Commonwealth of Pennsylvania

Substance Use Disorder 1115 Waiver

Number 11-W-00308/3

Evaluation Design

Updated January 31, 2020

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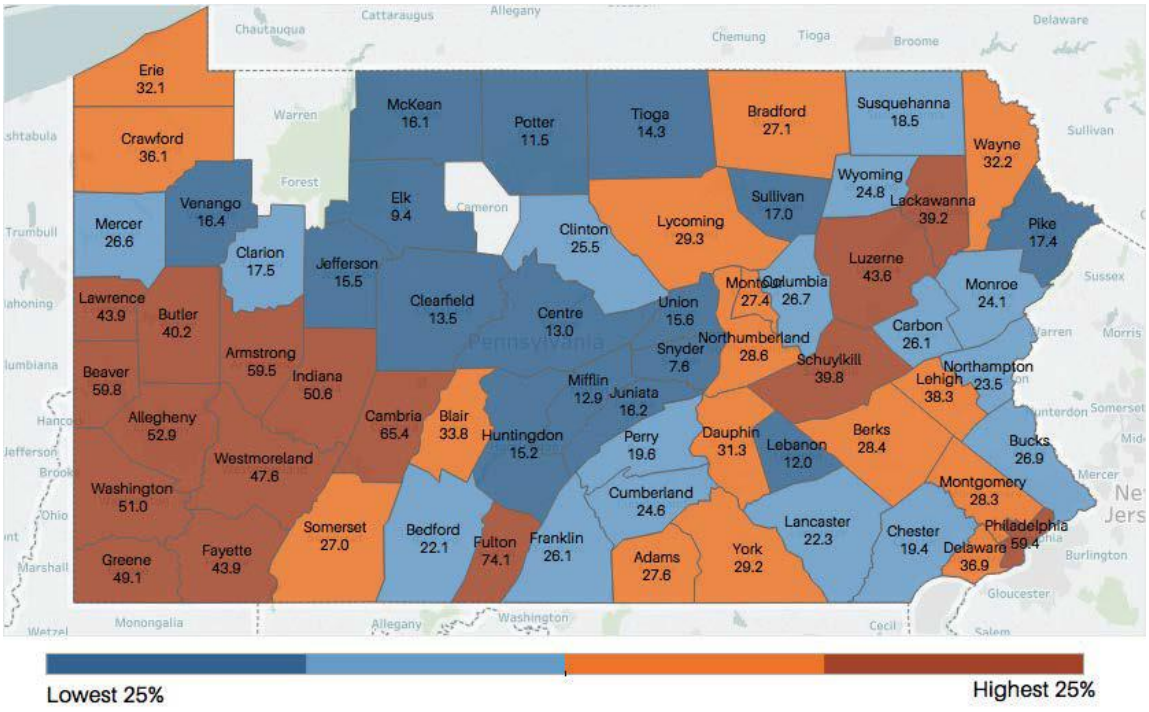
A. General Background Information

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.[2] 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.

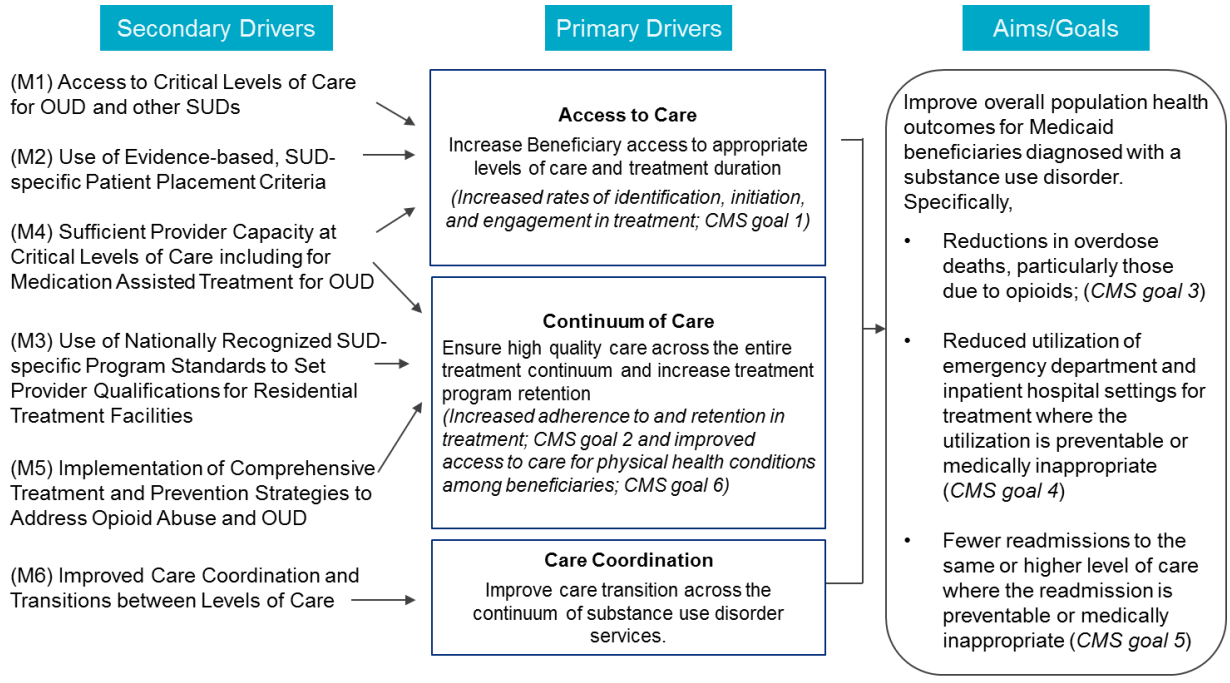
DHS/OMHSAS OBJECTIVES	TARGET FOR IMPROVEMENT
1. Increase beneficiary identification and access to appropriate levels of treatment duration.	• 1% annual increase in the number of individuals enrolled in Medicaid managed care with a SUD diagnosis. • 1% annual increase in the rate of the members with a 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:

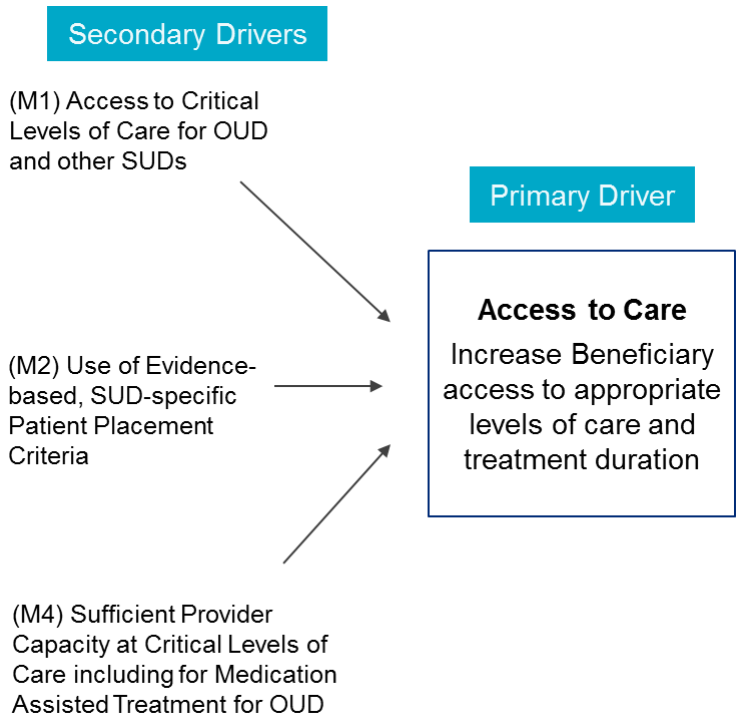
- Reductions in overdose deaths, particularly those due to opioids. (CMS goal 3)
- Reduced utilization of ED and inpatient hospital settings. (CMS goal 4)
- Fewer readmissions to the same or higher LOC. (CMS goal 5)

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.

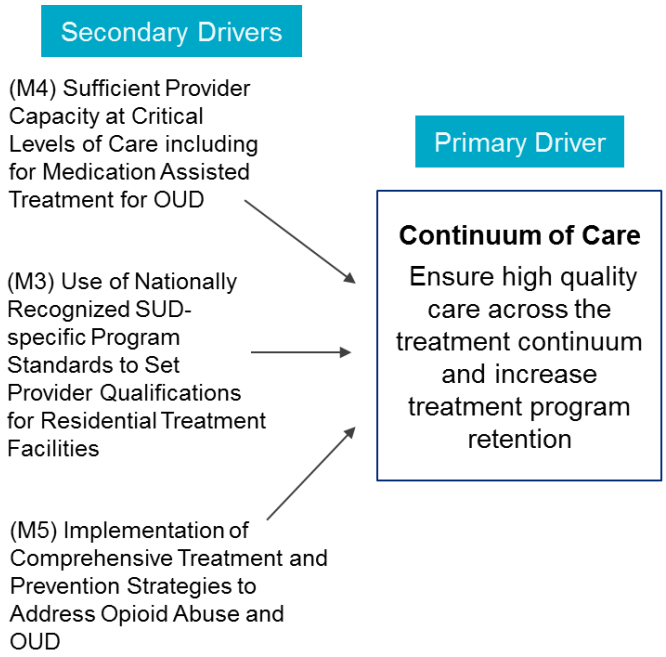
Milestone Two: Qualitative and quantitative data will be collected to describe each of the activities being undertaken in order to support Milestone 2 (see Driver Diagram). There are no specific outcome measures linked to milestone 2.

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.

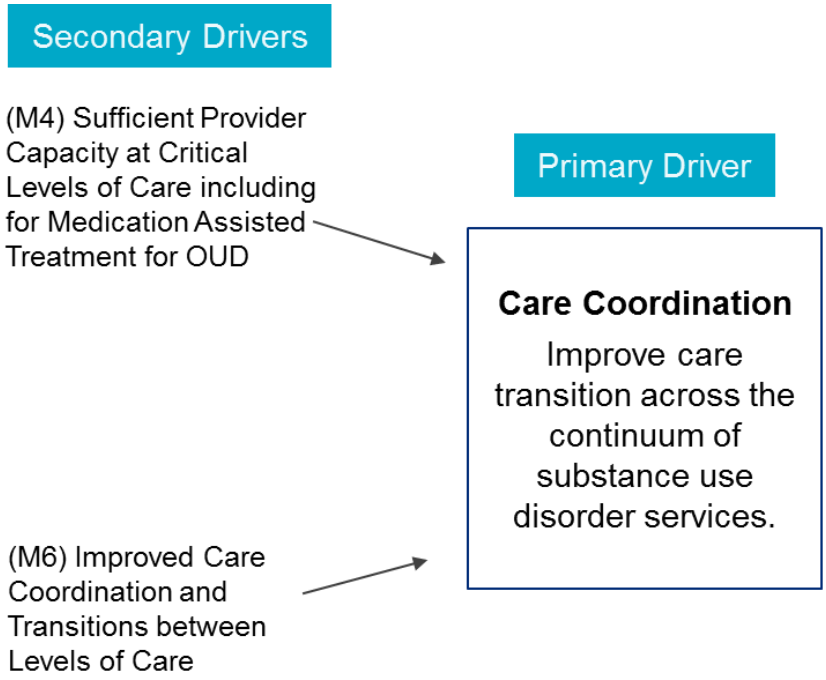
Milestone Five: For the outcome evaluation, each of the performance measures outlined in the Summary Design table will be used to demonstrate observed changes in the use of opioids at high dosage, use of opioids from multiple providers and concurrent use of opioids and benzodiazepines for the waiver 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.

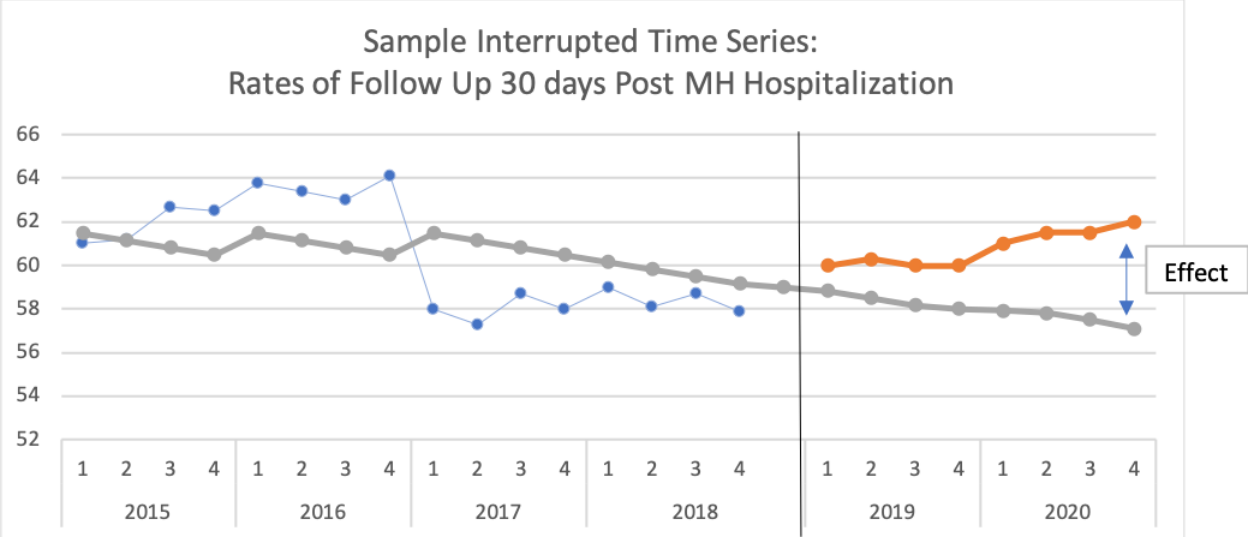
the changes in level and slope in the post-intervention period compared to the predicted trend (see "effect" in the graph below).

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

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.

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.

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.

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

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

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

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

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.

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*

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.)*

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).

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).

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

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

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.

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.

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.

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.

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

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**

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