxification and rehabilitation and Certified Recovery Specialist services are provided under the capitated contract as "in lieu of services". Federal grants and state funds can be utilized for all allowable services.

[6] Principles of Drug Addiction Treatment – A Research-Based Guide. (2012). Retrieved from https://www.drugabuse.gov/sites/default/files/podat_1.pdf

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 Behavioral Health (BH)-Managed Care Organization (MCO) contracts with a variety of providers to complete the LOC assessment. This may include the Single County Authority (SCA), licensed intake and evaluation providers or licensed outpatient providers. Clinical services are determined based upon a comprehensive assessment process and the application of the standardized placement criteria in *American Society of Addiction Medicine-Patient Placement criteria* (ASAM-PPC-2R).

2. Demonstration 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 will continue through September 30, 2022 (four years and three months).

3. Description of the Demonstration

The purpose of the Section 1115 Demonstration waiver amendment is to afford continued access to high quality, medically necessary treatment for opioid use disorder (OUD) and other SUDs. The Evaluation Design developed and described throughout this document will apply to this SUD Demonstration waiver amendment.

The demonstration will 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. Reduce overdose deaths, particularly those due to opioids;
2. Reduce utilization of ED and inpatient hospital settings; and
3. Reduce readmissions to the same or higher LOC.

The Commonwealth believes that these three 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;
- Adopting all ASAM levels of care and the ASAM patient placement criteria in Medicaid managed care;
- Ensuring provider capacity at critical levels of care including Medication assisted treatment for OUD;
- Implementing nationally recognized SUD-specific program standards to set provider qualifications for residential treatment facilities;
- Implementing comprehensive treatment and prevention strategies to address Opioid abuse and OUD; and
- Improving care coordination and transitions between levels of care.

Medicaid and Medicaid Managed Care

In the HealthChoices program, BH services (mental health [MH] and substance use services) are "carved out" and administered separately from physical health (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. The Office of Mental Health and Substance Abuse Services (OMHSAS) in the Department of Human Services (DHS) oversees the HealthChoices Behavioral Health (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.

Department of Drug and Alcohol Programs

While the Department of Drug and Alcohol Programs (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 Drug & Alcohol 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 drug and alcohol 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 drug and alcohol 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; and
- Procedures for coordination with the SCA for placement and payment for care provided to members in residential treatment facilities 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 fee-for-service and managed care delivery systems, federal grants and Commonwealth funds. The continuum includes:

- Inpatient Drug and Alcohol (Detoxification and Rehabilitation Services)
- Outpatient Drug and Alcohol, including Methadone Maintenance Services
- Medication Assisted Treatment (MAT)
- Residential Drug and Alcohol 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 utilized 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 FY 2014-2015, the SCAs reported providing treatment to 32,417 unique individuals.

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 (ASAM PPC-2R) for children and adolescents under the age of 21. The Pennsylvania Client Placement Criteria (PCPC)[7] is currently being utilized for adults. The transition to ASAM criteria for adults began in July 2018 and the transition is continuing.

OMHSAS-DDAP Coordination

While 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.

Drug Addiction Treatment Act of 2000 and the SUD Delivery System

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 waives the requirement for obtaining a separate Drug Enforcement Administration registration as a Narcotic Treatment Program for

[7] Pennsylvania's Client Placement Criteria for Adults – Third Edition. (2014). Retrieved from http://www.ddap.pa.gov/Manuals/PA%20Client%20Placement%20Criteria%20(PCPC)%20Edition%203%20Manual.pdf

qualified physicians administering, dispensing, and prescribing specific Food and Drug Administration-approved controlled substances such as buprenorphine in settings beyond OTPs.

DATA 2000 increases 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.[8] According to a survey conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), physicians and patients alike reported an average of an 80% reduction in opioid abuse when asked whether buprenorphine was effective in treating addiction. Additionally, responses to the survey indicated that buprenorphine and similar medications increase other indices of recovery.[9]

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.

In FY 2015-2016, 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 FY 2014-2015, when 30,421 individuals received residential services. In fiscal year 2016-2017 the number of individuals covered by Medicaid with SUD was 235, 748. This was an increase of 6% from fiscal year 2015-2016 and a 34% increase from fiscal year 2014-2015. 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 2017 was 119,523 with 61% being newly eligible diagnosed because of the Medicaid expansion. In fiscal year 2017-2018 38,565 individuals received SUD residential services that includes 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 opioid use disorder. 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.[10] 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.[11] 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.

[8] 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
[9] MAT Legislation, Regulations, and Guidelines. Retrieved from https://www.samhsa.gov/medication-assisted-treatment/legislation-regulations-guidelines
[10] Local Area Unemployment Statistics Map. Retrieved from https://www.samhsa.gov/medication-assisted-treatment/legislation-regulations-guidelines
[11] Population Estimates. Retrieved from https://www.census.gov/quickfacts/fact/table/PA/PST045216

B. Evaluation Questions and Hypothesis

Evaluation questions and hypotheses to be addressed were derived from and organized based on the Driver Diagram below. The overall aims of the project are to: 1) Reduce overdose deaths, particularly those due to opioids; 2) Reduce utilization of ED and inpatient hospital settings; and 3) Reduce readmissions to the same or higher LOC. To accomplish these goals, the demonstration includes several key activities (called primary drivers) including increasing access to care, ensuring high quality of care across the entire treatment continuum and increasing treatment program retention, and improving care transition across the continuum of SUD services. The three primary drivers for this change are supported by six secondary drivers. These secondary drivers become the **milestones** in the Commonwealth's implementation plan:

- Increase access to critical levels of care for OUD and other SUDs;
- Implement evidence-based, SUD-specific Patient Placement Criteria;
- Ensure sufficient provider capacity at critical levels of care including Medication assisted treatment for OUD;
- Implement nationally recognized SUD-specific program standards to set provider qualifications for residential treatment facilities;
- Implement comprehensive treatment and prevention strategies to address Opioid abuse and OUD;
- Improve care coordination and transitions between levels of care.

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

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

Research questions were selected to address the Demonstration's major program goals, to be accomplished by Demonstration activities associated with each of the **six program milestones**. Specific hypotheses regarding the Demonstration's impact are posed for each of these evaluation questions. These are linked to the program's milestones and 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

The goal of the SUD waiver is to improve overall population health outcomes for Medicaid managed care beneficiaries diagnosed with an SUD. Specifically, the waiver will:

1. Reduce overdose deaths, particularly those due to opioids;
2. Reduce utilization of ED and inpatient hospital settings; and
3. Reduce readmissions to the same or higher LOC.

Each of these objectives is translated into quantifiable targets for improvement so that the performance of the Demonstration in relation to these targets can be measured. These targets for improvement are

used to create the aims in the Driver Diagram and to support the hypotheses in the program evaluation design. 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 in consultation with OMHSAS leadership. Through analysis of data and discussion with partners, the Commonwealth determined these were reasonable and achievable performance goals. Where possible and relevant, the Commonwealth considered baseline data and trends.

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 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.

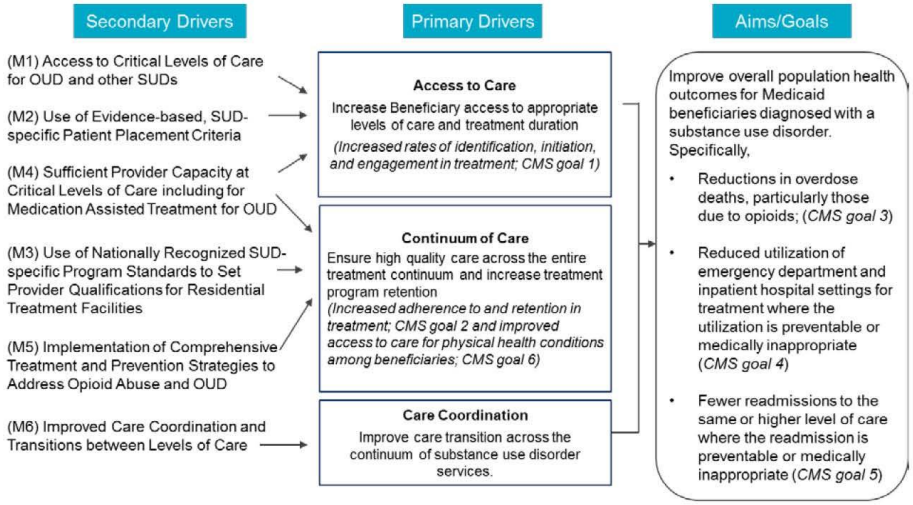
DHS/OMHSAS OBJECTIVES	TARGET FOR IMPROVEMENT
1. Increase beneficiary identification and access to appropriate levels of treatment duration.	• 1% annual increase in the number of individuals enrolled in Medicaid managed care with a SUD diagnosis. • 1% annual increase in the rate of the members with a SUD diagnosis (members) accessing each LOC. • 2.5% annual increase in the rate of members with a SUD accessing any services. • 1% annual increase in the rate of members with an SUD treated in an IMD. • Maintain an IMD LOS less than 30 days. • Maintain number of providers. • 2.5% annual increase in residential and inpatient bed capacity. • 1% overall increase in the number of new providers accepting Medicaid patients.
2. Increase rates of initiation and engagement of treatment.	• 1% annual increase 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.)*
3. Ensure high quality care across the entire treatment continuum and increase treatment program retention.	• All residential providers receive ASAM guidance for all LOCs by July 2020. • All residential have MAT onsite or access to MAT by July 2020. • All provider grant agreement/contracts have been updated to reflect new guidance by July 2020.
4. Increased adherence to and retention in treatment.	• 1% annual decrease in the use of opioids at high dosage (Pharmacy Quality Alliance [PQA], NQF #2940, Medicaid Adult Core Set). • 1% annual decrease in concurrent use of prescribed opioids and benzodiazepines (PQA). • 1% annual increase in continuity of pharmacotherapy for OUD (RAND, NQF #3175).

DHS/OMHSAS OBJECTIVES	TARGET FOR IMPROVEMENT
	• 1% decrease in the rate of overdose deaths in the Commonwealth.
5. Improved access to care for PH conditions among beneficiaries.	• 1.5% annual increase in utilization of preventive/ambulatory visits for adult Medicaid managed care beneficiaries with SUD.
6. Improve care transition across the continuum of SUD services.	• 1% increase in the rate of follow-up after discharge from the ED within seven 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.)* • 1% decrease in the rate of re-admissions among beneficiaries with SUD.

2. Driver Diagrams, Research Questions and Hypotheses

The program aims represent the ultimate goals of the waiver. The primary drivers represent strategic improvements (primary drivers) to achieve the program aims. The secondary drivers are the interventions (milestones) that will need to be reached in order achieve the strategic improvements. The performance measures outlined with the research question and hypothesis for each milestone describe specific activities completed as part of the implementation. The driver diagrams below present the connections between the milestones, strategic improvements and aims.

Driver Diagram



Measuring Effects on the Three Aims

CMS has established milestones (interventions or secondary drivers) and performance measures associated with those milestones to achieve the goals of the waiver. Some of those performance measures being used to monitor progress of the activities can also be used to indicate that the program aims have been met. Ultimately, the activities and milestones organized under the primary drivers of

improved access to care, improved continuum of care and improved care coordination are designed to further the three main project aims:

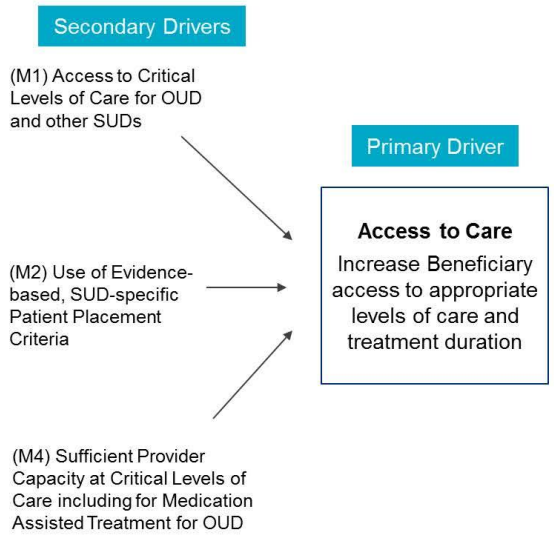
- Reductions in overdose deaths, particularly those due to opioids. (CMS goal 3)
- Reduced utilization of ED and inpatient hospital settings. (CMS goal 4)
- Fewer readmissions to the same or higher LOC. (CMS goal 5)

For the outcome evaluation, select performance measures will be used to demonstrate observed changes in the following outcomes, using an interrupted time-series design:

- Rate of overdose deaths overall
- Rate of opioid deaths
- Rate of ED utilization
- Rate of hospitalization
- Rate of readmissions to same or higher LOC

Additional performance measures will be collected to monitor progress on meeting the milestones and project goals. These performance measures are grouped and described under the related primary drivers.

Access to Care Driver



The overall aim of the Access to Care Driver is to increase beneficiary access to appropriate LOCs and treatment duration. This corresponds directly to CMS goal 1: increased rates of identification, initiation and engagement in treatment.

Three milestones describe how the Demonstration will improve access to care: improving access to critical LOCs, using evidence-based SUD placement criteria, and improving provider capacity. The Summary Design Tables at the end of this document describe the three research questions that will be used to determine the degree to which the Demonstration is able to accomplish each of these.

Milestone One: Qualitative data will be collected to describe each of the activities being undertaken in order to support Milestone One (see Driver Diagram). There are no specific outcome measures.

For the outcome evaluation, each of the performance measures in the Summary Design Tables will be used to demonstrate observed changes in provider capacity, better assignment of patients to the appropriate LOC, and, therefore, better **access to care** for the waiver population. Descriptive, time series analyses will be used to show changes in the number/percentage of providers delivering SUD services at each LOC.

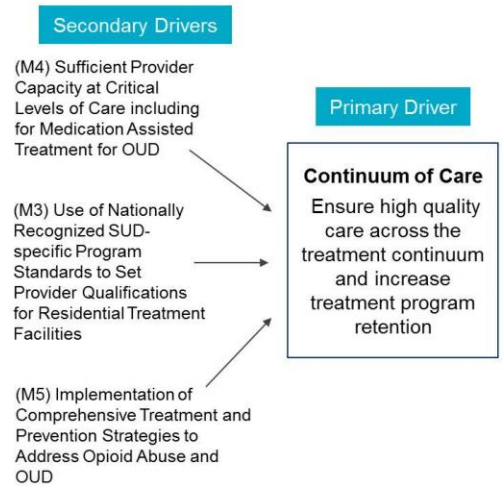
Milestone Two: Qualitative and quantitative data will be collected to describe each of the activities being undertaken in order to support Milestone 2 (see Driver Diagram). There are no specific outcome measures linked to milestone 2.

Milestone Four: For the outcome evaluation, the performance measures in the Summary Design table will be used to demonstrate observed changes in provider capacity, better assignment of patients to the appropriate LOC, and, therefore, better **access to care** for the waiver population. Descriptive, time series analyses will be used to show changes in the number/percentage of providers delivering SUD services at each LOC.

To show changes in access to care, an interrupted time series design will, if possible, be used to show change over time in the following outcomes (from the performance measures listed in Milestone 1):

- Rate of individuals enrolled in any treatment service (rate of treatment engagement)
- Rate of individuals enrolled in each LOC
- Rate of individuals served in an IMD
- LOS in IMD

Continuum of Care Drivers



The overall aim of the continuum of care primary driver is to ensure high quality of care across the treatment continuum and increase program retention. This corresponds directly to the following CMS goals:

- Increased adherence to and retention in treatment. (CMS goal 2)
- Improved access to care for PH conditions among beneficiaries. (CMS goal 6)

The Evaluation design for Milestone 4 was discussed previously, under the access to care primary driver.

Milestone Three: Milestone 3 is described in the Summary Design Table and addresses insuring that there is sufficient provider capacity at critical LOCs.

Qualitative data will be used to describe the processes used to update residential provider guidance for all LOCs by July 2020 including requiring MAT onsite; as well as the process for updating provider guidance (Medicaid only providers or contracts). The evaluation will also include a qualitative review and report of all residential treatment providers for those updated standards by July 2020.

The quantitative measures used for this milestone will be the number and percentage of providers whose grant agreement/contracts or guidance have been updated to reflect the new ASAM criteria.

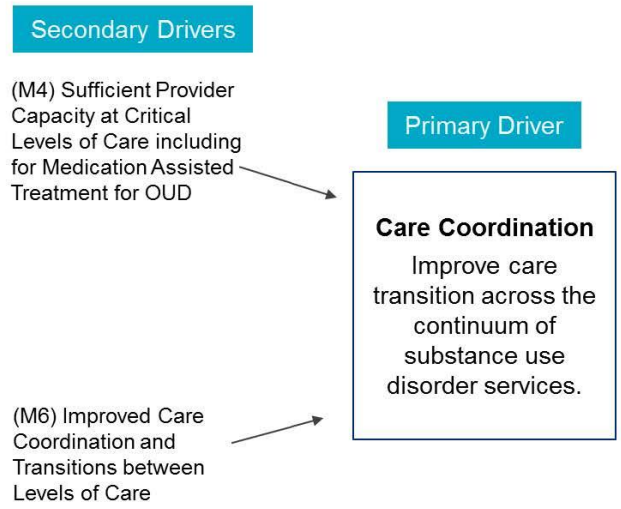
Milestone Five: For the outcome evaluation, each of the performance measures outlined in the Summary Design table will be used to demonstrate observed changes in the use of opioids at high dosage, use of opioids from multiple providers and concurrent use of opioids and benzodiazepines for the waiver population. PeopleStat will calculate all of the performance measures; they will use the Medicaid data warehouse and a state-specific IMD database for the majority of measures. PeopleStat has direct access to the data warehouse. The exception is the number of overdose deaths which is

calculated using vital statistics data. Vital statistics information on overdose deaths is maintained on the Vital Statistics website and is calculated by PeopleStat. All data is obtained by the OMHSAS SUD 1115 project manager who sends a request to the source of the information (PDMP, eHealth, DDAP, and PeopleStat).

To show changes in the CMS goals **of increased retention in treatment and improved access to physical care**, an interrupted time series design will be used to show change over time in the following outcomes:

- Continuity of pharmacotherapy for OUD (RAND, NQF #3175)
- Access to preventive/ambulatory health services for adult Medicaid managed care beneficiaries with SUD

Care Coordination Driver



The overall aim of the care coordination driver is to improve care transition across the continuum of SUD services. This is not one of the CMS specified goals, but is a primary driver in meeting the three main project aims.

Milestone Six: PeopleStat will calculate the performance measures outlined in the data summary table using the Medicaid data warehouse. For the outcome evaluation, to show improvements in care coordination, an interrupted time series design will be used to show change over time in the following outcome:

- Follow-up after discharge from the ED for MH or alcohol or other drug dependence (NCQA, NQF #2605, Medicaid Adult Core Set)

C. Methodology

1. Evaluation Design

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

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); and
3. Demonstrate progress in meeting the overall project goals/aims.

A combination of qualitative and quantitative approaches will be used throughout the evaluation. Qualitative methods will include key informant interviews with OMHSAS and provider staff regarding waiver activities as well as document reviews of contracts, policy guides and manuals. Quantitative methods will include descriptive statistics showing change over time in both counts and rates for specific metrics and interrupted time series analysis to assess the degree to which the timing of waiver interventions affect changes across specific outcome measures.

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

The evaluation will analyze how Pennsylvania is carrying out its implementation plan and track any changes it makes to its initial design as implementation proceeds. Both planned changes that are part of the demonstration design (e.g., implementation of ASAM) and operational and policy modifications Pennsylvania makes based on changing circumstances will be identified. 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.

During on-going communication with the Commonwealth, detailed information on how Pennsylvania has implemented each milestone including how it has structured the ASAM implementation, identified providers at each ASAM level, implemented PDMP and other Health Information Technology (HIT) changes, and structured care coordination between levels of care for beneficiaries enrolled in the demonstration will be collected. The evaluation will analyze the scope of each of these milestones 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 milestones.

Key informant interviews and document reviews will occur at four critical junctures: initially, prior to the mid-point assessment, prior to the interim evaluation report being written and prior to the final summative evaluation report being finalized. Specifically, the initial qualitative analysis will occur February–June 2019. The second qualitative analysis will occur July–September, 2020. The third

qualitative analysis will occur July–September, 2021. The final qualitative analysis will occur October–December 2023.

The interview questions and documents which will be reviewed are listed under each milestone. The key informant interviews will be conducted with key staff members in the following departments who are directly responsible for SUD 1115 implementation and operations: OMHSAS, DDAP, the DHS PeopleStat program, the Pennsylvania PDMP, and the Pennsylvania eHealth Partnership Program. Note: the DHS PeopleStat program, the Pennsylvania PDMP, and the Pennsylvania eHealth Partnership Program will be interviewed to ensure that the performance measures and HIT portions of the demonstration are implemented consistently with the implementation protocol.

To maximize efficiency in the evaluation, most outcome measures align with performance measures being reported to CMS for each of the six milestones.

PeopleStat will calculate the quantitative performance measures. PeopleStat acts independently of OMHSAS and OMAP. It has direct access to the data warehouse utilized by the Medicaid agency for encounter data and claims. The data will be automatically updated any time a provider submits a claim or encounter data. PeopleStat will calculate all performance measures using the period of time specified in the CMS technical manual (e.g., monthly, quarterly or annual).

2. Target and Comparison Populations

The comparison population groups in this design will be comprised of the target population, which will serve as its own comparison group longitudinally, where the research question will compare service utilization differences across the demonstration period.

The Target population includes 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 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 state funds, which provides cash payments and MA, or MA only (Medically Needy Only and Non-Money Payment), to families which 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 which provides non-money payment MA and/or payment of the Medicare premium, deductibles, or coinsurance to disabled persons and persons age 65 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 HC Program.

- *Supplemental Security Income (SSI) without Medicare*: Monthly cash payments made to persons who are aged, blind, or have been disabled for less than two years and will become eligible for Medicare when the disability has lasted for two 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 which 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 which 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 (MG)00 – Children ages 1-5 inclusive and income at or below 157% Federal Poverty Level (FPL). Youth ages 6-18 inclusive and income at or below 119%. Infants and pregnant women at or below 215% FPL. MG19 – Youth ages 6-18 inclusive with income at or below 119% FPL. MG27 – Income at or below 33% FPL. MG 71 – Transitional Medical Assistance.
- *Newly Eligible Groups under Affordable Care Act (ACA)*: Childless adults with income less than or equal to 133% of the applicable FPL. Parents and designated care takers and individuals ages 19 or 20 with income between 4% and 133% of the applicable FPL.

Evaluation Period

The evaluation period is July 1, 2018 through September 30, 2022. The Draft Summative Evaluation Report analysis will allow for a 12-month run out of encounter data. Results across this time period will be included in the Draft Summative Evaluation Report due to CMS by March 30, 2024. Draft interim results derived from a portion of this evaluation period, July 1, 2018 through June 30, 2021 (with three month run out of encounter data) will be reported in the Draft Interim Evaluation Report due to CMS on September 30, 2021.

3. 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. PeopleStat will calculate all performance measures using the Medicaid data warehouse and a state-specific IMD database except for overdose deaths, which is calculated using vital statistics data, and the PDMP and eHealth measures which are calculated using PDMP and eHealth data. Vital Statistics information on overdose deaths is maintained on the website. The data is obtained when the OMHSAS SUD 1115 project manager sends a note to the source of the information (PDMP, eHealth, DDAP, and PeopleStat). Peoplestat has direct access to the data warehouse.

PeopleStat will calculate all of the performance measures; they will use the Medicaid data warehouse and a state-specific IMD database for the majority of measures. The exceptions include the number of

overdose deaths which is calculated using vital statistics data, and the PDMP and eHealth measures which are calculated using PDMP and eHealth data.

Vital statistics information on overdose deaths is maintained on the Vital Statistics website. The data is obtained when the OMHSAS SUD 1115 project manager sends a note to the source of the information (PDMP, eHealth, DDAP, and PeopleStat). Peoplestat has direct access to the data warehouse.

Measuring Achievement of Overall Project Aims			
Measure Type	**Description**	**Data Type**	**Data Source**
Outcome	Rate of overdose deaths overall	Quantitative	Vital Statistics data
Outcome	Rate of opioid deaths	Quantitative	Vital Statistics data
Outcome	Rate of ED utilization	Quantitative	Claims/encounters (PeopleStat)
Outcome	Rate of hospitalization	Quantitative	Claims/encounters (PeopleStat)
Outcome	Rate of readmissions to same or higher LOC	Quantitative	Claims/encounters (PeopleStat)

Measuring Primary Drivers/Milestone Hypotheses			
Primary Driver: Access to Care			
Hypothesis 1: The 1115 SUD Demonstration will increase access to the specified critical LOCs for individuals in Pennsylvania Medicaid managed care compared to prior to the waiver.			
Measure Type	**Description**	**Data Type**	**Data Source**
Process	Description of activities undertaken for Milestone 1.	Qualitative	• Key Informant Interviews • Document Review, including: – OMHSAS BH contracts – OMHSAS coding documentation – OMHSAS bulletins
Process	Number and percentage of individuals enrolled in Medicaid managed care with an SUD diagnosis.	Quantitative	Claims/encounters (PeopleStat)
Outcome	Rate of individuals enrolled in any treatment service (rate of treatment engagement).	Quantitative	Claims/encounters (PeopleStat)
Outcome	Rate of individuals enrolled in each LOC.	Quantitative	Claims/encounters (PeopleStat)
Outcome	Rate of individuals served in an IMD.	Quantitative	Claims/encounters (PeopleStat) and state-specific IMD database
Outcome	LOS in IMD.	Quantitative	Claims/encounters (PeopleStat) and state-specific IMD database
Hypothesis 2: The 1115 SUD Demonstration will lead to use of ASAM placement criteria by all providers by the end of the first year of the Demonstration project.			
Measure Type	**Description**	**Data Type**	**Data Source**
Process	Number and percentage of contracts modified to require utilization review	Quantitative	Document Review including:

Measuring Primary Drivers/Milestone Hypotheses			
Primary Driver: Access to Care			
	based on ASAM admission, continuing stay and discharge criteria for all ASAM levels of care.		• OMHSAS behavioral health contracts
Process	Number of managed care organizations that begin prior authorization and utilization review based on ASAM residential placement criteria.	Quantitative	Document Review including: • OMHSAS BH PC contracts • DDAP bulletins including ASAM placement guidelines • OMHSAS bulletins • OMHSAS instructions to BH contractors • OMHSAS results from BH organization PC onsite reviews
Process	Number of providers trained to use ASAM as assessment tool	Quantitative	Document Review, including: • DDAP and OMHSAS Provider training records on the ASAM placement criteria
Process	Medicaid ASAM placement guidelines created for Medicaid only providers.	Quantitative	Document Review including: • OMHSAS behavioral health BH PC contracts • DDAP bulletins including ASAM placement guidelines • OMHSAS bulletins • OMHSAS instructions to BH contractors • OMHSAS results from BH organization PC onsite reviews
Process	Provider education on ASAM placement guidelines conducted in first 12 months.	Quantitative	Document Review, including: • DDAP and OMHSAS Provider training records on the ASAM placement criteria
Hypothesis 3: The 1115 SUD Demonstration will increase provider capacity as defined below for SUD treatment at critical LOCs for individuals in Pennsylvania Medicaid managed care.			
Measure Type	**Description**	**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.	Quantitative	Document Review • OMAP Medicaid Provider enrollment database records • SAMHSA/DDAP Data 2000 provider enrollment records
Process	Number of new providers accepting Medicaid patients.	Quantitative	Document Review, including: • OMHSAS results from BH organization PC onsite reviews

Measuring Primary Drivers/Milestone Hypotheses			
Primary Driver: Access to Care			
Process	Number and percentage of providers enrolled in Medicaid and providing each of the following critical LOCs: early intervention, outpatient services, intensive outpatient and partial hospitalization services, residential and inpatient services, withdrawal management and MAT.	Quantitative	Document Review, including: • OMAP Medicaid Provider enrollment database records • SAMHSA/DDAP Data 2000 provider enrollment records

Measuring Primary Drivers/Milestone Hypotheses			
Primary Driver: Continuum of Care			
Hypothesis 4: The 1115 SUD Demonstration will establish ASAM criteria and program standards to set provider qualifications for all Residential Facilities by January 2021.			
Measure Type	**Description**	**Data Type**	**Data Source**
Process	Description of activities undertaken for Milestone 1.	Qualitative	• Key Informant Interviews • Document Review • OMHSAS BH PC contracts • DDAP bulletins • OMHSAS bulletins • OMHSAS instructions to BH contractors • DDAP and OMHSAS provider training records • OMAP Medicaid Provider enrollment database records
Process	Number and rate of providers reviewed for compliance.	Quantitative	Document Review, including: • OMHSAS results from BH organization PC onsite reviews • OMHSAS and DDAP onsite provider reviews
Process	Number and rate of providers in compliance.	Quantitative	Document Review, including: • OMHSAS results from BH organization PC onsite reviews • OMHSAS and DDAP onsite provider reviews
Hypothesis 5: The 1115 SUD Demonstration will improve outcomes for individuals in Pennsylvania Medicaid managed care.			
Measure Type	**Description**	**Data Type**	**Data Source**
Outcome	Initiation of AOD treatment: initiation of AOD treatment through an inpatient admission, outpatient visit, intensive	Quantitative	Claims/encounters (PeopleStat)

Measuring Primary Drivers/Milestone Hypotheses			
Primary Driver: Continuum of Care			
	outpatient encounter or partial hospitalization within 14 days of the index episode start date/eligible population.		
Outcome	Number/rate of Medicaid members prescribed opioids at high dosage.	Quantitative	Claims/encounters (PeopleStat)
Outcome	Number/rate of Medicaid members prescribed opioids from multiple providers (four or more).	Quantitative	Claims/encounters (PeopleStat)
Outcome	Number/rate of Medicaid members prescribed opioids and benzodiazepines concurrently.	Quantitative	Claims/encounters (PeopleStat)
Outcome	Number/rate of Medicaid members with pharmacotherapy for SUD with at least 180 days of continuous treatment.	Quantitative	Claims/encounters (PeopleStat)
Outcome	Follow-up after discharge from the ED for AOD dependence within 7 days or 30 days: beneficiaries with an outpatient visit, intensive outpatient visit or partial hospitalization with a MH practitioner within 7 days or 30 days after an ED visit with a principal diagnosis of AOD dependence/ED visits with a principal diagnosis of AOD.	Quantitative	Claims/encounters (PeopleStat)
Outcome	Rate of overdose deaths in the Commonwealth: number of overdose deaths/number of deaths.	Quantitative	Claims/encounters (PeopleStat)
Outcome	Number/rate of Medicaid members with an SUD diagnosis that had an ambulatory or preventative care visit.	Quantitative	Claims/encounters (PeopleStat)

Measuring Primary Drivers/Milestone Hypotheses			
Primary Driver: Care Coordination			
Hypothesis 6: The 1115 SUD Demonstration will improve follow-up after discharge from EDs and decrease re-admissions for individuals in Pennsylvania Medicaid managed care with SUD.			
Measure Type	**Description**	**Data Type**	**Data Source**
Outcome	Number/rate of follow-up after discharge from the ED for MH or AOD.	Quantitative	Claims/encounters

4. Analytic Methods

Multiple analytic techniques will be used, depending on the type of data for the measure and the use of the measure in the evaluation design (e.g., process measure vs. outcome measures).

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

Descriptive statistics including frequency distributions and time series (presentation of rates over time) will be used for quantitative process measures in order to describe the output of specific waiver activities. These analysis techniques will also be used for some short-term outcome measures in cases where the role of the measure is to describe changes in the population, but not to show specific effects of the waiver Demonstration.

An interrupted time series design will be used to describe the effects of waiver implementation. Specific outcome measure(s) will be collected for multiple time periods both before and after start of intervention. Segmented regression analysis will be used to measure statistically the changes in level and slope in the post-intervention period (after the waiver) compared to the pre-intervention period (before the waiver). The interrupted time series (ITS) design will be dependent on PeopleStat's ability to produce historical data on specific outcome measures (see Methodology Limitation section for more information). The ITS design uses historical data to forecast the "counterfactual" of the evaluation, that is to say, what would happen if the Demonstration did not occur. We propose using basic time series linear modeling to forecast these "counterfactual" rates for three years following the Demonstration implementation.[12] The more historical data available, the better these predictions will be. ITS models are commonly used in situations where a contemporary comparison group is not available.[13] The Commonwealth has considered options for a contemporary comparison group. Since the demonstration will target managed care members, a comparison group made up of fee for service members was considered. However, many of the demonstration changes take place at the provider level and will, therefore also impact fee for service members, thus contaminating the comparison group.

For this demonstration, establishing the counterfactual is somewhat nuanced. The driver diagram and evaluation hypotheses assume that Demonstration activities will have overall positive impacts on outcome measures. The figure below illustrates an ITS design that uses basic regression forecasting to establish the counterfactual – this is represented by the grey line in the graphic. The counterfactual is based on historical data (the blue line). It uses time series averaging (trend smoothing) and linear regression to create a predicted trend line (shown below as the grey line). The orange line in the graph is the (sample) actual observed data. Segmented regression analysis will be used to measure statistically

[12] E Kontopantelis (2015). Regression based quasi-experimental approach when randomisation is not an option: interrupted time series analysis. British Medical Journal (BMJ). Retrieved: https://www.bmj.com/content/350/bmj.h2750.

[13] Ibid.

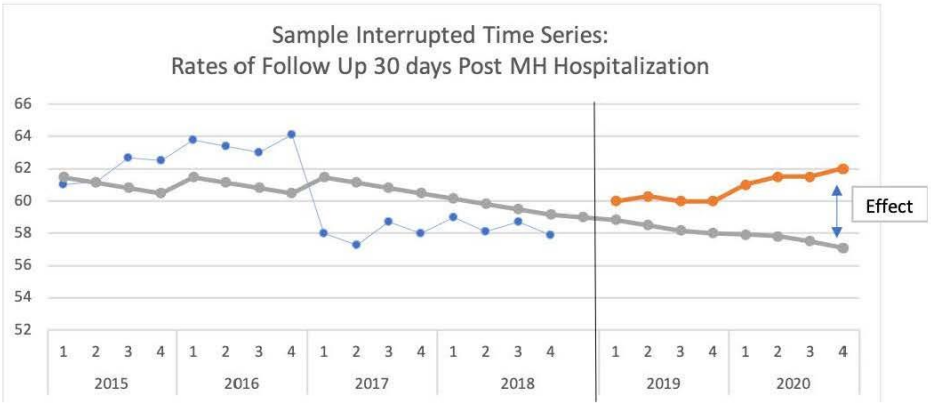
the changes in level and slope in the post-intervention period compared to the predicted trend (see "effect" in the graph below).

$$Y_t = \beta_0 + \beta_1 T + \beta_2 X_t + \beta_3 T X_t$$

Where β_0 represents the baseline observation, β_1 is the change in the measure associated with a time unit (quarter or year) increase (representing the underlying pre-intervention trend), β_2 is the level change following the intervention and β_3 is the slope change following the intervention (using the interaction between time and intervention: TX_t).[14]

This can be represented graphically as follows.

Figure 1: (SAMPLE data only) Rates of Follow Up Post Mental Health Hospitalization



Pre-demonstration data from 2015 to July 1, 2018 will be calculated using the monthly, quarterly, or annual period of time as specified in the CMS technical specifications for each metric. Trends in these data for each measure will be used to predict the counterfactual (what would have happened without the Demonstration). Outcomes measures will be calculated beginning July 1, 2018 through the end of the waiver demonstration project (September 30, 2022)

One potentially confounding factor of this design is that many of the Demonstration activities proposed are not new interventions, but represent programs that would no longer be funded without the waiver, due to other rule changes. It is very difficult to predict a trend line in that situation (programs being discontinued). However, if historical data is available for several years prior to these programs' implementation, it is possible to use more sophisticated linear modeling to predict a decreasing trend (change to more negative outcomes) that would have happened without the Demonstration.

[14] Bernal, J.L., Cummins, S. and 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.

However, even though programmatic changes in this demonstration are modest, the hypotheses put forth in this document do assume some small improvement over current trends. If the data is not available to forecast negative trends that may happen without these programs, the current model should still be able to show the minor improvements indicated in these hypotheses.

5. Summary Design Table for the Evaluation of the Demonstration

Milestone 1: Improve access to critical LOCs for OUD and other SUDs for individuals in Medicaid managed care. Critical LOCs are defined as early intervention, outpatient services, intensive outpatient and partial hospitalization services, residential and inpatient services, withdrawal management and MAT.							
Hypothesis 1: The 1115 SUD Demonstration will increase access to the specified critical LOCs for individuals in Pennsylvania Medicaid managed care compared to prior to the waiver.							
Research question 1: Has access to critical LOCs as defined below improved in Medicaid managed care?							
Analytic Approach: Interrupted time series; regression analysis for change over time after waiver implementation.							
Driver: Access to Care (primary); Access to critical LOC's for OUD and other SUDs (secondary)							
Key Informant Interview questions (Interviewee: OMHSAS): • What are the services available 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 LOC? • What are the activities undertaken to improve access to critical LOC for OUD and other SUDs for individuals in Medicaid managed care?							
Document review with source listed: • OMHSAS BH contracts • OMHSAS coding documentation • OMHSAS bulletins • Manuals and training records							
Measure	**Steward**	**Numerator**	**Denominator**	**Data Source**	**Measurement Period**	**Reporting Frequency**	**Target**
Number and percentage of individuals enrolled in Medicaid managed care with an SUD diagnosis.	CMS	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	All Medicaid managed care beneficiaries enrolled for any amount of time during the measurement period	Encounter data/claims	Monthly	Quarterly	1% annual increase in the number of individuals enrolled in Medicaid managed care with a SUD diagnosis.

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Milestone 1: Improve access to critical LOCs for OUD and other SUDs for individuals in Medicaid managed care. Critical LOCs are defined as early intervention, outpatient services, intensive outpatient and partial hospitalization services, residential and inpatient services, withdrawal management and MAT.							
		the measurement period and/or in the 11 months before the measurement period.					
Number and percentage of individuals enrolled in Medicaid managed care using each of the following critical LOCs: early intervention, outpatient services, intensive outpatient and partial hospitalization services, residential and inpatient services, withdrawal management and MAT.		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, intensive outpatient and partial hospitalization services, residential and inpatient services, withdrawal management and MAT.	All Medicaid managed care beneficiaries with a SUD diagnosis enrolled for any amount of time during the measurement period.	Encounter data/claims	Month	Quarterly	1% annual increase in the rate of the members with a with SUD diagnosis (members) accessing each LOC.

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Milestone 1: Improve access to critical LOCs for OUD and other SUDs for individuals in Medicaid managed care. Critical LOCs are defined as early intervention, outpatient services, intensive outpatient and partial hospitalization services, residential and inpatient services, withdrawal management and MAT.							
Number and percentage of individuals enrolled in Medicaid managed care using any SUD treatment service, facility claim, or pharmacy claim.	CMS	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.	Encounter data/claims	Month	Quarterly	2.5% annual increase in the rate of members with a SUD accessing any services.
Number and percentage of individuals enrolled in Medicaid managed care treated in an IMD for SUD.	CMS	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 within the measurement period.	All Medicaid managed care beneficiaries enrolled for any amount of time during the measurement period.	Encounter data/claims	Year	Annually	1% annual increase in the rate of members with an SUD treated in an IMD.

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Milestone 1: Improve access to critical LOCs for OUD and other SUDs for individuals in Medicaid managed care. Critical LOCs are defined as early intervention, outpatient services, intensive outpatient and partial hospitalization services, residential and inpatient services, withdrawal management and MAT.							
Average LOS for individuals enrolled in Medicaid managed care treated in an IMD for SUD.		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.	Encounter data/claims; State-specific IMD database	Year	Annually	Maintain an IMD LOS less than 30 days.
Research question 2: 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? Note: Performance measures for this research question are included in the table below:							
• Number and percentage of individuals enrolled in Medicaid managed care with an SUD diagnosis. • Number and percentage of individuals enrolled in Medicaid managed care using each of the following critical LOCs: early intervention, outpatient services, intensive outpatient and partial hospitalization services, residential and inpatient services, withdrawal management and MAT. • Number and percentage of individuals enrolled in Medicaid managed care using any SUD treatment service, facility claim or pharmacy claim. • Number and percentage of individuals enrolled in Medicaid managed care treated in an IMD for SUD and the average LOS in the IMD.							
Analytic Approach: Interrupted time series; regression analysis for change over time after waiver implementation							

Milestone 2: Use of Evidence-based, SUD-specific Patient Placement Criteria.
Hypothesis 2: The 1115 SUD Demonstration will lead to use of ASAM placement criteria by all providers by the end of the first year of the Demonstration project.
Research question 1: Has the use of evidence-based SUD-specific patient placement criteria (ASAM criteria) been implemented across all LOCs for all patient populations?
Analytic Approach: Qualitative narrative analysis; counts
Driver: Access to Care (primary); Use of evidence-based placement criteria (secondary)
Key Informant Interview questions (Interviewee: 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 implementation of the ASAM placement criteria for individuals in Medicaid managed care?
Document review with source listed: • OMHSAS BH primary contractor (PC) contracts

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

- DDAP bulletins including ASAM placement guidelines
- OMHSAS bulletins
- OMHSAS instructions to BH contractors
- OMHSAS results from BH organization PC onsite reviews
- DDAP and OMHSAS Provider training records on the ASAM placement criteria
- Office of Medical Assistance Programs (OMAP) Medicaid Provider enrollment database records
- SAMHSA/DDAP Data 2000 provider enrollment records

Measure	Steward	Numerator	Denominator	Data Source	Measurement Period	Reporting Frequency	Target
Number and percentage of contracts modified to 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	PC contracts	Year	Annual	All provider grant agreement/contracts have been updated to reflect new guidance by July 2020.
Number of MCOs that begin prior authorization and utilization review based on ASAM residential placement criteria.	Pennsylvania	Number of PCs conducting prior authorization and utilization review based on ASAM.	Total number of PCs	PC onsite reviews	Year	Annual	
Number of providers trained to use ASAM as assessment tool.	Pennsylvania	Number of providers training to use ASAM as an assessment.	Total number of providers	DDAP and OMHSAS training records	Year	Annual	
Medicaid ASAM placement guidelines created	Pennsylvania	Number of ASAM placement guidelines	Total number of Medicaid only providers	ASAM placement guidelines	Year	Annual	All residential providers receive ASAM guidance for

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Milestone 2: Use of Evidence-based, SUD-specific Patient Placement Criteria.							
for Medicaid-only providers.		created for Medicaid only providers.					all LOCs by July 2020.
Provider education on ASAM placement guidelines conducted in first 12 months	Pennsylvania	Number of providers training to use ASAM placement criteria.	Total number of providers	DDAP and OMHSAS training records	Year	Annual	

Milestone 4: Improve provider capacity at critical LOCs including MAT for OUD in Medicaid.							
Hypothesis 3: The 1115 SUD Demonstration will increase provider capacity as defined below for SUD treatment at critical LOCs for individuals in Pennsylvania Medicaid managed care.							
Research question 1: Has the availability of providers in Medicaid accepting new patients including MAT improved under the Demonstration?							
Analytic Method: Qualitative narrative analysis; counts							
Driver: Access to Care (primary); Sufficient provider capacity (secondary)							
Document review with source listed: • OMAP Medicaid Provider enrollment database records • OMHSAS results from BH organization onsite reviews • OMHSAS and DDAP results from provider licensure/onsite document reviews							
Measure	**Steward**	**Numerator**	**Denominator**	**Data Source**	**Measurement Period**	**Reporting Frequency**	**Target**
Maintenance of existing providers	CMS	The total number of eligible SUD providers.	SUD providers who were enrolled in Medicaid and qualified to deliver Medicaid SUD services during the measurement period.	Provider enrollment database Claims (if necessary)	Year	Annually	Maintain number of providers
Bed capacity	Pennsylvania	The total number of beds open	The total number of beds licensed	Licensure/onsite document review	Year	Annually	2.5% annual increase in residential

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Milestone 4: Improve provider capacity at critical LOCs including MAT for OUD in Medicaid.							
Hypothesis 3: The 1115 SUD Demonstration will increase provider capacity as defined below for SUD treatment at critical LOCs for individuals in Pennsylvania Medicaid managed care.							
Research question 1: Has the availability of providers in Medicaid accepting new patients including MAT improved under the Demonstration?							
Analytic Method: Qualitative narrative analysis; counts							
Driver: Access to Care (primary); Sufficient provider capacity (secondary)							
			and contracting with Medicaid.				and inpatient bed capacity.
The number of new providers accepting Medicaid patients.	CMS	The total number of new eligible SUD providers accepting Medicaid patients.	New SUD providers who were enrolled in Medicaid and qualified to deliver Medicaid SUD services during the measurement period.	Provider enrollment database Claims (if necessary)	Year	Annually	1% overall increase in the number of new providers accepting Medicaid patients.

Milestone 3: Use of Nationally recognized SUD-specific program standards to set provider qualifications for residential treatment facilities.
Hypothesis 4: The 1115 SUD Demonstration will establish ASAM criteria and program standards to set provider qualifications for all Residential Facilities by January 2021
Research question 1: Has OMHSAS established ASAM criteria and program standards to set provider qualifications for all Residential Facilities?
Analytic Method: Qualitative narrative analysis; counts
Driver: Continuum of Care (primary); Use of nationally-recognized SUD standards of care (secondary)
Key Informant Interview questions (Interviewees: OMHSAS and DDAP): • What program standards were set to ensure provider qualifications for all residential facilities? • What processes were used to update the residential provider standards and provider guidance (contracts, bulletins)? • How do they differ from the Commonwealth's previous system? • To what extent did Pennsylvania implement the ASAM placement LOC? What activities have been undertaken to review for compliance with those program standards?
Document review: • OMHSAS BH PC contracts • DDAP bulletins

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Milestone 3: Use of Nationally recognized SUD-specific program standards to set provider qualifications for residential treatment facilities.

- OMHSAS bulletins
- OMHSAS instructions to BH contractors
- OMHSAS results from BH organization PC onsite reviews
- OMHSAS and DDAP onsite provider reviews
- DDAP and OMHSAS provider training records

OMAP Medicaid Provider enrollment database records

Measure	Steward	Numerator	Denominator	Data Source	Measurement Period	Reporting Frequency	Target
Description of activities undertaken for Milestone 1: Implementation successes and challenges.	N/A	None Qualitative data	Key Informant Interviews Document Review	See interview questions & document review sources above	July 1, 2018 through September 30, 2020 (annual interviews and reviews 2020, 2021, 2022)	Annually	The Commonwealth will undertake the activities outlined in the protocol.
Number and rate of providers reviewed for compliance.	Pennsylvania	Number of providers reviewed	Total number of providers	OMHSAS and DDAP onsite reviews	Year	Annual	All residential providers will be reviewed for ASAM compliance initially and every three years thereafter or as needed.
Number and rate of providers in compliance.	Pennsylvania	Number of providers in compliance	Number of providers reviewed	OMHSAS and DDAP onsite reviews	Year	Annual	The Commonwealth will utilize review compliance to set a baseline rate of providers in compliance. That rate will improve over time.

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Milestone 5: Improvements in comprehensive treatment and prevention strategies to address opioid abuse and OUD for individuals in Medicaid managed care.							
Hypothesis 5: The 1115 SUD Demonstration will improve outcomes for individuals in Pennsylvania Medicaid managed care under the following measures: • AOD IET • Use of opioids at high dosage. • Use of opioids from multiple providers. • Concurrent use of opioids and benzodiazepines. • Continuity of pharmacotherapy for OUD. • Follow-up after discharge from the ED for MH or alcohol or other drug dependence. • Rate of overdose deaths in the Commonwealth. • Access to preventive/ambulatory health services for adult Medicaid managed care beneficiaries with SUD.							
Research question: Will improvements in treatment and prevention strategies in Medicaid managed care improve outcomes of individuals with an SUD in Medicaid managed care as demonstrated by: more effective initiation of treatment, decrease use of opioid at high dosages, reduce use of multiple opioids from multiple providers, reduce concurrent use of opioids and benzodiazepines, improve continuity of pharmacotherapy for OUD, decreased overdose deaths and access to preventive/ambulatory services?							
Analytic Approach: Interrupted time series; regression analysis for change over time after waiver implementation							
Driver: Continuum of Care (primary); Implementation of comprehensive treatment and prevention strategies (secondary)							
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?							
Measure	**Steward**	**Numerator**	**Denominator**	**Data Source**	**Measurement Period**	**Reporting Frequency**	**Target**
Initiation of AOD treatment: initiation of AOD treatment through an inpatient admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the	NCQA, NQF #0004, Medicaid Adult Core set	Initiation of AOD Treatment—percentage of beneficiaries who initiated treatment through an inpatient AOD admission,	Patients with a new episode of AOD abuse or dependence: Age 18 and older as of December 31 of the measurement year.	Encounter data/claims	Year	Annually	1% annual increase in each AOD Initiation and Engagement of Alcohol and other Drug Dependence Treatment (IET) measure NCQA, NQF #0004, Medicaid Adult Core set). *(Note: There*

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Milestone 5: Improvements in comprehensive treatment and prevention strategies to address opioid abuse and OUD for individuals in Medicaid managed care.							
index episode start date/eligible population.		outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or MAT within 14 days of the diagnosis.	Report the following diagnosis cohorts for each age stratification: • Alcohol abuse or dependence • Opioid abuse or dependence • Other drug abuse or dependence • Total AOD abuse or dependence Continuous enrollment 60 days (2 months) prior to the IESD through 48 days after the IESD (109 total days).				*are two rates reported; the goal will be 1% annual increase in each rate.)*
Engagement of AOD treatment: two or more inpatient admissions, outpatient visits, intensive outpatient encounters or partial hospitalizations beginning the day after the initiation encounter through 29 days after the initiation event/eligible population.	NCQA, NQF #0004, Medicaid Adult Core set	Engagement of AOD Treatment—percentage of beneficiaries who initiated treatment and who had two or more additional AOD services or MAT within 34 days of the initiation visit.	Patients with a new episode of AOD abuse or dependence: Age 18 and older as of December 31 of the measurement year. Report the following diagnosis cohorts for each age stratification: • Alcohol abuse or dependence • Opioid abuse or dependence	Encounter data/claims	Year	Annually	1% annual increase in each AOD Initiation and Engagement of Alcohol and other Drug Dependence Treatment (IET) measure NCQA, NQF #0004, Medicaid Adult Core set). *(Note: There are two rates reported; the goal will be 1% annual increase in each rate.)*

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Milestone 5: Improvements in comprehensive treatment and prevention strategies to address opioid abuse and OUD for individuals in Medicaid managed care.							
			• Other drug abuse or dependence • Total AOD abuse or dependence Continuous enrollment 60 days (2 months) prior to the Index Episode Start Date (IESD) through 48 days after the IESD (109 total days).				
Use of opioids at high dosage: (beneficiaries 18 and older who received prescriptions for opioids with a daily dosage greater than 120 morphine milligram equivalents for 90 consecutive days or longer/beneficiaries 18 and older who received prescriptions for opioids)*1,000.	NCQA, NQF #2940, Medicaid Adult Core set	Rate per 1,000 beneficiaries age 18 and older included in the denominator without cancer who received prescriptions for opioids with a daily dosage greater than 120 morphine milligram equivalents for 90 consecutive days or longer. Patients in hospice are also excluded.	Any Medicaid managed care enrollee age 18 and older as of January 1 of the measurement year. No more than one gap in continuous enrollment of up to 31 days during the measurement year.	Encounter data/claims	Year	Annually	1% annual decrease in the use of opioids at high dosage (Pharmacy Quality Alliance [PQA], NQF #2940, Medicaid Adult Core Set).

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Milestone 5: Improvements in comprehensive treatment and prevention strategies to address opioid abuse and OUD for individuals in Medicaid managed care.							
Use of opioids from multiple providers: (beneficiaries who received prescriptions for opioids from four or more prescribers and four or more pharmacies/beneficiaries who received prescriptions for opioids)*1,000.	PQA	The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.)	Any Medicaid managed care enrollee age 18 and older as of January 1 of the measurement year. No more than one gap in continuous enrollment of up to 31 days during the measurement year.	Encounter data/claims	Year	Annually	
Concurrent use of opioids and benzodiazepines: beneficiaries with concurrent use of prescription opioids and benzodiazepines/ beneficiaries.	PQA, Medicaid Adult Core set	Beneficiaries age 18 and older with concurrent use of prescription opioids and benzodiazepines. Patients with a cancer diagnosis or in hospice are excluded.	Beneficiaries age 18 and older enrolled in Medicaid managed care. Patients with a cancer diagnosis or in hospice are excluded.	Encounter data/claims			1% annual decrease in concurrent use of prescribed opioids and benzodiazepines (PQA).
Continuity of pharmacotherapy for OUD: beneficiaries with 180 days continuous pharmacotherapy treatment with an OUD medication/beneficiaries with diagnosis of OUD during an inpatient, intensive outpatient, partial hospitalization, outpatient, detoxification	USC, NQF #3175	Percentage of adults in the denominator with pharmacotherapy for OUD who have at least 180 days of continuous treatment.	Beneficiaries age 18 and older enrolled in Medicaid managed care.	Encounter data/claims	Year	Annually	1% annual increase in continuity of pharmacotherapy for OUD (RAND, NQF #3175).

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Milestone 5: Improvements in comprehensive treatment and prevention strategies to address opioid abuse and OUD for individuals in Medicaid managed care.							
or ED encounter during the measurement period and at least one claim for an OUD medication.							
Follow-up after discharge from the ED for MH within 7 days or 30 days: beneficiaries with an outpatient visit, intensive outpatient visit or partial hospitalization with a MH practitioner within 7 days or 30 days after an ED visit with a principal diagnosis of mental illness/ED visits with a principal diagnosis of mental illness.	NCQA, NQF #2605, Medicaid Adult Core set	30-Day Follow-Up A follow-up visit with any practitioner, with a principal diagnosis of MH within 30 days after the ED visit (31 total days). Include visits that occur on the date of the ED visit. 7-Day Follow-Up A follow-up visit with any practitioner, with a principal diagnosis of MH within 7 days after the ED visit (8 total days). Include visits that occur on the date of the ED visit.	Beneficiaries age 18 and older enrolled in Medicaid managed care	Encounter data/claims	Year	Annually	1% increase in the rate of follow-up after discharge from the ED within seven 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.)*
Follow-up after discharge from the ED for AOD dependence within 7 days or 30 days: beneficiaries with an outpatient visit, intensive outpatient visit	NCQA, NQF #2605, Medicaid Adult Core set	30-Day Follow-up. A follow-up visit with any practitioner, with a principal diagnosis of AOD	Beneficiaries age 18 and older enrolled in Medicaid managed care	Encounter data/claims	Year	Annually	1% increase in the rate of follow-up after discharge from the ED within seven days and within 30 days for MH or alcohol and other

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Milestone 5: Improvements in comprehensive treatment and prevention strategies to address opioid abuse and OUD for individuals in Medicaid managed care.							
or partial hospitalization with a MH practitioner within 7 days or 30 days after an ED visit with a principal diagnosis of AOD dependence/ED visits with a principal diagnosis of AOD.		abuse or dependence within 30 days after the ED visit (31 total days). Include visits that occur on the date of the ED visit. 7-Day follow-up A follow-up visit with any practitioner, with a principal diagnosis of AOD abuse or dependence within 7 days after the ED visit (8 total days). Include visits that occur on the date of the ED visit.					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.*
Rate of overdose deaths in the Commonwealth: number of overdose deaths/number of deaths.	CMS	The number of overdose deaths among eligible beneficiaries.	Beneficiaries enrolled in Medicaid managed care for at least one month (30 consecutive days) during the measurement period.	Encounter data/claims	Year	Annually	1% decrease in the rate of overdose deaths in the Commonwealth.
Access to preventive/ambulatory health services for adult Medicaid managed care	NCQA	Medicaid managed care members who had an ambulatory or	Beneficiaries enrolled in Medicaid managed care for at least one month (30 consecutive days)	Encounter data/claims	Year	Annually	1.5% annual increase in utilization of preventive/ambulatory visits for adult Medicaid managed

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Milestone 5: Improvements in comprehensive treatment and prevention strategies to address opioid abuse and OUD for individuals in Medicaid managed care.							
beneficiaries with SUD: the number of Medicaid beneficiaries with SUD who had an ambulatory or preventive care visit/number of beneficiaries with SUD.		preventive care visit during the measurement year.	during the measurement period.				care beneficiaries with SUD.

Milestone 6: Improved care coordination and transition between LOCs for individuals in Medicaid managed care							
Hypothesis 6: The 1115 SUD Demonstration will improve follow-up after discharge from EDs and decrease re-admissions for individuals in Pennsylvania Medicaid managed care with SUD.							
Research question: Has the Demonstration impacted access to care for individuals with SUD in Medicaid managed care by linking beneficiaries with community-based services and supports following stays in residential and inpatient treatment facilities and reducing re-admission rates for treatment? The following measures are described above: • Follow-up after discharge from the ED for MH or AOD dependence: Follow-up after discharge from the ED for MH within 7 days or 30 days: beneficiaries with an outpatient visit, intensive outpatient visit or partial hospitalization with a MH practitioner within 7 days or 30 days after an ED visit with a principal diagnosis of mental illness/ED visits with a principal diagnosis of mental illness. • Follow-up after discharge from the ED for AOD dependence within 7 days or 30 days: beneficiaries with an outpatient visit, intensive outpatient visit or partial hospitalization with a MH practitioner within 7 days or 30 days after an ED visit with a principal diagnosis of AOD dependence/ED visits with a principal diagnosis of AOD.							
Analytic Approach: Interrupted time series; regression analysis for change over time after waiver implementation							
Driver: Care Coordination (primary); Improved coordination and transitions between levels of care (secondary)							
Measure	**Steward**	**Numerator**	**Denominator**	**Data Source**	**Measurement Period**	**Reporting Frequency**	**Target**
Number and percentage of re-admissions among beneficiaries with SUD: number of acute inpatient readmissions within 30 days of discharge from an acute	NCQA	The number of acute inpatient stays among beneficiaries with SUD during the measurement period followed by an acute	The beneficiaries enrolled in Medicaid managed care.	Encounter data/claims	Year	Annually	1% decrease in the rate of re-admissions among beneficiaries with SUD.

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Milestone 6: Improved care coordination and transition between LOCs for individuals in Medicaid managed care							
inpatient stay/number of acute inpatient stays among beneficiaries with SUD		readmission within 30 days. For this metric, acute inpatient stays and a discharge on or between the first day of the measurement period and 30 days prior to the last day of the measurement period are considered index hospital stays (with the exception of stays that meet exclusion criteria). Acute inpatient stays with an admission date within 30 days of a discharge date associated with an index hospital stay are index readmission stays.					

Performance Measures for cost Note: there are no hypotheses regarding these metrics.

The evaluation design has been updated with this information.

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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
Total Medicaid SUD spending in Medicaid managed care during the measurement period.	Commonwealth	Portion of the Medicaid managed care rate spent on SUD during the measurement period.	Medicaid managed care rates	Encounter data/claims	Year	Interim and final evaluation reports	Maintenance of SUD spending in capitation rates.
Total Medicaid SUD spending on residential treatment within IMDs in Medicaid managed care during the measurement period.	Commonwealth	Portion of the Medicaid managed care rate spent on IMDs during the measurement period.	Medicaid managed care rates	Encounter data/claims	Year	Interim and final evaluation reports	Maintenance of IMD spending in capitation rates.
Costs by source of care for high cost individual 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 during the measurement period.	Medicaid managed care rates	Encounter data/claims	Year	Interim and final evaluation reports	Proportion of spending on different service categories in capitation rates for high cost individuals with SUD.

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Cost data will be analyzed using descriptive, time series analysis. This will show the changes in cost over time, from the period (at least one year) prior to the Demonstration waiver, and the years following. Changes over time will be analyzed to determine whether costs increase, decrease or stay the same.

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D. Methodological Limitations

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

Many of the metrics being computed by PeopleStat for the waiver will be new to OMHSAS. It is unclear at this time the degree to which it will be possible to generate historical data needed to forecast the slope of the "counterfactual" trend line (what would have happened without the Demonstration). This historical data is an important component of the ITS design, but also supports the descriptive time series analysis. In particular, there will be a limitation in estimating the slope of what the trend line would be without the Demonstration if we do not have data to model what would happen to the measures should the programs, already in operation, cease.

In addition to historical data, it is possible that the Commonwealth's data systems will additionally have current issues that make data errors more likely. For example, there are differences in the use of procedure codes between OMAP and OMHSAS that could cause services to be coded differently. In addition, the evaluation plan relies on encounter data, which will reflect the service delivered, but not the actual cost to Medicaid. In order to account for this, cost measures will be included on the portion of the Medicaid capitation rate.

The current system has a runout of 12 months, and will need to take into account timing around pulling data to calculate numerators and denominators for the measures. In addition, when encounter data is corrected, the new data does not replace the old automatically, meaning that an encounter can be reported multiple times. An important cleaning procedure will be to identify and remove duplicate encounter records.

The runout or latency period is established based on requirements of the primary contractor and its BH-MCO to adjudicate a claim and subsequently submit an encounter to the state. Claim submission by a provider may take up to 180 days before the primary contractor and its BH-MCO are no longer obligated to pay the claim. The Department contractually requires that all claims are adjudicated by the BH-MCO within 90 days after claim submission.

The Department requires the Primary Contractor or its BH-MCO to submit an encounter, or "pseudo claim," each time a Member has an encounter with a Provider. All encounters must be HIPAA Compliant and submitted and approved in PROMISe™ (i.e., pass PROMISe™ edits) within 90 days following the date that the BH-MCO paid/adjudicated the provider's claim or encounter. The Primary Contractor and its subcontractor(s) shall be responsible for maintaining appropriate systems and mechanisms to obtain all

necessary data from its health care providers to ensure its ability to comply with the Department's encounter data reporting requirements.

There is the possibility of duplicated data within PROMISe data. For example, when encounter data is corrected, the new data does not replace the old automatically, meaning than an encounter can be reported multiple times. An important cleaning procedure is to identify and remove duplicate encounter records.

The Managed Care Organization (MCO) encounter data for both PH and BH services is submitted to the state through the commonwealth's Secure Encryption system called SeGOV. The encounter passes through SeGOV and enters the commonwealth's Electronic Data Interchange (EDI) HIPAA Translator that ensures the data submitted meets HIPAA guidelines. After the file passes the checks in the HIPAA Translator it is sent to the Medicaid Management Information System for validation checks on the contents of the encounter.

To de-duplicate the data PeopleStat reviews the claim type for the claim, then uses a specific series of fields to rank the records and eliminates all but the first based on a series of fields, i.e. if RID and MCO and BEGIN_DATE are used in the sort for the ranking, the first record based on those three fields should be kept. There are six groupings of fields for these sorts based on the type of claim – Inpatient, Outpatient, Professional, Pharmacy, Long-Term Care and Dental.

PeopleStat acts independently of OMHSAS and OMAP. It has direct access to the data warehouse utilized by the Medicaid agency for encounter data and claims. The data will be automatically updated any time a provider submits a claim or encounter data. PeopleStat will calculate all performance measures in the frequency outlined in the performance measure chart above.

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 P and its BH-MCO. These encounters are first processed through the SeGOV encryption software, then the HIPAA Translator, and then Pennsylvania DHS HIPAA-compliant Provider Reimbursement and Operations Management Information System (PROMIS*e*™). In PROMISe, the encounters are edited to ensure that Federal and State 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.

While the interrupted time series design is the strongest available in the absence of a randomized trial or matched control group, there are some threats to the validity of results in the design.[15] The primary threat is that of history, or other changes over time happening during the waiver period. This

[15] 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.

interrupted time series design is only valid to the extent that the waiver program was the only thing that changed during the evaluation period. Other changes to policies or programs could affect the outcomes being measured here. We will attempt to control this threat by considering other policy and program changes happening concurrent to the waiver period interventions. The analysis will note the dates of other changes and analyze the degree to which the slope of the trend line changes after implementation of other interventions are made.

A related threat to the validity of this evaluation is external (history). Because OMHSAS has not identified a comparison group (a group of Medicaid managed care members who would be eligible for the waiver interventions but who will not receive them and/or for whom data will not be collected), it will be difficult to attribute causality. It will be less certain whether the changes observed in outcomes are due entirely to the waiver interventions, rather than some external, outside cause (including other program and policy changes described earlier). However, the interrupted time series design controls for this threat to some degree, by linking what would have likely happened (e.g., forecasting the trajectory of counts and rates over time) without any program changes and comparing this forecast to actual changes over time. To strengthen this design as much as possible, as many data points will be collected as possible across multiple years preceding waiver changes. This will allow for adjustment of seasonal or other, cyclical variations in the data. Additionally, the design will examine multiple change points, identifying key areas of major program and policy adjustments, so that with each major milestone accomplishment, corresponding changes to metrics can be observed. One potentially confounding factor of this design is that many of the Demonstration activities proposed are not new interventions, but represent programs that would no longer be funded without the waiver, due to other rule changes. It is very difficult to predict a trend line in that situation (programs being discontinued). However, if historical data is available for several years prior to these programs' implementation, it is possible to use more sophisticated linear modeling to predict a decreasing trend (change to more negative outcomes) that would have happened without the demonstration.

However, even though programmatic changes in this demonstration are modest, the hypotheses put forth in this document do assume some small improvement over current trends. If the data is not available to forecast negative trends that may happen without these programs, the current model should still be able to show the minor improvements indicated in these hypotheses.

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

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

Another threat to validity in this design may be the ability to measure the outcome rate of interest for the desired period of time both before and after waiver implementation. Evaluators will work closely with the OMHSAS and their data teams to assure that complete data is available for each measure and discuss any specific data concerns or considerations on a measure by measure basis.

According to the literature on interrupted time series analysis, estimating the level and slope parameters requires a minimum of eight observations before and after implementation in order to have sufficient power to estimate the regression coefficients.[15] Evaluators will need to work closely with OMHSAS and their data teams to gather as many data points as possible and discuss limitations within the evaluation findings if enough points cannot be collected.

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

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

E. Attachments

1. Independent Evaluator

As part of the Standard Terms and Conditions (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 Government Human Services Consulting (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 Behavioral Health 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 assisting state governments with the design, implementation and evaluation of publicly sponsored health care programs. Mercer currently has over 25 states under contract and has worked with over 35 different states in total. They have assisted states like Arizona, Connecticut, Missouri and New Jersey in performing independent evaluations of their Medicaid programs; many of which include 1115 Demonstration waiver evaluation experience. Mercer also has unique knowledge of the Commonwealth of Pennsylvania, where they conduct rate setting activities for both physical health and behavioral health 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 their 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 K. Nelson MD	Engagement Leader	Laura.K.Nelson@mercer.com
Heather Huff, MA	Program Manager	Heather.Huff@mercer.com
Barbara Anger, CPC	Certified Professional Coder	Barbara.Anger@mercer.com

NAME	POSITION	EMAIL ADDRESS
Nicole Fowle, MPH	Project Manager	Nicole.Fowle@mercer.com
Brenda Jenney, PhD	Statistician	Brenda.Jenney@mercer.com
Brenda Jackson, MPP	Policy and Operations Sector	Brenda.Jackson@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 Medical Assistance (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.

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

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

In regards to Mercer's proposed subcontractors, all have assured Mercer there will be no conflicts and that they will take any steps required by Mercer or DHS to mitigate any perceived conflict of interest. To the extent that we need to implement a conflict mitigation plan with any of our valued subcontractors, we will do so. Mercer is happy to discuss with DHS any other steps desired or needed to meet your needs in this area.

Mercer, 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 or degree with the performance of its services. Mercer has further assured that in the performance of this contract, it will not knowingly employ any person having such interest. Mercer additionally certified that no member of Mercer's Board or any of its officers or directors has such an adverse interest.

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NO CONFLICT OF INTEREST

Given Mercer's broad client base and diverse business offerings, we encounter situations where the interests of one client may be in conflict with the interests of another, or even with the interests of our Company itself. We identify such situations promptly, resolve them with integrity, and treat our clients fairly. More specifically, our Code of Conduct requires consultants to:

- Identify potential business conflicts of interest promptly.
- Determine an appropriate course of action to manage the conflict. Potential resolutions for a conflict are:
  - Disclosing the relationships to the relevant parties;
  - Obtaining consent from the party at risk;
  - Establishing information barriers (ethical walls); or
  - Declining the engagement.

Mercer, 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 or degree with the performance of its services. Mercer has further assured that in the performance of this contract, it will not knowingly employ any person having such interest. Mercer additionally certified that no member of Mercer's Board or any of its officers or directors has such an adverse interest.

Heather Huff, Principal
Printed name

Signature

August 5, 2019
Date

MARSH & McLENNAN COMPANIES

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2. Evaluation Budget

	DY 1 7/1/18 – 6/30/19	DY2 7/1/19 – 6/30/20	DY3 7/1/20 – 6/30/21	DY4 7/1/21 – 6/30/22	DY5 7/1/22 – 9/30/22	Final Evaluation 12/31/2024	Total Evaluation Cost
STAFF COSTS							
OMHSAS (see the break-down in the table below)	$54,346	$54,346	$54,346	$54,346	$13,586	$54,346	$285,316
STATE SYSTEM PARTNERS							
PeopleStat	$19,500	$19,500	$19,500	$19,500	$4,875	$19,500	$102,375
DDAP	$80,000	$80,000	$80,000	$80,000	$20,000	$80,000	$420,000
INDEPENDENT EVALUATOR/CONTRACTOR							
Mercer	$203,502	$55,000	$85,000	$115,000	$25,000	$285,000	$768,502
TOTAL	**$357,348**	**$208,846**	**$238,846**	**$268,846**	**$63,461**	**$438,846**	**$1,576,193**

		DY1 07/01/18 - 06/30/19		DY2 07/01/19 - 06/30/20		DY3 07/01/20 - 06/30/21		DY4 07/01/21 - 06/30/22		DY5 07/01/22 - 09/30/22		Final Evaluation 12/31/24		Total OMHSAS Staff Cost
OMHSAS Staff	**FTE for 1115 Evaluation**	**Annual Salary plus Benefits**	**FTE Equivalent Salary plus Benefits**	**Annual Salary plus Benefits**	**FTE Equivalent Salary plus Benefits**	**Annual Salary plus Benefits**	**FTE Equivalent Salary plus Benefits**	**Annual Salary plus Benefits**	**FTE Equivalent Salary plus Benefits**	**Quarter Year Salary plus Benefits**	**FTE Equivalent Salary plus Benefits**	**Annual Salary plus Benefits**	**FTE Equivalent 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	$29,836	$3,580	$119,343	$14,321	$75,186
Director, Bureau of Program Management and Planning	5%	$155,463	$7,773	$155,463	$7,773	$155,463	$7,773	$ 155,463	$7,773	$38,866	$1,943	$155,463	$7,773	$40,809
Community & Hospital Operations representative	7%	$119,343	$8,354	$ 119,343	$8,354	$119,343	$8,354	$119,343	$8,354	$29,836	$2,089	$119,343	$8,354	$43,859
Director Area Operations	5%	$155,463	$ 7,773	$155,463	$7,773	$155,463	$7,773	$155,463	$7,773	$38,866	$1,943	$155,463	$7,773	$40,809
Quality Management Director	5%	$136,196	$6,810	$136,196	$6,810	$136,196	$6,810	$136,196	$6,810	$34,049	$1,702	$136,196	$6,810	$35,752
Director Bureau of Quality Management & Data Review	2%	$145,514	$2,910	$145,514	$2,910	$145,514	$2,910	$145,514	$2,910	$36,378	$728	$145,514	$2,910	$15,279
Division Director OMHSAS Bureau of Quality Management & Data Review	3%	$124,753	$3,743	$ 124,753	$3,743	$124,753	$3,743	$124,753	$3,743	$31,188	$936	$124,753	$3,743	$19,649
Quality Assurance/Risk Management Director	2%	$133,089	$2,662	$133,089	$2,662	$133,089	$2,662	$133,089	$2,662	$33,272	$665	$133,089	$2,662	$13,974
TOTAL		$1,089,164	**$54,346**	$1,089,164	**$54,346**	$1,089,164	**$54,346**	$1,089,164	**$54,346**	$272,291	**$13,586**	$1,089,164	**$54,346**	**$285,316**

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3. Timeline and Major Deliverables

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	39, 50	March 31, 2019
Final Evaluation Design — due 60 days after CMS comments are received	39, 50a	60 days post comments
Publish Final Evaluation Design on Commonwealth website — 30 days after CMS approval	39, 45, 50(a)	30 days after CMS approval
Mid-point assessment due	25	November 15, 2020
Draft Interim Report due	42	September 30, 2021
Final Interim Report — due 60 days after CMS comments are received	42(d)	60 days post comments
Publish Final Interim Report on Commonwealth website — 30 days after CMS approval is received	45	30 days after CMS approval
Draft Summative Evaluation Report — due 18 months following Demonstration	43	March 31, 2024
Final Summative Evaluation Report — due 60 days after CMS comments are received	43(a)	60 days post comments
Publish Final Summative Evaluation Report on Commonwealth website — 30 days after CMS approval is received	43(b)	30 days after CMS approval

Appendix B
Additional Data: Full ITS Analysis Results and Subpopulation Charts

Full ITS Regression Analysis Output Tables

Metric #3 — SUD DX

Total — Metric #3 SUD DX					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	17099.827	90.741	188.447	< 2e-16	***
data$demonstration	10125.75	491.032	20.621	< 2e-16	***
data$time	88.427	4.277	20.676	< 2e-16	***
data$covid	-904.095	191.286	-4.726	1.63E-05	***
data$demonstration:data$time	-92.623	11.151	-8.306	2.77E-11	***

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Dual — Metric #3 SUD DX					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	2533.4254	9.5807	264.43	< 2e-16	***
data$demonstration	714.9373	51.8448	13.79	< 2e-16	***
data$time	5.0506	0.4516	11.185	8.69E-16	***
data$covid	-94.9806	20.1966	-4.703	1.77E-05	***
data$demonstration:data$time	-7.6939	1.1774	-6.535	2.18E-08	***

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Senior — Metric #3 SUD DX					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	832.1651	4.4834	185.611	< 2e-16	***
data$demonstration	-11.2565	24.2613	-0.464	0.645	
data$time	-2.1591	0.2113	-10.218	2.57E-14	***
data$covid	-9.9575	9.4512	-1.054	0.297	
data$demonstration:data$time	0.818	0.551	1.485	0.143	

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Pregnant — Metric #3 SUD DX					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	1362.6429	17.9591	75.875	< 2e-16	***
data$demonstration	251.5889	97.1838	2.589	0.0123	*
data$time	15.4923	0.8464	18.303	< 2e-16	***
data$covid	-30.7515	37.8588	-0.812	0.4201	
data$demonstration:data$time	-12.0005	2.207	-5.437	1.28E-06	***

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Metric #6 — Any Service

Total — Metric #6 Any Service					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	49569.22	1916.96	25.858	< 2e-16	***
data$demonstration	18605.08	10373.42	1.794	0.0784	.
data$time	535.05	90.35	5.922	2.15E-07	***
data$covid	-29346.8	4041.06	-7.262	1.40E-09	***
data$demonstration:data$time	-454.66	235.58	-1.93	0.0588	.

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Dual — Metric #6 Any Service					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	4886.329	197.468	24.745	< 2e-16	***
data$demonstration	1643.44	1068.572	1.538	0.1298	
data$time	20.554	9.307	2.208	0.0314	*
data$covid	-3143.05	416.272	-7.55	4.73E-10	***
data$demonstration:data$time	-17.746	24.267	-0.731	0.4677	

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Children — Metric #6 Any Service					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	157.102	42.933	3.659 0	0.000568	***
data$demonstration	-514.526	232.327	-2.215 0	0.030945	*
data$time	28.122	2.024	13.898	< 2e-16	***
data$covid	-463.672	90.505	-5.123 3	9.90E-07	***
data$demonstration:data$time	-4.445	5.276	-0.843 0	0.403139	

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Seniors — Metric #6 Any Service					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	768.53	42.015	18.292	< 2e-16	***
data$demonstration	435.559	227.358	1.916	0.0606	.
data$time	-2.847	1.98	-1.438	0.1562	
data$covid	-763.375	88.569	-8.619 8	6.50E-13	***
data$demonstration:data$time	6.407	5.163	1.241	0.2199	

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Pregnant — Metric #6 Any Service					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	1848.01	95.191	19.414	< 2e-16	***
data$demonstration	528.321	515.114	1.026	0.30955	
data$time	58.288	4.487	12.992	< 2e-16	***
data$covid	-1362.93	200.667	-6.792	8.26E-09	***
data$demonstration:data$time	-40.423	11.698	-3.456	0.00107	**

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Metric #7 — Early Intervention

Total — Metric #7 Early Intervention					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	1954.173	107.395	18.196	< 2e-16	***
data$demonstration	1685.322	581.156	2.9	0.00535	**
data$time	88.497	5.062	17.484	< 2e-16	***
data$covid	-1804.65	226.394	-7.971	9.71E-11	***
data$demonstration:data$time	-43.921	13.198	-3.328	0.00157	**

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Dual — Metric #7 Early Intervention					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	151.3063	9.8006	15.438	< 2e-16	***
data$demonstration	-229.064	53.0348	-4.319	6.60E-05	***
data$time	0.8588	0.4619	1.859	0.0683	.
data$covid	-146.076	20.6602	-7.07	2.89E-09	***
data$demonstration:data$time	6.1725	1.2044	5.125	3.96E-06	***

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Children — Metric #7 Early Intervention					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	85.454	8.0163	10.66	5.38E-15	***
data$demonstration	-150.695	43.3793	-3.474	0.00101	**
data$time	0.4499	0.3778	1.191	0.23882	
data$covid	-79.1799	16.8988	-4.686	1.88E-05	***
data$demonstration:data$time	2.5359	0.9851	2.574	0.01277	*

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Seniors — Metric #7 Early Intervention					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	21.67619	1.9589	11.066	1.31E-15	***
data$demonstration	-71.7934	10.60034	-6.773	8.89E-09	***
data$time	-0.23475	0.09233	-2.543	0.0138	*
data$covid	-35.5851	4.12946	-8.617	8.70E-12	***
data$demonstration:data$time	2.21684	0.24073	9.209	9.82E-13	***

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Pregnant — Metric #7 Early Intervention					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	192.3794	14.5224	13.247	< 2e-16	***
data$demonstration	30.9837	78.5863	0.394	0.69491	
data$time	4.6672	0.6845	6.819	7.47E-09	***
data$covid	-92.7918	30.614	-3.031	0.00371	**
data$demonstration:data$time	-2.147	1.7847	-1.203	0.23411	

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Metric #8 — Outpatient Services

Total — Metric #8 Outpatient Services					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	40320.76	1701.89	23.692	< 2e-16	***
data$demonstration	19944.74	9209.6	2.166	0.0347	*
data$time	577.58	80.21	7.201	1.77E-09	***
data$covid	-26769	3587.68	-7.461	6.62E-10	***
data$demonstration:data$time	-542.99	209.15	-2.596	0.0121	*

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Dual — Metric #8 Outpatient Services					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	4777.083	179.899	26.554	< 2e-16	***
data$demonstration	1330.015	973.5	1.366	0.177	
data$time	8.704	8.479	1.027	0.309	
data$covid	-2912.82	379.236	-7.681	2.90E-10	***
data$demonstration:data$time	-9.948	22.108	-0.45	0.654	

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Children — Metric #8 Outpatient Services					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	561.143	103.738	5.409	1.42E-06	***
data$demonstration	-838.72	561.367	-1.494	0.1409	
data$time	8.109	4.889	1.659	0.1029	
data$covid	-425.483	218.686	-1.946	0.0568	.
data$demonstration:data$time	11.96	12.749	0.938	0.3523	

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Seniors — Metric #8 Outpatient Services					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	781.111	39.014	20.021	< 2e-16	***
data$demonstration	353.402	211.122	1.674	0.0998	.
data$time	-4.815	1.839	-2.619	0.0114	*
data$covid	-726.981	82.244	-8.839	3.82E-12	***
data$demonstration:data$time	7.772	4.795	1.621	0.1107	

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Pregnant — Metric #8 Outpatient Services					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	2051.676	123.833	16.568	< 2e-16	***
data$demonstration	69.068	670.105	0.103	0.918	
data$time	37.045	5.836	6.347	4.40E-08	***
data$covid	-1323.83	261.045	-5.071	4.80E-06	***
data$demonstration:data$time	-21.496	15.218	-1.413	0.163	

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Metric #9 — Medicaid Managed Care

Total — Metric #9 Medicaid Managed Care					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	7866.6	312.5	25.173	< 2e-16	***
data$demonstration	2368.34	1691.06	1.401	0.167	
data$time	33.19	14.73	2.254	0.0282	*
data$covid	-4588.43	658.77	-6.965	4.30E-09	***
data$demonstration:data$time	-84.75	38.4	-2.207	0.0315	*

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Dual — Metric #9 Medicaid Managed Care					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	545.1	54.38	10.024	5.12E-14	***
data$demonstration	287.399	294.268	0.977	0.33302	
data$time	2.706	2.563	1.056	0.29562	
data$covid	-349.578	114.635	-3.049	0.00352	**
data$demonstration:data$time	-7.833	6.683	-1.172	0.24619	

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Children — Metric #9 Medicaid Managed Care						
Coefficients:						
	Estimate	**Std. Error**		**t value**	**Pr(>|t|)**	
(Intercept)	99.6381	18.179	4	5.481	1.09E-06	***
data$demonstration	-166.458	98.375	4	-1.692	0.0963	.
data$time	0.461	0.856	8	0.538	0.5927	
data$covid	-52.6179	38.323	0	-1.373	0.1753	
data$demonstration:data$time	2.6405	2.234	1	1.182	0.2423	

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**						

Seniors — Metric #9 Medicaid Managed Care					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	107.046	4.5187	23.69	< 2e-16	***
data$demonstration	19.3812	24.4524	0.793	0.431	
data$time	-1.2562	0.213	-5.899	2.34E-07	***
data$covid	-71.3172	9.5257	-7.487	6.01E-10	***
data$demonstration:data$time	0.8868	0.5553	1.597	0.116	

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Pregnant — Metric #9 Medicaid Managed Care					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	264.39	21.876	12.086	< 2e-16	***
data$demonstration	39.302	118.38	0.332	0.74115	
data$time	2.335	1.031	2.264	0.02751	*
data$covid	-166.765	46.116	-3.616	0.00065	***
data$demonstration:data$time	-3.167	2.688	-1.178	0.24388	

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Metric #10 — SUD Residential and Inpatient Services

Total — Metric #10 SUD Residential and Inpatient Services					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	1000.967	245.744	4.073	0.00015	***
data$demonstration	5906.811	1329.814	4.442	4.35E-05	***
data$time	7.281	11.582	0.629	0.53219	
data$covid	-4194.44	518.041	-8.097	6.07E-11	***
data$demonstration:data$time	-1.924	30.2	-0.064	0.94944	

Signif. codes: 0 ‘*’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1**					

Dual — Metric #10 SUD Residential and Inpatient Services					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	41.40476	13.71764	3.018	0.00385	**
data$demonstration	371.8326	74.23135	5.009	6.00E-06	***
data$time	0.10875	0.64654	0.168	0.86704	
data$covid	-251.019	28.91748	-8.681	6.88E-12	***
data$demonstration:data$time	-0.06547	1.68577	-0.039	0.96916	

Signif. codes: 0 ‘*’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1**					

Seniors — Metric #10 SUD Residential and Inpatient Services					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	2.4571	1.9222	1.278	0.2065	
data$demonstration	88.8346	10.4019	8.54	1.16E-11	***
data$time	-0.0112	0.0906	-0.124	0.9021	
data$covid	-34.8537	4.0522	-8.601	9.23E-12	***
data$demonstration:data$time	-0.6843	0.2362	-2.897	0.0054	**

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Pregnant — Metric #10 SUD Residential and Inpatient Services					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	42.7397	9.114	4.689	1.85E-05	***
data$demonstration	251.2585	49.3192	5.095	4.42E-06	***
data$time	-0.0565	0.4296	-0.132	0.896	
data$covid	-138.044	19.2127	-7.185	1.88E-09	***
data$demonstration:data$time	-0.6607	1.12	-0.59	0.558	

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Metric #11 — WM

Total — Metric #11 WM					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	15.6683	53.2814	0.294	0.77	
data$demonstration	1746.904	288.3257	6.059	1.29E-07	***
data$time	0.5465	2.5112	0.218	0.829	
data$covid	-889.76	112.3198	-7.922	1.17E-10	***
data$demonstration:data$time	-4.8039	6.5478	-0.734	0.466	

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Metric #12 — MAT

Total — Metric #12 MAT					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	3791.99	1067.11	3.553	0.000789	***
data$demonstration	47679.15	5774.56	8.257	3.33E-11	***
data$time	834.46	50.29	16.591	< 2e-16	***
data$covid	-15754.4	2249.53	-7.003	3.72E-09	***
data$demonstration:data$time	-1110.57	131.14	-8.469	1.51E-11	***

Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Dual — Metric #12 MAT					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	282.605	29.631	9.537	2.96E-13	***
data$demonstration	1761.549	160.345	10.986	1.73E-15	***
data$time	2.35	1.397	1.683	0.0981	.
data$covid	130.799	62.464	2.094	0.0409	*
data$demonstration:data$time	-38.879	3.641	-10.677	5.07e-15	***

Signif. codes: 0 ‘*’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1**					

Children — Metric #12 MAT					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	27.5429	11.1199	2.477	0.01636	*
data$demonstration	6.4501	60.174	0.107	0.91503	
data$time	1.6328	0.5241	3.115	0.00292	**
data$covid	0.2127	23.4413	0.009	0.99279	
data$demonstration:data$time	-1.538	1.3665	-1.126	0.26526	

Signif. codes: 0 ‘*’ 0.001 ‘**’ 0.01 ‘*’ 0.05 ‘.’ 0.1 ‘ ’ 1**					

Seniors — Metric #12 MAT					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	45.1317	5.8514	7.713	2.56e-10.	***
data$demonstration	357.3735	31.664	11.286	6.13E-16	***
data$time	-1.1347	0.2758	-4.115	0.000131	***
data$covid	18.0433	12.335	1.463	0.149221	
data$demonstration:data$time	-5.9772	0.7191	-8.312	2.71E-11	***

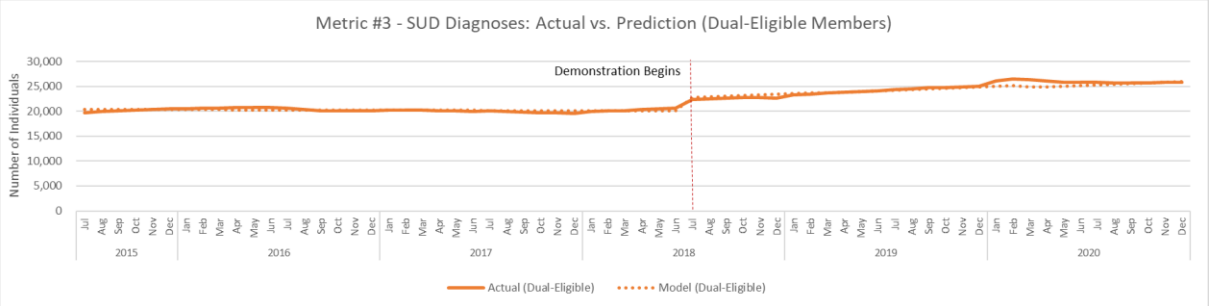
Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Pregnant — Metric #12 MAT					
Coefficients:					
	Estimate	**Std. Error**	**t value**	**Pr(>|t|)**	
(Intercept)	44.113	21.748	2.028	0.047374	*
data$demonstration	255.303	117.685	2.169	0.034393	*
data$time	4.177	1.025	4.075	0.000149	***
data$covid	-77.27	45.845	-1.685	0.097566	.
data$demonstration:data$time	-7.013	2.673	-2.624	0.011226	*

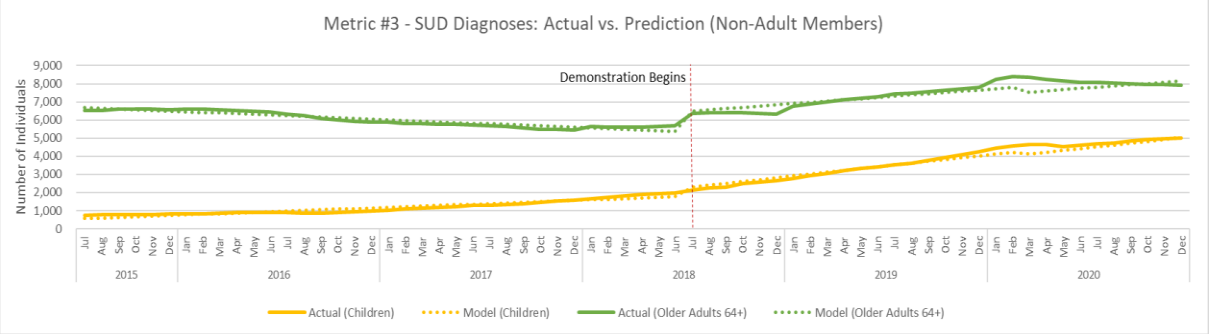
Signif. codes: 0 '*' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1**					

Subpopulation Charts

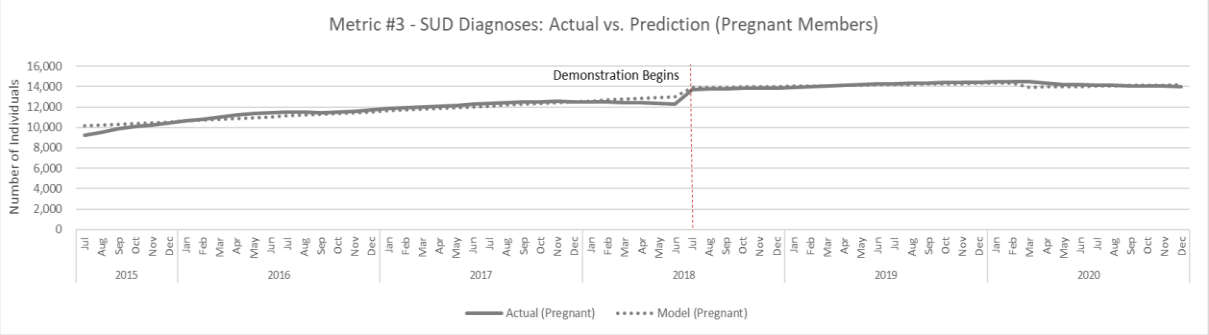
The ITS analysis for Metric #3 across dual-eligible members revealed an initial increase in individuals (approximately 2,698) with SUD diagnoses upon the Demonstration beginning. This was followed by an additional increase of approximately 123 more individuals per month. The effect of the Demonstration over time was highly statistically significant ($p < .001$).



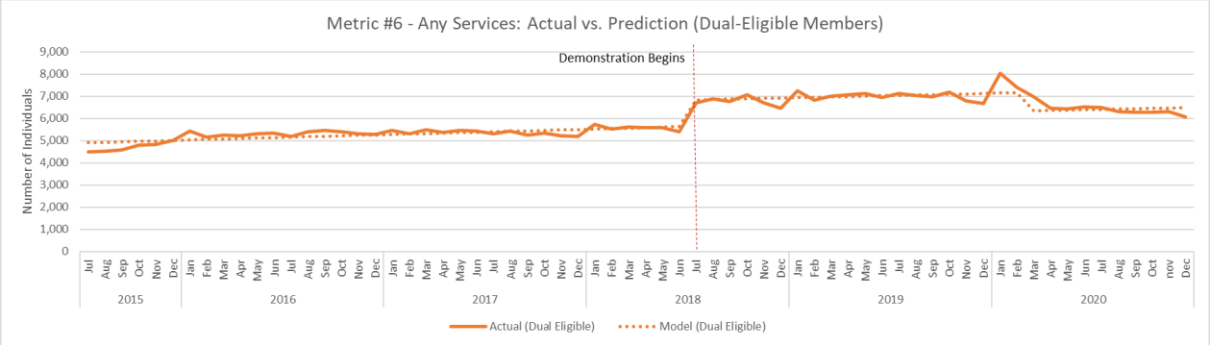
The ITS analysis for Metric #3 across non-adult members revealed an initial increase in individuals (approximately 538 children and 1,116 older adults) with SUD diagnoses upon the Demonstration beginning. This was followed by additional increases of approximately 101 more children and 68 older adults per month. The effect of the Demonstration over time was highly statistically significant across both children and older adults ($p < .001$).



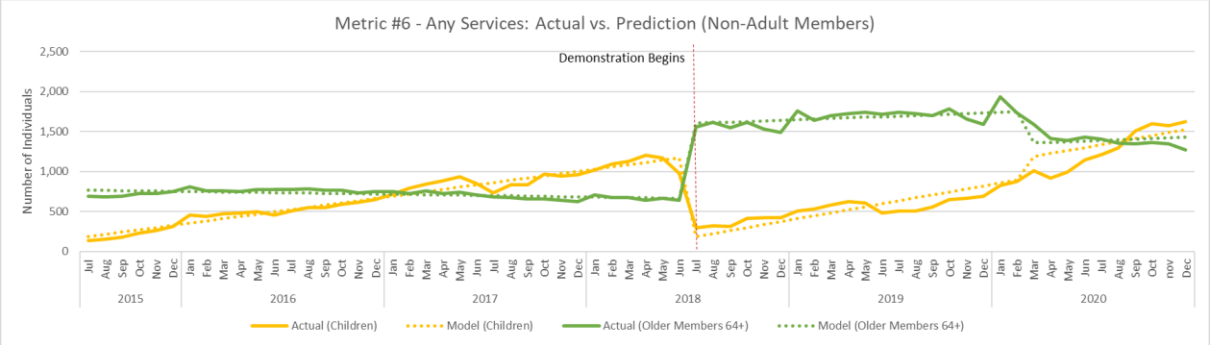
The ITS analysis for Metric #3 across pregnant members revealed an initial increase in individuals (approximately 872) with SUD diagnoses upon the Demonstration beginning. This was followed by an additional increase of approximately 26 more individuals per month. The effect of the Demonstration over time was highly statistically significant ($p < .001$).



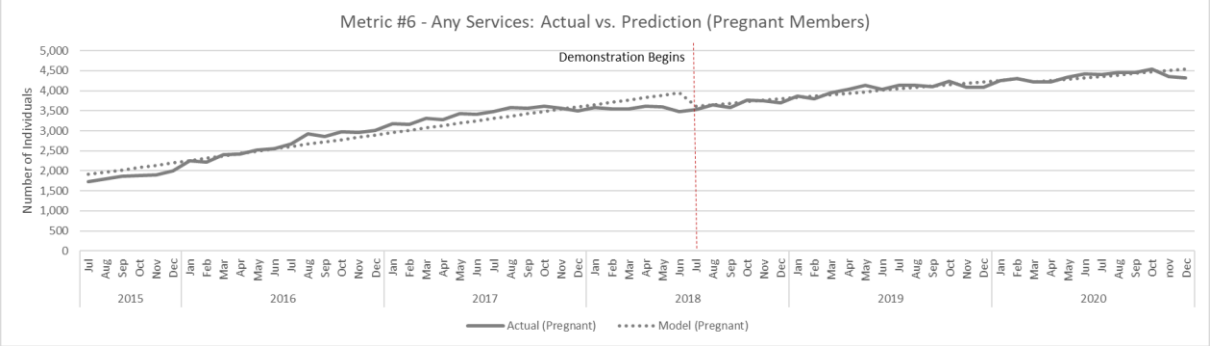
The ITS analysis for Metric #6 across dual-eligible members revealed an initial increase in individuals (approximately 1,207) receiving any services upon the Demonstration beginning. This was followed by an additional increase of approximately 17 more individuals per month. The effect of the Demonstration over time was not statistically significant.



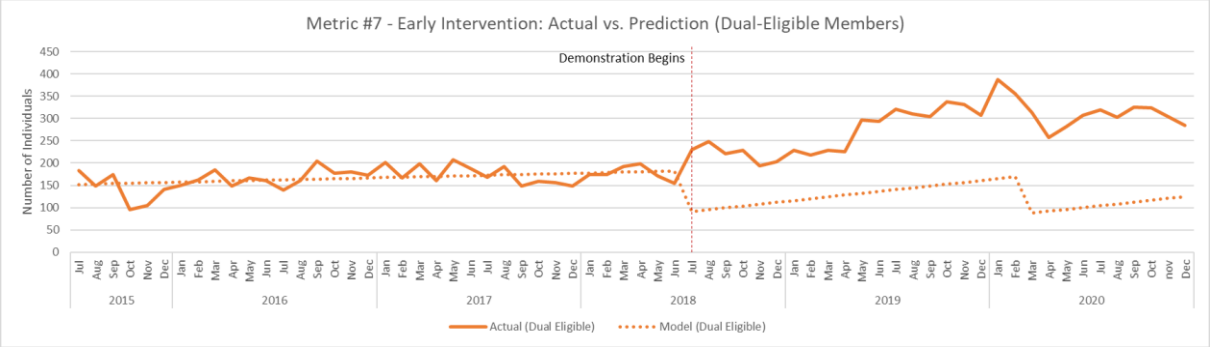
The ITS analysis for Metric #6 across non-adult members revealed an initial decrease in children (approximately 983) and initial increase in older adults (approximately 938) receiving any services upon the Demonstration beginning. This was followed by an increase of approximately 37 more children and eight older adults per month. The effect of the Demonstration over time was statistically significant for children ($p < .05$) and highly statistically significant for older adults ($p < .001$).



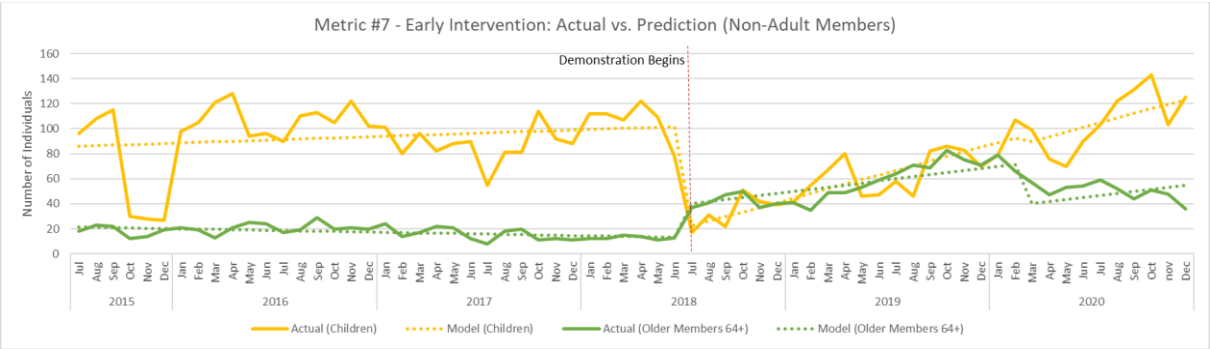
The ITS analysis for Metric #6 across pregnant members revealed an initial decrease in individuals (approximately 330) receiving any services upon the Demonstration beginning. This was followed by an increase of approximately 36 more individuals per month. The effect of the Demonstration over time was highly statistically significant ($p < .001$).



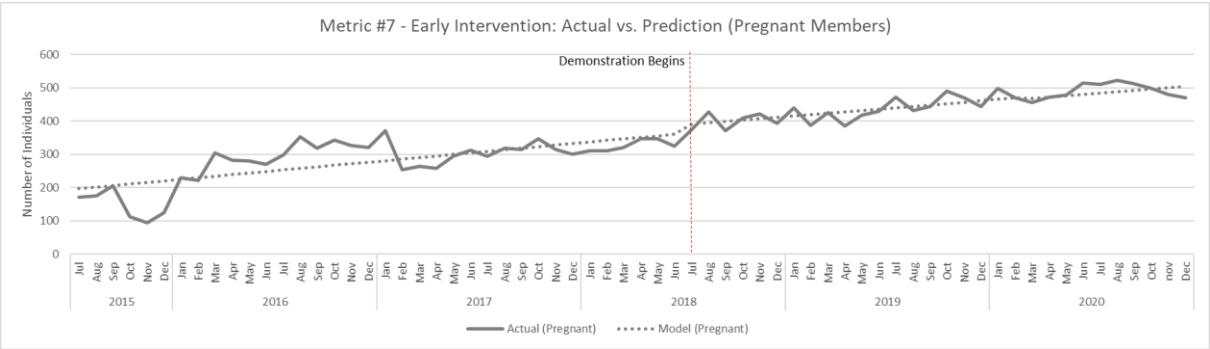
The ITS analysis for Metric #7 across dual-eligible members revealed an initial decrease in individuals (approximately 91) receiving early intervention services upon the Demonstration beginning. This was followed by an increase of approximately four more individuals per month. The effect of the Demonstration over time was highly statistically significant ($p < .001$).



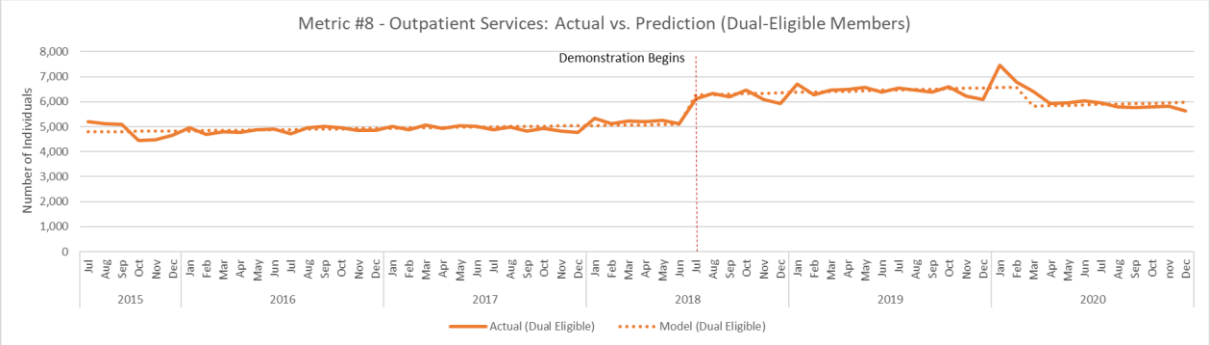
The ITS analysis for Metric #7 across non-adult members revealed an initial decrease in children (approximately 79) and an initial increase in older adults (approximately 27) receiving early intervention services upon the Demonstration beginning. This was followed by an increase of approximately four more children and two older adults per month. The effects of the Demonstration over time were statistically significant ($p < .001$) for both children and older adults.



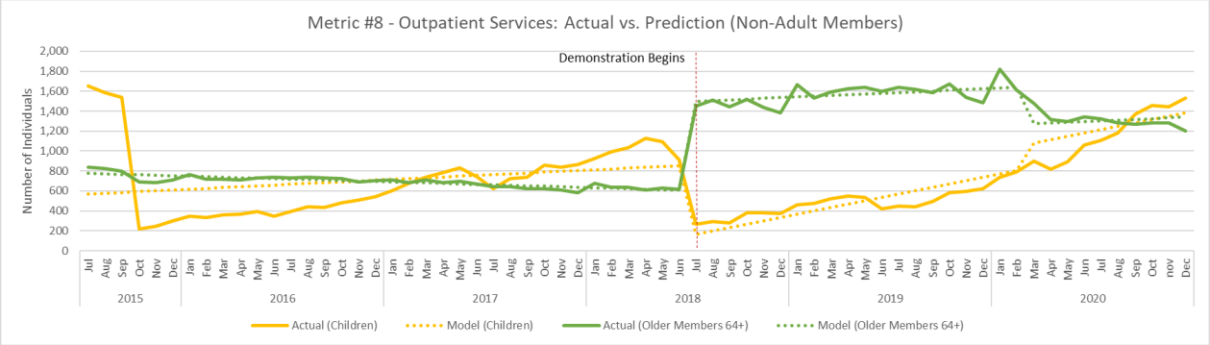
The ITS analysis for Metric #7 across pregnant members revealed an initial increase in individuals (approximately 31) receiving early intervention services upon the Demonstration beginning. This was followed by an increase of approximately four more individuals per month. The effect of the Demonstration over time was not statistically significant.



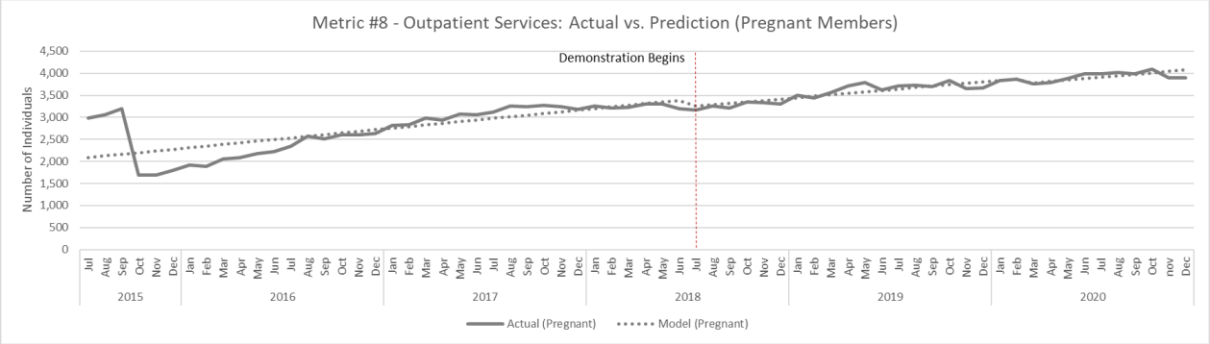
The ITS analysis for Metric #8 across dual-eligible members revealed an initial increase in individuals (approximately 1,183) receiving outpatient services upon the Demonstration beginning. This was followed by an additional increase of approximately 16 more individuals per month. The effect of the Demonstration over time was not statistically significant.



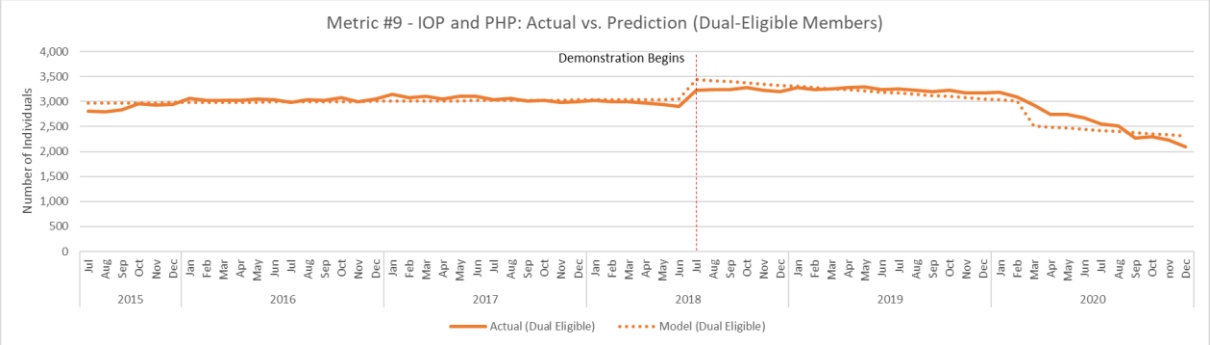
The ITS analysis for Metric #8 across non-adult members revealed an initial decrease in children (approximately 688) and an initial increase in older adults (approximately 891) receiving outpatient services upon the Demonstration beginning. This was followed by an increase of approximately 34 more children and seven older adults per month. The effects of the Demonstration over time were statistically significant for children ($p < .05$) and highly statistically significant for older adults ($p < .001$).



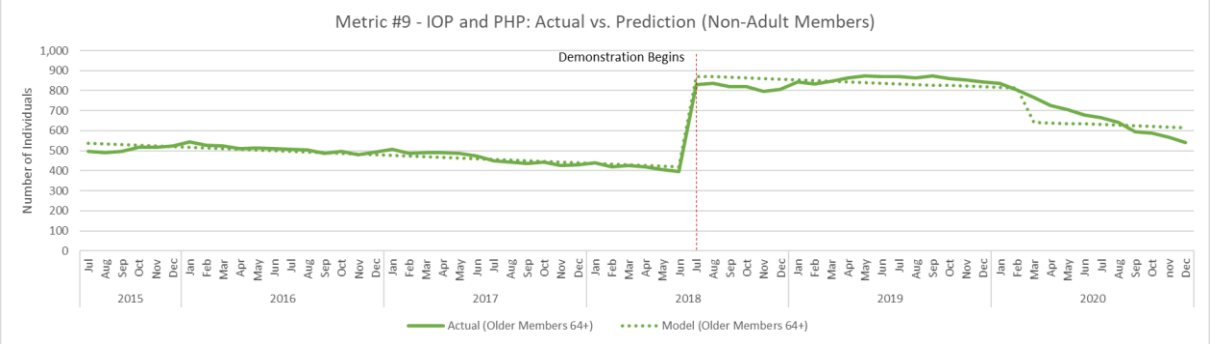
The ITS analysis for Metric #8 across pregnant members revealed an initial decrease in individuals (approximately 134) receiving outpatient services upon the Demonstration beginning. This was followed by an increase of approximately 33 more individuals per month. The effect of the Demonstration over time was not statistically significant.



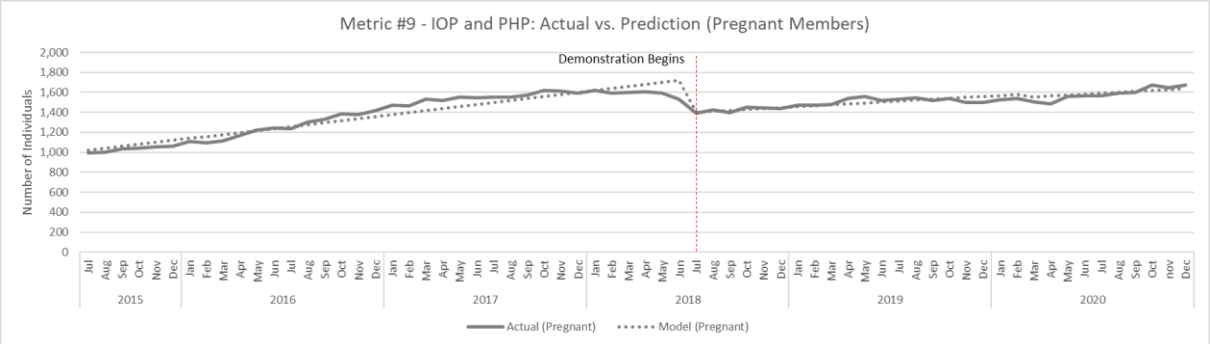
The ITS analysis for Metric #9 across dual-eligible members revealed an initial increase in individuals (approximately 393) receiving IOP and PHP services upon the Demonstration beginning. This was followed by a decline of approximately 23 fewer individuals per month. The effect of the Demonstration over time was highly statistically significant ($p < .001$).



The ITS analysis for Metric #9 across non-adult members revealed an initial increase in older adults (approximately 452) receiving IOP and PHP services upon the Demonstration beginning. This was followed by a decline of approximately three fewer individuals per month. The effect of the Demonstration over time was not statistically significant.

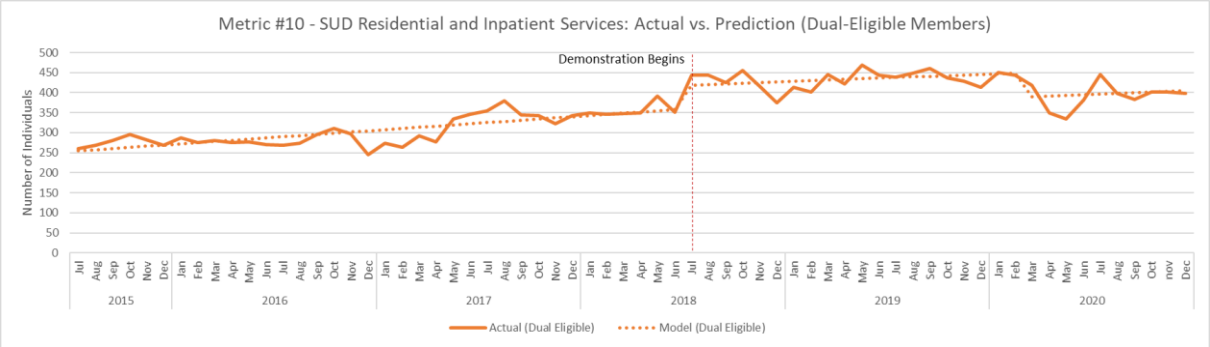


The ITS analysis for Metric #9 across pregnant members revealed an initial decrease in individuals (approximately 320) receiving IOP and PHP services upon the Demonstration beginning. This was followed by an increase of approximately nine more individuals per month. The effect of the Demonstration over time was highly statistically significant ($p < .001$).

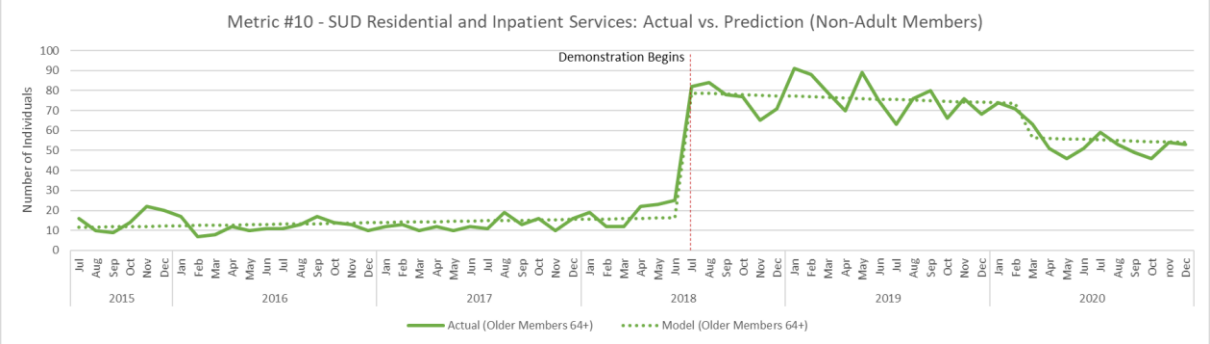


The ITS analysis for Metric #10 across dual-eligible members revealed an initial increase in individuals (approximately 60) receiving SUD residential and inpatient services upon the

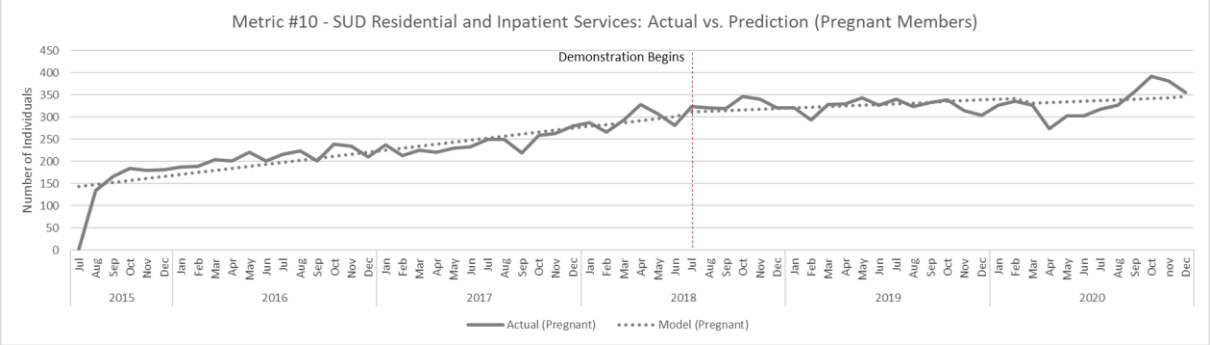
Demonstration beginning. This was followed by an increase of approximately two more individuals per month. The effect of the Demonstration over time was not statistically significant.



The ITS analysis for Metric #10 across Older Members age 64+ revealed an initial increase in older adults (approximately 62) receiving SUD residential and inpatient services upon the Demonstration beginning. This was followed by a decline of approximately three fewer individuals per year. The effect of the Demonstration over time was not statistically significant.

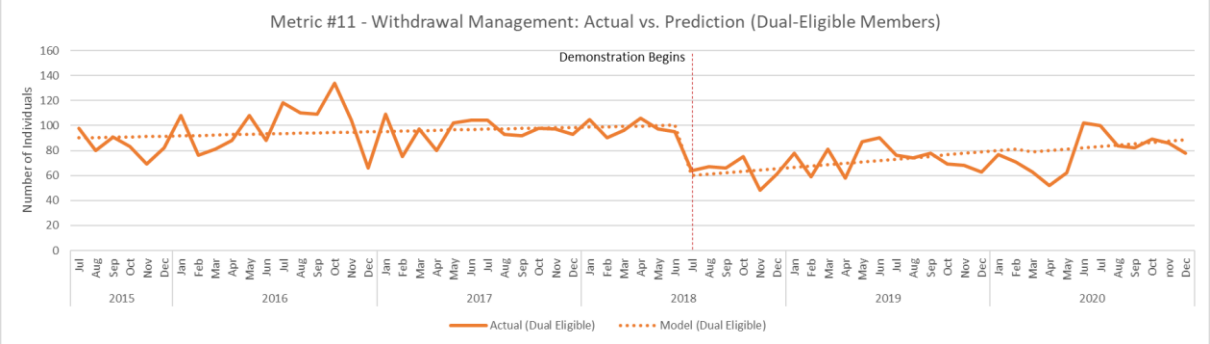


The ITS analysis for Metric #10 across pregnant members revealed an initial increase in individuals (approximately nine) receiving SUD residential and inpatient services upon the Demonstration beginning. This was followed by an increase of approximately two more individuals per month. The effect of the Demonstration over time was statistically significant ($p < .01$).

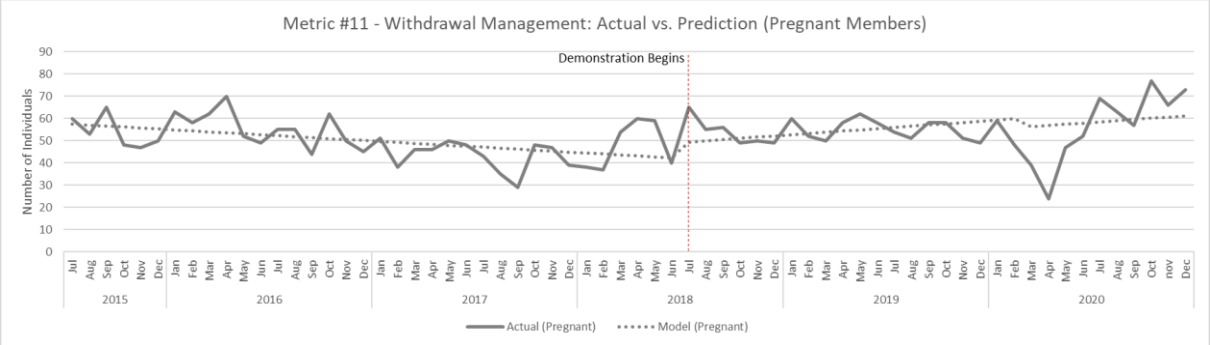


The ITS analysis of Metric #11 across dual-eligible members revealed an initial decrease in individuals (approximately 40) receiving WM services upon the Demonstration beginning.

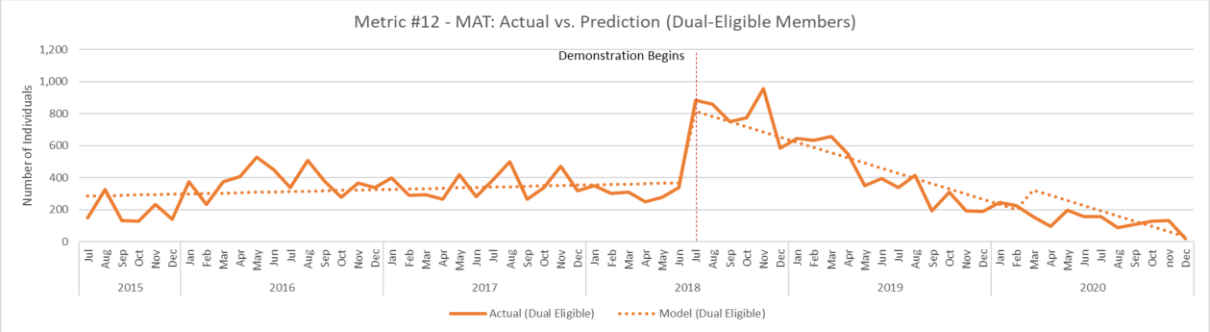
This was followed by an increase of approximately one more individual per month. The effect of the Demonstration over time was not statistically significant.



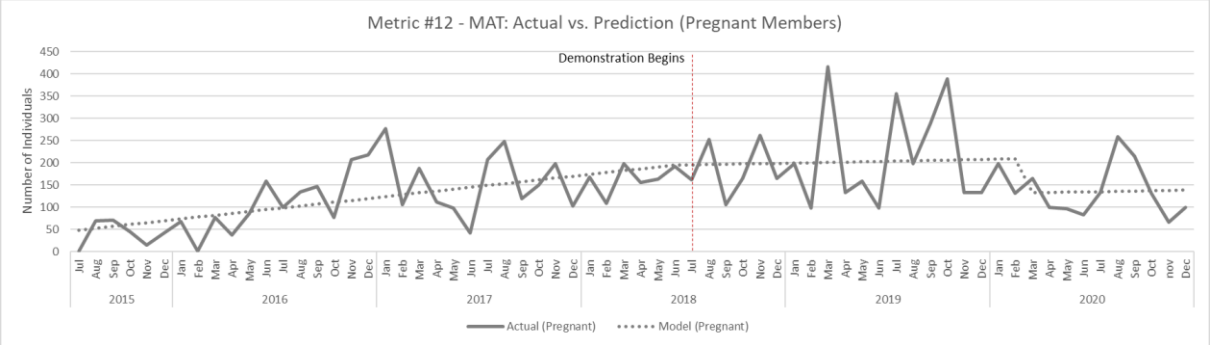
The ITS analysis of Metric #11 across pregnant members revealed an initial increase in individuals (approximately seven) receiving WM services upon the Demonstration beginning. This was followed by an increase of approximately six more individuals per year. The effect of the Demonstration over time was statistically significant ($p < .01$).



The ITS analysis for Metric #12 across dual-eligible members revealed an initial increase in individuals (approximately 448) receiving MAT services upon the Demonstration beginning. This was followed by a decline of approximately 32 fewer individuals per month. The effect of the Demonstration over time was highly statistically significant (p <.001).



The ITS analysis for Metric #12 across pregnant members did not reveal a change in individuals receiving MAT services upon the Demonstration beginning. This was followed by an increase of approximately nine more individuals per year. The effect of the Demonstration was not statistically significant.



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