Commonwealth of Pennsylvania

Substance Use Disorder 1115 Waiver

Number 11-W-00308/3

Draft Evaluation Design

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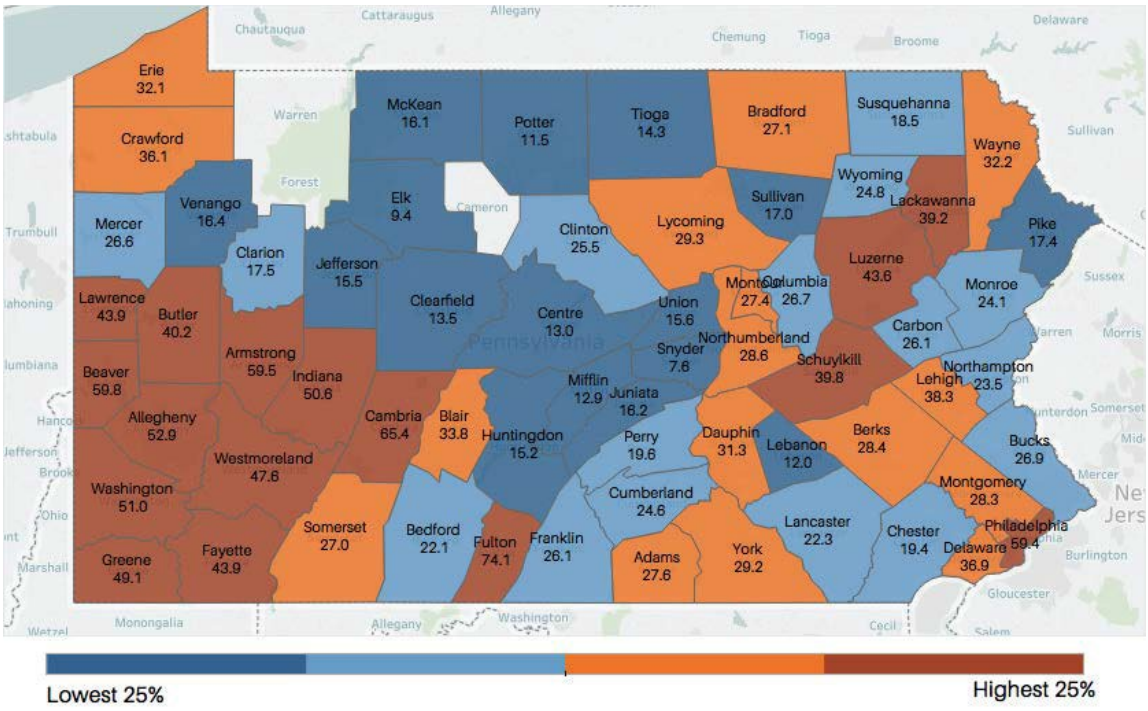
A. General Background Information

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 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.

[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

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 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.

[5] Opioid Program - Profile. Retrieved from https://public.tableau.com/profile/pdph#!/vizhome/UnintentionalDrugRelatedDeaths/

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

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.

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.

Medicaid and Medicaid Managed Care

In the HealthChoices program, behavioral health (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 (herein referred to as BH-Managed Care Organizations [MCOs]) 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 Single County Authorities (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;
- 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 American Society of Addiction Medicine 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 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]

[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

[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

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 residential SUD Detoxification, residential SUD Halfway Houses, and residential SUD Rehabilitation. Of those individuals, 59.73% had a 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.

B. Evaluation Questions and Hypothesis

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 and by improving care transition across the continuum of SUD services.

[10] Local Area Unemployment Statistics Map. Retrieved from https://data.bls.gov/map/MapToolServlet?survey=la&map=state&seasonal=u

[11] Population Estimates. Retrieved from https://www.census.gov/quickfacts/fact/table/PA/PST045216

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. 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.

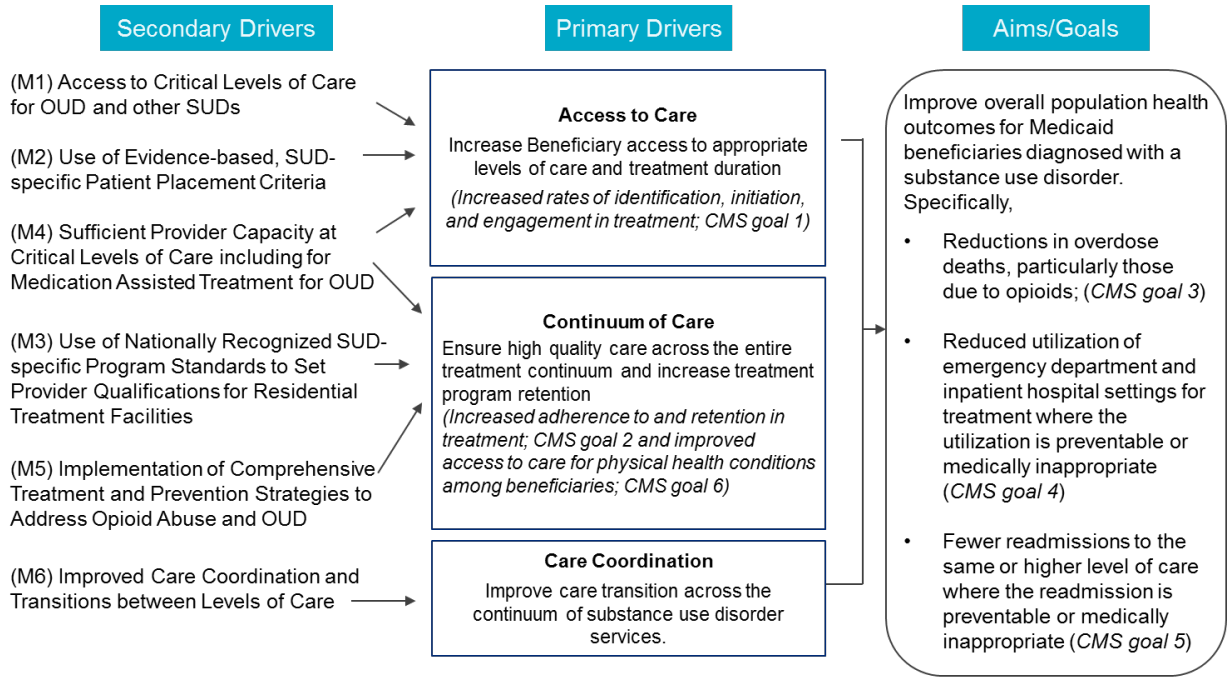
DHS/OMHSAS OBJECTIVES	TARGET FOR IMPROVEMENT
1. Increase beneficiary identification and access to appropriate levels of treatment duration.	• 1% annual increase in the number of individuals enrolled in Medicaid managed care with a SUD diagnosis. • 1% annual increase in the rate of the members with a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

DHS/OMHSAS OBJECTIVES	TARGET FOR IMPROVEMENT
	• 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 monitoring 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:

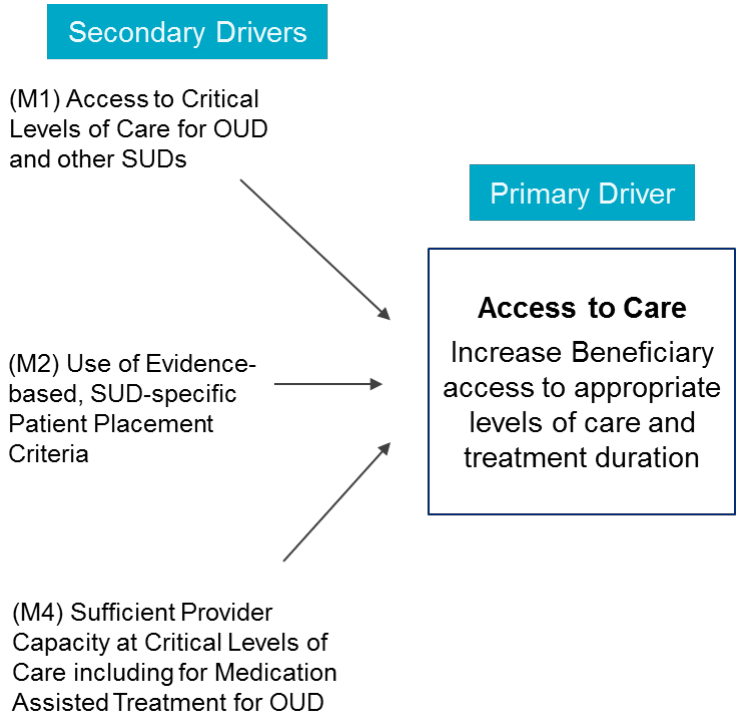
- Reductions in overdose deaths, particularly those due to opioids. (CMS goal 3)
- Reduced utilization of ED and inpatient hospital settings. (CMS goal 4)
- Fewer readmissions to the same or higher LOC. (CMS goal 5)

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.

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.
Research Question: Has access to critical LOCs as defined below improved in Medicaid managed care? 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?

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: 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.
Performance Measures: • Number and percentage of individuals enrolled in Medicaid managed care with a 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.

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

For the outcome evaluation, each of the above performance measures 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 2: Use of Evidence-based, SUD-specific Patient Placement Criteria.
Research Question: Has the use of evidence-based, SUD-specific patient placement criteria (ASAM criteria) been implemented across all LOCs for all patient populations?
Hypothesis: The 1115 SUD Demonstration will lead to use of ASAM placement criteria by all providers by July 2020.
Performance Measures (Process evaluation): • Number and percentage of contracts modified to require utilization review based on ASAM admission, continuing stay and discharge criteria for all ASAM LOCs. • Number of MCOs that begin prior authorization and utilization review based on ASAM residential placement criteria. • Number of providers trained to use ASAM as assessment tool. • Medicaid ASAM placement guidelines created for Medicaid only providers. • Provider education on ASAM placement guidelines conducted in first 12 months.

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

Milestone 4: Improve provider capacity at critical LOCs including MAT for OUD in Medicaid.
Research Question: Has the availability of providers in Medicaid and accepting new patients, including MAT, improved under the Demonstration?
Hypothesis: The 1115 SUD Demonstration will increase provider capacity as defined below for SUD treatment at critical LOCs for individuals in Pennsylvania Medicaid.
Performance Measures: • Maintenance of existing providers. • Bed capacity.

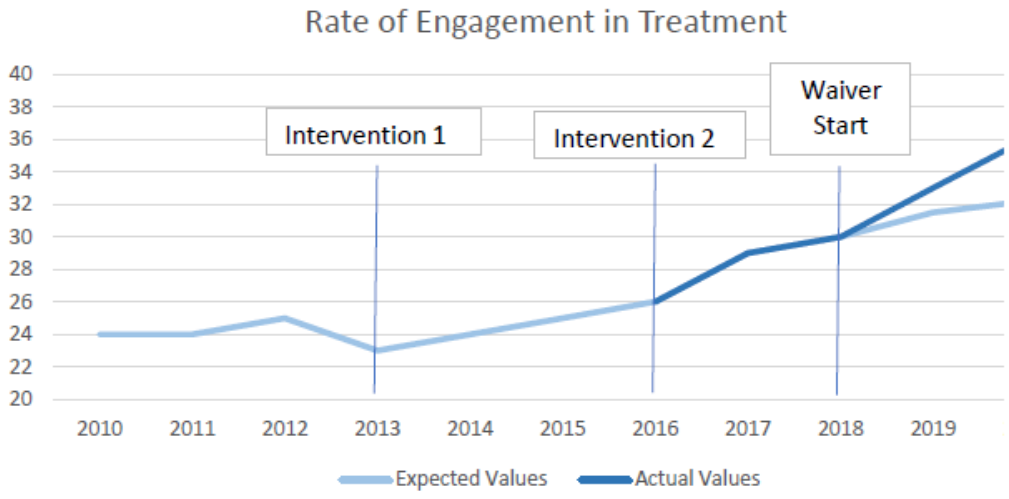
For the outcome evaluation, each of the above performance measures will be used to demonstrate observed changes in provider capacity, better assignment of patients to the appropriate LOC, and, therefore, better **access to care** for the waiver population. Descriptive, time series analyses will be used 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 be used to show change over time in the following outcomes (from the performance measures listed in Milestone 1):

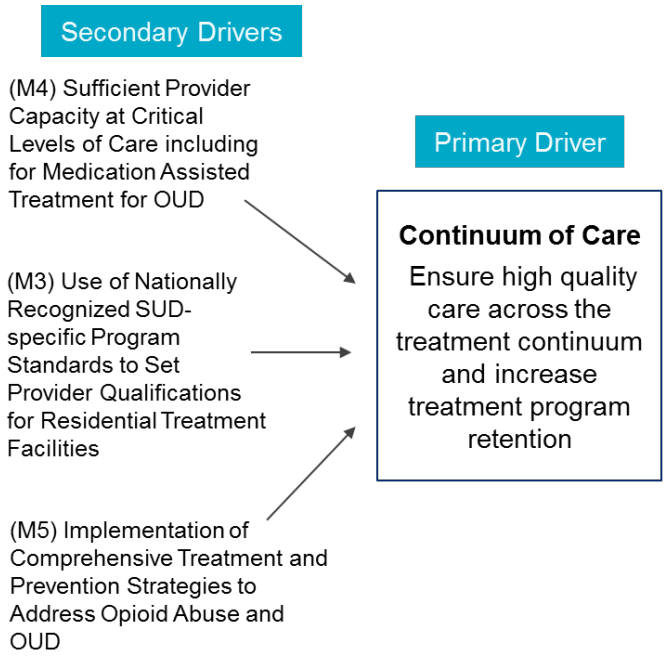
- Rate of individuals enrolled in any treatment service (rate of treatment engagement).
- Rate of individuals enrolled in each LOC.
- Rate of individuals served in an IMD.
- LOS in IMD.

Figure 1: (SAMPLE data only) Rates of Treatment Engagement

The first two intervention points show programmatic or policy changes occurring prior to the waiver that impacted rates of engagement. The interrupted time series analysis below assumes that these previous changes would have resulted in continued modest increases in treatment engagement rates, and shows that the actual rates increase more than projected rates directly following waiver implementation.



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 3, as described below addresses insuring that there is sufficient provider capacity at critical LOCs (see below).

Milestone 3: Use of Nationally recognized SUD-specific program standards to set provider qualifications for residential treatment facilities.
Research Question: Has OMHSAS established ASAM criteria and program standards to set provider qualifications for all residential treatment facilities?
Hypothesis: The 1115 SUD Demonstration will establish ASAM criteria and program standards to set provider qualifications for all residential treatment facilities by January 2021.
Performance Measures: • All residential providers received guidance for all LOCs by July 2020. • All residential providers have MAT on-site or access to by 2020. • Number and percentage of providers whose grant agreement/contracts have been updated to reflect new guidance.

Qualitative data will be used to describe the processes used to update residential provider guidance for all LOCs by July 2020 including requiring MAT on-site; 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.

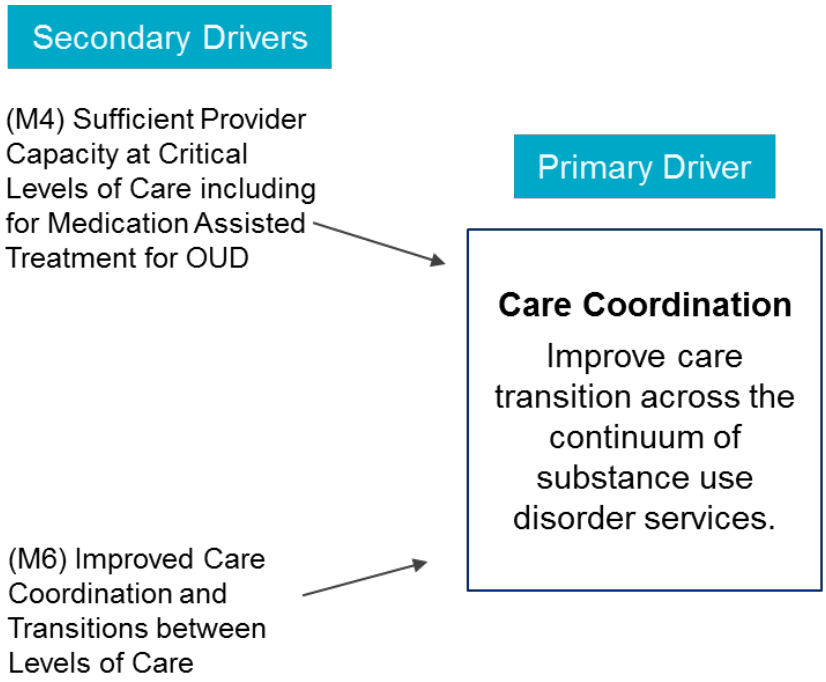
Milestone 5: Improvements in comprehensive treatment and prevention strategies to address opioid abuse and OUD for individuals in Medicaid managed care.
Research Question: Will improvements in treatment and prevention strategies in Medicaid managed care improve outcomes of individuals with SUD in Medicaid managed care as demonstrated by: more effective initiation of treatment, decreased use of opioid at high dosages, reduced use of multiple opioids from multiple providers, reduced concurrent use of opioids and benzodiazepines, improved continuity of pharmacotherapy for OUD, decreased overdose deaths and access to preventive/ambulatory services?
Hypothesis: The 1115 SUD Demonstration will improve outcomes for individuals enrolled in Pennsylvania Medicaid managed care.
Performance Measures: • AOD IET (NCQA, NQF #0004, Medicaid Adult Core set). • Use of opioids at high dosage (PQA, NQF #2940, Medicaid Adult Core Set). • Use of opioids from multiple providers (PQA, NQF #2950). • Concurrent use of opioids and benzodiazepines (PQA). • Continuity of pharmacotherapy for OUD (RAND, NQF #3175). • Rate of overdose deaths the Commonwealth; report the cause of death as specifically as possible (e.g., prescription versus illicit opioid). • Access to preventive/ambulatory health services for adult Medicaid managed care beneficiaries with SUD.

For the outcome evaluation, each of the above performance measures 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.

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 6: Improved care coordination and transition between LOCs for individuals in Medicaid managed care.
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?
Hypothesis: 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.
Performance Measures: • Follow-up after discharge from the ED for MH or alcohol or other drug dependence (NCQA, NQF #2605, Medicaid Adult Core set). • Number and percentage of re-admissions among beneficiaries with SUD.

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.

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

2. Target and Comparison Populations

The primary 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. 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.

3. 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.

4. Evaluation Measures and Data Sources

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

Measuring Achievement of Overall Project Aims			
Measure Type	**Description**	**Data Type**	**Data Source**
Outcome	Rate of overdose deaths overall	Quantitative	Claims/encounters (PeopleStat)
Outcome	Rate of opioid deaths	Quantitative	Claims/encounters (PeopleStat)
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: 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
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)
Outcome	LOS in IMD.	Quantitative	Claims/encounters (PeopleStat)
Hypothesis: The 1115 SUD Demonstration will establish criteria and review facilities for compliance with provider qualifications for all residential treatment facilities by July 2020.			
Measure Type	**Description**	**Data Type**	**Data Source**
Process	Number and percentage of contracts modified to require utilization review based on ASAM admission, continuing stay and discharge criteria for all ASAM levels of care.	Quantitative	Document Review
Process	Number of managed care organizations that begin prior authorization and utilization review based on ASAM residential placement criteria.	Quantitative	Document Review

Measuring Primary Drivers/Milestone Hypotheses			
Process	Number of providers trained to use ASAM as assessment tool.	Quantitative	Document Review
Process	Medicaid ASAM placement guidelines created for Medicaid only providers.	Quantitative	Document Review
Process	Provider education on ASAM placement guidelines conducted in first 12 months.	Quantitative	Document Review
Hypothesis: The 1115 SUD Demonstration will increase provider capacity as defined below for SUD treatment at critical LOCs for individuals in Pennsylvania Medicaid managed care.			
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
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

Measuring Primary Drivers/Milestone Hypotheses			
Primary Driver: Continuum of Care			
Hypothesis: 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
Process	Number and rate of providers reviewed for compliance.	Quantitative	TBD
Process	Number and rate of providers in compliance.	Quantitative	TBD
Hypothesis: The 1115 SUD Demonstration will improve outcomes for individuals in Pennsylvania Medicaid managed care.			
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)

Measuring Primary Drivers/Milestone Hypotheses			
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	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: 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 alcohol or other drug dependence.	Quantitative	Claims/encounters

5. 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). The table below summarizes the overall evaluation plan, including analytic methods for each measure.

Descriptive, content analysis will be used to present data related to process evaluation measures gathered from document reviews, key informant interviews, etc. 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).

6. Summary Design Table for the Evaluation of the Demonstration

RESEARCH QUESTION	MEASURE	POPULATION	DATA SOURCE	ANALYTIC METHOD
Hypothesis 1: The 1115 SUD Demonstration will increase access to the specified critical LOCs for individuals in Pennsylvania Medicaid managed care compared to prior to the waiver.				
Has access to critical LOCs as defined below improved in Medicaid managed care?	• 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.	Individuals enrolled in Medicaid managed care	Encounter data	Interrupted time series; regression analysis for change over time after waiver implementation
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?	• 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.	Individuals enrolled in Medicaid managed care	Encounter data	Interrupted time series; regression analysis for change over time after waiver implementation

RESEARCH QUESTION	MEASURE	POPULATION	DATA SOURCE	ANALYTIC METHOD
	• 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.			
Hypothesis 2: The 1115 SUD Demonstration will lead to use of ASAM placement criteria by all providers by the end of the first year of the Demonstration project.				
Has the use of evidence-based, SUD-specific patient placement criteria (ASAM criteria) been implemented across all LOCs for all patient populations?	• Number and percentage of contracts modified to require utilization review based on ASAM admission, continuing stay and discharge criteria for all ASAM LOCs. • Number of MCOs that begin prior authorization and utilization review based on ASAM residential placement criteria. • Number of providers trained to use ASAM as assessment tool. • Medicaid ASAM placement guidelines created for Medicaid-only providers. • Provider education on ASAM placement guidelines conducted in first 12 months.	Medicaid managed care providers	Documents (contracts, agreements, manuals)	Qualitative narrative analysis; counts
Hypothesis 3: The 1115 SUD Demonstration will increase provider capacity as defined below for SUD treatment at critical LOCs for individuals in Pennsylvania Medicaid managed care.				
Has the availability of providers in Medicaid accepting new patients, including MAT, improved under the Demonstration?	• Maintenance of existing providers • Bed capacity	Medicaid providers	Licensure and open bed report	Qualitative narrative analysis, counts

RESEARCH QUESTION	MEASURE	POPULATION	DATA SOURCE	ANALYTIC METHOD
Hypothesis 4: The 1115 SUD Demonstration will establish ASAM criteria and program standards to set provider qualifications for all Residential Facilities by January 2021.				
Has OMHSAS established ASAM criteria and program standards to set provider qualifications for all Residential Facilities?	• All residential providers received guidance for all LOC by July 2020. • All residential providers have MAT on-site or access to by 2020. • Number and percentage of providers whose grant agreements/contracts have been updated to reflect new guidance.	Medicaid managed care providers	Contracts, agreements	Qualitative narrative analysis, counts
Hypothesis: 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.				
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	• Initiation of AOD treatment (NCQA, NQF #0004, Medicaid Adult Core set): initiation of AOD treatment through an inpatient admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the index episode start date/eligible population. • Engagement of AOD treatment (NCQA, NQF #0004, Medicaid Adult Core set): two or more inpatient admissions, outpatient visits, intensive outpatient encounters or partial hospitalizations beginning the day after the initiation encounter through 29	Medicaid managed care population	• Encounter data • Prescription drug monitoring program • Commonwealth data on cause of death	Interrupted time series analysis; regression

RESEARCH QUESTION	MEASURE	POPULATION	DATA SOURCE	ANALYTIC METHOD
access to preventive/ambulatory services?	days after the initiation event/eligible population. • Use of opioids at high dosage (NCQA, NQF #2940, Medicaid Adult Core set): (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. • Use of opioids from multiple providers (PQA): (beneficiaries who received prescriptions for opioids from four or more prescribers and four or more pharmacies/beneficiaries who received prescriptions for opioids)*1,000. • Concurrent use of opioids and benzodiazepines (PQA, Medicaid Adult Core set): beneficiaries with concurrent use of prescription opioids and benzodiazepines/ beneficiaries. • Continuity of pharmacotherapy for OUD (USC, NQF #3175): 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 or ED encounter			

RESEARCH QUESTION	MEASURE	POPULATION	DATA SOURCE	ANALYTIC METHOD
	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 (NCQA, NQF #2605, Medicaid Adult Core set): 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 (NCQA, NQF #2605, Medicaid Adult Core set): 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. • Rate of overdose deaths in the Commonwealth: number of overdose deaths/number of deaths. • Access to preventive/ambulatory health services for adult Medicaid managed care beneficiaries with SUD (NCQA): the number of Medicaid beneficiaries with SUD who had an ambulatory or preventive care visit/number of beneficiaries with SUD.			

RESEARCH QUESTION	MEASURE	POPULATION	DATA SOURCE	ANALYTIC METHOD
Hypothesis: 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.				
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?	• Follow-up after discharge from the ED for MH or alcohol or other drug dependence (NCQA, NQF #2605, Medicaid Adult Core set): 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 (NCQA, NQF #2605, Medicaid Adult Core set): 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. • Number and percentage of re-admissions among beneficiaries with SUD (NCQA): number of acute inpatient readmissions within 30 days of discharge from an acute inpatient stay/number of acute inpatient stays among beneficiaries with SUD.	Medicaid managed care population	Encounters	Interrupted time series analysis; regression

D. Methodological Limitations

The primary limitations to the evaluation methodology presented here are related to the difficulty in directly attributing changes after waiver implementation to the activities undertaken as part of the waiver.

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.[12] The primary threat is that of history, or other changes over time happening during the waiver period. This 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 for this threat by considering other policy and program changes happening concurrent to the waiver period interventions.

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.[12] 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.

As previously noted, a primary limitation of this design is the lack of a suitable control population. The overall strength of inference is weaker in this design because there will not be a Demonstration of outcomes for a similar group of individuals who did not receive the waiver interventions, eliminating the ability to make strong statements around what would have happened to the treatment population had the waiver not been available.

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.

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

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
Nicole Fowle, MPH	Project Manager	Nicole.Fowle@mercer.com

NAME	POSITION	EMAIL ADDRESS
Brenda Jenney, PhD	Statistician	Brenda.Jenney@mercer.com
Brenda Jackson	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.

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 12/31/24	Total Evaluation Cost
OMHSAS	$ 53,010	$ 53,010	$ 53,010	$ 53,010	$ 13,252	$ 53,010	$278,302
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
Mercer	$ 203,502	$ 55,000	$ 85,000	$ 115,000	$ 25,000	$ 285,000	$ 768,502
External Quality Review Organization	$276,558	$12,400	$12,400	$12,400	$12,400	$12,400	$338,558
TOTAL	**$632,570**	**$219,910**	**$249,910**	**$279,910**	**$75,527**	**$449,910**	**$1,907,737**

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	TBD
Publish Final Evaluation Design on Commonwealth website — 30 days after CMS approval	39, 45, 50(a)	TBD
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)	TBD
Publish Final Interim Report on Commonwealth website — 30 days after CMS approval is received	45	TBD
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)	TBD
Publish Final Summative Evaluation Report on Commonwealth website — 30 days after CMS approval is received	43(b)	TBD