DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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State Demonstrations Group

July 31, 2023

Lisa Lee
Commissioner, Department of Medicaid Services
Cabinet for Health and Family Services
275 East Main Street
Frankfort, KY 40601

Dear Director Lee:

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Interim Evaluation Report, which is required by the Special Terms and Conditions (STCs), specifically STC #53, "Interim Evaluation Report" of the "Kentucky Helping to Engage and Achieve Long Term Health" (Project Nos. 11-W-00306/4 and 21-W-00067/4), commonly called "Kentucky HEALTH." The demonstration was approved on January 12, 2018, and is effective through September 30, 2023. This Interim Evaluation Report covers the period from April 2019 through June 2022. CMS determined that the Evaluation Report, submitted on September 30, 2022 and revised on February 16, 2023, is in alignment with the CMS-approved Evaluation Design and the requirements set forth in the STCs, and therefore, approves the state's Kentucky HEALTH Interim Evaluation Report.

Results from the report are promising. The numbers of Medicaid providers for SUD treatments, providers eligible to prescribe medications for opioid use disorder, and facilities dispensing methadone all increased since the beginning of the demonstration. Likewise, the number of residential and IMD facilities increased as did the number of Medicaid beneficiaries using a residential or IMD service. Moreover, the number of emergency department (ED) visits for beneficiaries with a SUD diagnosis decreased over the course of the demonstration, and non-ED outpatient visits for beneficiaries with an opioid use disorder diagnosis increased. The rate at which individuals with a SUD diagnosis sought follow-up treatment on a 10 or 30-day basis following an ED visit remained unchanged, but this might have been due to the COVID-19 period and the associated barriers regarding access to care. Whereas these findings are mostly promising, the evaluation was largely reliant on descriptive statistics and interrupted time series analyses with no comparison group. We look forward to future evaluation reports on the state's demonstration and anticipate more rigorous analysis methods, where possible.

In accordance with STC #57, the approved Evaluation Report may now be posted to the state's Medicaid website within 30 days. CMS will also post the Interim Evaluation Report on Medicaid.gov.

We look forward to our continued partnership on the Kentucky HEALTH section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Paula M. Kazi -S

Digitally signed by Paula M. Kazi -S
Date: 2023.07.31 10:50:10 -04'00'

Paula M. Kazi
Acting Director
Division of Demonstration Monitoring and Evaluation

cc: Keri Toback, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

INTERIM EVALUATION

Section 1115 Substance Use Disorder Demonstration

Kentucky Cabinet for Health & Family Services

Department for Medicaid Services

February 13, 2023

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List of Acronyms

Acronyms	Name
ACA	Affordable Care Act
ASAM	American Society of Addiction Medicine
BH	Behavioral Health
BHSO	Behavioral Health Service Organization
CARF	Commission on Accreditation of Rehabilitation Facilities
CHFS	Cabinet for Health and Family Services
CMHC	Community Mental Health Center
CMS	Medicare and Medicaid Services
COA	Council of Accreditation
DEA	Drug Enforcement Administration
DMS	Department for Medicaid Services
DY	Demonstration Year
ED	Emergency Department
HEALing	Helping End Addiction Long Term
IMD	Institutions for Mental Disease
ITS	Interrupted Time Series Analysis
KIPRC	Kentucky Injury Prevention Research Center
KORE	Kentucky Opioid Response Effort
LOC	Level of Care
MAT	Medication-assisted Treatment
MCO	Managed Care Organizations
MOUD	Medication for Opioid Use Disorder
MPPA	Kentucky Medicaid Provider Portal Application
MPE	Midpoint Evaluation
MSG	Multi-Specialty Group
NEMT	Non-Emergency Medical Transportation
NIH	National Institutes of Health
NTPs	Narcotic Treatment Programs
OUD	Opioid Use Disorder
PAs	Prior Authorizations
RCSU	Residential Crisis Stabilization Units
RTCs	Residential Treatment Centers
SAMHSA	Substance Abuse and Mental Health Services Administration
SBIRT	Brief Intervention and Referral to Treatment
SPA	State Plan Amendment
STC	Special Terms and Conditions
SUD	Substance Use Disorder

SECTION A: EXECUTIVE SUMMARY

Although the opioid crisis is national in scope, the Commonwealth of Kentucky has been particularly acutely affected, ranking among the top 10 states in opioid-related overdose deaths. Importantly, approximately 40% of adults with opioid addiction are within the Medicaid-insured population.

In response, the Department for Medicaid Services (DMS) within the Kentucky Cabinet for Health & Family Services (CHFS) proposed a substance use disorder (SUD) Demonstration project as a Section 1115 Demonstration Waiver project to expand ongoing efforts to address the opioid crisis. The purpose of the SUD Demonstration project is to "ensure that a broad continuum of care is available to Kentuckians with a substance use disorder (including an opioid use disorder [OUD])," with the primary goal of reducing overdose injuries and deaths. This proposal for the 1115 SUD Demonstration project was approved by the Centers for Medicare and Medicaid Services (CMS) on January 12, 2018. The implementation plan for the Demonstration was initially approved on October 5, 2018, with an amendment granted on November 4, 2019.

The overarching goal or purpose of Kentucky's 1115 SUD Waiver Demonstration is to reduce the impact opioids and other substances have on Kentucky Medicaid recipients, particularly injuries and deaths from accidental poisonings. To achieve this goal, the Commonwealth must achieve three primary objectives: increase the availability of SUD providers accepting Medicaid, increase utilization of Medicaid-supported SUD-related services, and increase the utilization of the best evidence-based treatment available: the use of medication for OUD (MOUD). To make these three objectives feasible, at the same time, the Commonwealth must also achieve a fourth goal; it must accrue cost savings by decreasing the usage of ED and inpatient hospital settings for SUD treatment, while increasing usage of other facilities.

To achieve the objectives in its 1115 SUD Demonstration Waiver, Kentucky proposed to:

1. Increase Medicaid SUD provider capacity, especially for MOUD, which will increase the availability of providers, thus allowing for increased utilization of SUD treatment, including MOUD.
2. Improve standards for residential SUD treatment provider qualifications, which will expand the availability of successful residential providers, this allowing for increased utilization of SUD treatment, including MOUD.
3. Expand access to the levels of care for SUD, which will decrease the usage of ED and hospitals for SUD care, and increase the utilization of other providers, thus allowing for increased utilization of SUD treatment, including MOUD.
4. Improve SUD screening accuracy for patient placement in the appropriate service level of SUD treatment, which will increase the availability of providers, thus allowing for increased utilization of SUD treatment, including MOUD, as well as decreasing the usage of ED and hospitals for SUD care.
5. Improve coordination among the levels of care, which will increase the use of appropriate care and decrease the usage of ED and hospitals for SUD care.
6. Improve SUD prevention practices, which will decrease the need for SUD treatment by decreasing the number of Kentucky citizens with SUD.

The following evaluation hypotheses were developed based on the presumed results and what the Commonwealth proposed to do:

H1a: The Demonstration will increase the ratio of outpatient Medicaid SUD/OUD providers overall (PD1), and those specifically offering MOUD and methadone as part of MOUD, to beneficiaries in areas of greatest need (SD1).

H1b: The Demonstration will increase the ratio of SUD/OUD providers offering residential treatment, especially IMDs, to beneficiaries (PD1, SD1, SD2).

H1c: The Demonstration will increase the utilization of SUD/OUD services (PD1, PD2, SD1, SD3, SD4, SD5).

H1d: The Demonstration will decrease the rate of ED visits and inpatient admissions within the beneficiary population for SUD/OUD (PD4, SD1, SD2, SD3, SD4, SD5).

H2a: Among beneficiaries receiving care for SUD/OUD, the Demonstration will decrease the rate of ED visits for SUD/OUD (PD4, SD6).

H2b: Among beneficiaries receiving care for SUD/OUD, the Demonstration will reduce hospital readmissions for SUD/OUD care (PD4, SD5).

H3a: The Demonstration will decrease the rate of overdose deaths due to opioids (Purpose).

F1a: The Demonstration will decrease the total SUD/OUD expenditures.

F1b: The Demonstration will decrease SUD/OUD and non-SUD/OUD expenditures, with SUD/OUD expenditures disaggregated into IMD and non-IMD expenditures**.**

F1c: The Demonstration will decrease expenditures disaggregated by source of treatment—namely, inpatient expenditures, emergency department (ED) expenditures, non-ED outpatient expenditures, and pharmacy expenditures.

The approved Evaluation Design Plan is a mixed-methods approach, drawing from a range of data sources, measures, and analytics to best produce relevant and actionable study findings. Two principal analytic methods are used to achieve the goals in the Interim report:

- Longitudinal analysis of descriptive statistics
- Thematic analysis of provider and beneficiary interviews.

In addition, an interrupted time series analysis (ITS) was conducted as a single-group segmented analysis on a dependent variable of the proportion of the Medicaid population receiving SUD services, using multiple intervention points and controls for population, providers, and economic conditions.

The study period for this Interim Evaluation includes two years of pre-waiver data, and three measurement years after implementation, consisting of July 1, 2019, to June 30, 2022.[1] These measurement years are the principal unit of analysis for this assessment and are referred to as Demonstration Years.

This evaluation activity is challenged in differentiating the direct impact of the 1115 Waiver Demonstration mechanisms versus DMS's efforts to support those mechanisms as well as other state initiatives, as they occur concurrently and are directed toward similar goals. Moreover, with increased polysubstance use, increased contaminants in illicit substances (both level and types), and the multi-dimensional impact of the COVID-19 pandemic on mental health, substance misuse, and quality of life, Kentucky confronts even greater challenges in addressing SUD now than it did at the initiation of the waiver Demonstration. It is within this context that interpretations of the current data analysis are provided.

The following preliminary conclusions were drawn based on the data available to us and using the approved analysis techniques.

1. The number of Medicaid performing providers for SUD treatments, the number of Medicaid providers eligible to prescribe MOUD, and the facilities dispensing methadone all increased from the baseline years through the 2021 Demonstration year (ending 6/30/22).
2. The number of residential and IMD facilities increased during the Demonstration period from 75 to 124. The number of Medicaid beneficiaries using a residential or IMD service increased to 20,811 in the last Demonstration year, a 30 percent increase from the last baseline year.
3. The number of ED visits for beneficiaries with a SUD diagnosis among beneficiaries decreased in the latest Demonstration year compared to the last baseline year.
4. Non-ED outpatient visits for beneficiaries with an OUD diagnosis increased but per capita beneficiary costs decreased. These measures did not show parallel results for beneficiaries with an SUD diagnosis.
5. The rate at which individuals with an SUD diagnosis sought follow-up treatment on a 10 or 30-day basis following an ED visit remained unchanged in comparing the Demonstration and baseline years. This could be confounded by the COVID-19 period and the associated barriers to access to care.
6. The rate of hospital admissions for SUD-related diagnoses remains ambiguous. (Improvement in administrative data capture should make analysis of this measure more effective for the Final Summative Report.)
7. While improvements are shown regarding self-reported life outcomes after treatment, continued illicit drug usage was also indicated. There were no notable changes in outcomes from 2018-2020.

[1] Measurement years are defined as a 12-month period between July 1 and June 30 and referred to as Demonstration Years. Demonstration Year 1 = July 1, 2019 – June 30, 2020; Demonstration Year 2 = July 1, 2020 – June 30 2021; Demonstration Year 3 = July 1, 2021 – June 30 2022.

8. SUD expenditures increased during the initial years of the Demonstration. Annual SUD spending increased from $470,822,040 in the 2018BY to $802,873,322 in the 2021DY. This amounted to a 45% increase per SUD diagnosed beneficiary, from $4,228 to $6,133.
9. ITS results indicated a statistically significant positive effect for the proportion of the Medicaid population receiving SUD services associated with the introduction of the Demonstration as well as the change in the Kentucky IMD policy prior to the waiver.

In sum, the Commonwealth has been successful in increasing the availability of SUD-related services to Medicaid beneficiaries along several dimensions. But the immediate impact of these changes has been tempered by the COVID-19 pandemic. Final recommendations for Medicaid policymakers, advocates, and stakeholders will be made upon the completion of the Final Summative Report. Particularly given current uncertainty around the impact of COVID-19, it is currently premature to suggest any changes in policy, procedures, or practices.

Issues with data availability and issues including centralized billing for multiple locations and the use of an administrative billing provider did not allow for the direct testing of all hypotheses. Proxy measures were used in a few cases, but other hypotheses are not addressed in this Interim Report. Steps are in process to support their testing for the Final Summative Report.

Additionally, a specific recurring problem is the use of counties as a unit of analysis for several of the research questions. The Commonwealth has 120 counties, many in rural areas, sparsely populated (only 19/120 have more than 50,000 residents) and covering geographically small areas (median size 306 sq mi). Patients often travel outside of their home counties to obtain healthcare services. Consequently, the use of counties as a unit of analysis results in null sets and their exclusion in some analytics complicates inferential reliability. The state uses geographic Health Districts as administrative and data units. For the Final Summative Report Health Districts will be used as a unit of analysis and overlaid on counties.

A summary of the status of all planned statistical measures described in the evaluation design is available in Appendix A. This includes a description and status of all measures in both this Interim Report and those delayed for inclusion in the Final Summative Report. Apart from specific integrated results relative to the hypotheses and evaluation questions, a summary of the thematic analysis of interview results will be presented as grouped responses from the four quadrants earlier identified, which embedded Health Districts overlaid on corresponding counties.

SECTION B: GENERAL BACKGROUND INFORMATION

B.1 Introduction

Although the opioid crisis is national in scope, the Commonwealth of Kentucky has been particularly acutely affected, ranking among the top 10 states in opioid-related overdose deaths (CDC, 2022). Furthermore, approximately 67% of overdose deaths in Kentucky occur within the Medicaid-insured population, and 80% of hospitalizations for neonatal abstinence syndrome in Kentucky are reimbursed by Medicaid (Harvey & Ingram, 2022). Multiple sources of Kentucky Cabinet data provide converging evidence of the continued impact of substance misuse across Kentucky. To wit:

- While total heroin-related events (possession and trafficking citations, deaths, ED visits, hospitalizations, and tested lab submissions) decreased by 62.5% from the beginning of 2017 through the end of December 2021 and there was a 13.0% reduction in opioid-related events in the same time frame, fentanyl- and fentanyl analog-related events increased by 158.8%, and methamphetamine-related events increased by 22.2% (K-SURE, 2022).
- The rate of patients per 1,000 receiving daily MED (Opioid Morphine Equivalent Doses) >= 90 prescribing was 2.63 Q3 of 2021 (personal calculations from KY CFHS, 2021).
- The rate of reported NOWS (Neonatal Opioid Withdrawal Syndrome) births in Kentucky was 19.4 for every 1,000 live births; the most recent national estimate for NAS was 7.3 cases per 1,000 live births (KY Dept for Public Health Division of Maternal & Child Health, 2021).
- In 2021, 2,250 Kentuckians died from drug overdoses in 2021, as compared to 1,964 in 2020, which is a 15% increase, and 1,316 in 2019, which is a 71% increase (Harvey & Ingram, 2022).

In response to similar data, the Department for Medicaid Services (DMS) within the Kentucky Cabinet for Health & Family Services (CHFS) proposed a Substance Use Disorder (SUD/OUD) Demonstration project as a Section 1115 Demonstration Waiver project to expand ongoing efforts to address the opioid crisis. The purpose of the SUD/OUD Demonstration project is to "ensure that a broad continuum of care is available to Kentuckians with a substance use disorder (including an opioid use disorder [OUD])," with the primary goal of reducing overdose injuries and deaths. To achieve this purpose, Kentucky Medicaid implemented a plan to (1) increase beneficiary access to SUD/OUD providers offering treatment services and (2) expand SUD/OUD treatment benefits available to enrollees, thereby increasing utilization of SUD/OUD treatment services.

This proposal for the 1115 SUD/OUD Demonstration project was approved by the Centers for Medicare and Medicaid Services (CMS) on January 12, 2018. At the same time, CMS also approved a substance use disorder (SUD) program (described in STCs 92-100) available to all Kentucky Medicaid beneficiaries to ensure that a broad continuum of care is available to Kentuckians with SUD. This approval has remained in effect during the Demonstration period.

The implementation plan for the Demonstration was initially approved on October 5, 2018, with an amendment granted on November 4, 2019.[2]

The 1115 SUD/OUD Demonstration project built upon Kentucky's amendment to its state plan to include coverage of the ACA expansion population, effective January 1, 2014. As of September 2018, more than 454,000 individuals had received medical assistance under the Kentucky state plan because of Kentucky's decision to participate in that expansion. Kentucky's ACA expansion population includes not only childless adults but also many parents of dependent children, who otherwise were not eligible for coverage under the Kentucky state plan unless their household income was equal to or less than 24% of the federal poverty level. In addition to providing non-mandatory coverage for the adult expansion population, Kentucky's state plan provides coverage for other non-mandatory populations, such as the medically needy and lawfully residing immigrant children under age 19.

B.2 Name, Approval Date and Time Period Covered

Name: KY HEALTH Section 1115 Demonstration
Project Number: 11-W-00306/4 and 21-W-00067/4
Approval Date: November 20, 2018, with an updated implementation plan approved November 24, 2020, reissued June 16, 2020
Interim Evaluation Time Period: April 1, 2019 – June 30, 2022

Due to the timing of the approved waiver (April 1, 2019, through December 31, 2023) and the fact that Kentucky is preparing to submit a waiver extension application, the Interim Evaluation is being prepared in advance of the original schedule. This will allow for the Commonwealth to post the Interim Evaluation with its waiver extension application for public comment in accordance with 42 CFR 431 Subpart G. As a result, the study period for the Interim Evaluation includes two years of pre-waiver data, but the timing restrictions only permit one year of waiver data for annual metrics and 19 months of waiver data for monthly metrics.

[2] Kentucky's Substance Use Disorder (SUD/OUD) Demonstration project was included in a larger section 1115(a) Demonstration dubbed "KY Helping to Engage and Achieve Long Term Health" (KY HEALTH). The KY HEALTH Demonstration was originally approved on January 12, 2018. This Demonstration previously included the project component known as the Kentucky HEALTH program, which included two consumer-driven incentive tools and various eligibility provisions including a premium obligation, community engagement requirements, and non-eligibility periods for certain beneficiaries for failure to comply with the requirements associated with premiums, redeterminations, and reporting changes in circumstances, and community engagement. On June 29, 2018, a district court vacated the approval of the Kentucky HEALTH program, *Stewart v. Azar*, 313 F. Supp. 3d 237, 243 (D.D.C. 2018). After a subsequent approval of the Kentucky HEALTH program on November 20, 2018, a district court vacated the approval of the Kentucky HEALTH program for a second time. On December 16, 2019, Kentucky requested to formally withdraw the Kentucky HEALTH program component of the 1115 waiver, which was never implemented. CMS reissued the STCs of the KY HEALTH Demonstration relative to SUD and former foster children from other states on June 16, 2020, to effectuate the state's request.

B.3 Demonstration Goals and History

The central features of this Demonstration are:

1. Increased access to SUD/OUD providers by assessing Medicaid SUD/OUD provider capacity at critical levels of care and certifying residential treatment providers according to nationally recognized standards for SUD/OUD treatment.
2. Waiver of the Medicaid Institutions for Mental Disease (IMD) exclusion, allowing reimbursement for SUD/OUD treatment, crisis stabilization, and withdrawal management during short-term residential stays at certified IMD facilities with more than 16 beds.
3. Expanded coverage of medication-assisted treatment (MAT, below referred to as "MOUD," or Medication for Opioid Use Disorder) services to include methadone.

Two additional features are:

4. Expanded coverage to former foster care youth from another state (effective January 12, 2018).
5. Waiver of non-emergency transportation (NEMT) for methadone services, though exempting pregnant women, survivors of domestic violence, beneficiaries who are medically frail, former foster care youth, and l9- and 20-year-old beneficiaries.

The Commonwealth of Kentucky also received approval of its SUD Implementation Protocol on November 20, 2018, as required by special terms and conditions (STC) X.10 of the Commonwealth's section 1115 Demonstration. Previously, the Commonwealth and Kentucky Medicaid had launched a range of SUD initiatives, and Kentucky Medicaid already covered many services across the continuum of care for SUD, including outpatient and intensive outpatient services, partial hospitalization treatment, residential treatment, and medication-assisted treatment with buprenorphine and naltrexone. The SUD Demonstration built upon these initiatives and expanded Medicaid SUD benefits to strengthen efforts to combat the opioid crisis.

As set forth in the Implementation Plan, Kentucky aligned the six objectives of its Medicaid 1115 Demonstration waiver to specific milestone goals outlined by CMS for the SUD section 1115 waiver.

The central objectives for Kentucky's SUD 1115 Waiver Demonstration are:

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

As described in STC 93, Kentucky's SUD 1115 Waiver Demonstration milestone goals include:

1. Improve access to critical levels of care for Opioid Use Disorder (OUD) and other SUDs for Medicaid beneficiaries

2. Increase the use of evidence-based SUD screening criteria for patient placement in outpatient or residential care
3. Establish standards for residential treatment provider qualifications that meet nationally recognized SUD-specific program standards
4. Increase provider capacity at critical levels of care, including MOUD for OUD
5. Implement prescribing guidelines and other treatment and prevention strategies
6. Improve care coordination and transitions between levels of SUD care

Kentucky's approved Implementation Protocol outlined specific policy revisions under each milestone with planned implementation dates. Since receiving approval of the SUD waiver, Kentucky has been conducting implementation activities. Table B.3.1 summarizes Kentucky's achievements. Over the first year of the waiver, Kentucky has completed 15 out of the 15 identified activities in the Implementation Protocol.

1. **Table B.3.1 Summary of Key Policy Activities Supporting the Demonstration Goals**

Goal	Policy Activity	Effective Date
1. Improve access to critical levels of care	1.a) Amend regulations to include partial hospitalization as an allowable service	July 2019
	1b.) Amend regulations to include partial hospitalization as an allowable service	July 2019
	1c). Amend state plan to include coverage of methadone for medication-assisted treatment, with a waiver of the non-emergency medical transportation assurance except for children under age 21, former foster care youth, and pregnant women	July 2019
	1d) Expand, through state certification process [Goal #3], number of residential treatment providers eligible for the Institution of Mental Disease (IMD) exclusion	May 2019 April 2020
	1e) Amend service definitions to include withdrawal management in all levels of care, i.e., beyond hospital setting	July 2019
2. Increase the use of evidence-based SUD screening criteria for patient placement in outpatient or residential care	2a. Amend state plan to require all SUD providers to incorporate ASAM's 6-dimensional assessment into their patient assessment in determining placement into treatment	July 2019
3. Establish standards for residential treatment provider qualifications that meet nationally recognized SUD-	3a. Based on self-attestation to American Society of Addiction Medicine (ASAM) level of care in statewide survey, issue pending certification to eligible IMD facilities with 96 or fewer beds, permitting them to qualify for temporary IMD exclusion	April 2020

specific program standards	3b. Certify, through state certification program, residential treatment providers to ASAM levels of care, permitting certified IMD facilities with up to 96 beds to qualify for IMD exclusion	April 2020
4. Increase provider capacity at critical levels of care, including MOUD for OUD	4a. Conduct statewide survey of services, hours, staffing, and other characteristics of Medicaid-enrolled residential SUD providers	May 2019
	4b. Conduct statewide survey of Medicaid outpatient and residential SUD treatment providers, assessing SUD levels of care, services offered—particularly medication-assisted treatment (on-site or facilitated off-site)—and potential Medicaid enrollment	May 2019
5. Implement prescribing guidelines and other treatment and prevention strategies	5a. As part of an opioid utilization program, develop criteria for applying utilization controls of long acting and short acting opioids	November 2018
	5b. As part of an opioid utilization program, establish morphine milligram equivalent (MME) thresholds for short acting, long acting, and combination opioids, and employ a step-down methodology to reduce overall MME dosing limitations	November 2018
6. Improve care coordination and transitions between levels of SUD care	6a. Amend state plan to include care coordination within the definition of residential SUD treatment	July 2019
	6b. Amend state regulations to include care coordination duties to the definition of residential SUD treatment	

Kentucky Medicaid provides SUD coverage to its beneficiaries following the guidelines of American Society of Addiction Medicine (ASAM). Table B.3.2 below provides a summary of the ASAM levels of care, their definitions, and whether and how these types of services were impacted by Kentucky's 1115 SUD Demonstration Waiver project.

2. **Table B.3.2 The Impact of KY's 1115 SUD Waiver on ASAM Levels of Care**

ASAM Level of Care	ASAM Service Title	Brief Definition	Service Initiation
.5	Early Intervention	Constitutes a service for individuals who are at risk of developing substance-related problems, or a service for those for whom there is not yet sufficient information to document a diagnosable substance use disorder	Pre-existing Service
1.0	Outpatient Services	Less than nine hours of service/week (adults); less than six hours/week (adolescents) for recovery or motivational enhancement therapies/strategies	Pre-existing Service
2.1	Intensive Outpatient Services	Nine or more hours of service/week (adults); less than six or more hours/week (adolescents) to treat multi-dimensional instability	Pre-existing Service
2.5	Partial Hospitalization	20 or more hours of service/week for multidimensional instability not requiring 24-hour care	Pre-existing Service, but number of locations increased
3.0	Residential/Inpatient Services	Residential coverage has two levels of treatment. Short term services should have twenty-four (24) hour staff and have a duration of less than thirty (30) days	Pre-existing Service, but reimburse for facilities with fewer beds
3.1	Clinically Managed Low-Intensity Residential Services	24-hour structure with available trained personnel; at least five hours of clinical service/week and prepare for outpatient treatment	New Service
3.3	Clinically Managed Population Specific High-Intensity Residential Services	Adult only level of care typically offers 24-hour care with trained counselors to stabilize multidimensional imminent danger along with less intense milieu and group treatment for those with cognitive or other impairments unable to use full active milieu or therapeutic community	New Service

3.5	Clinically Managed High-Intensity Residential Services	Provides 24-hour care with trained counselors to stabilize multidimensional imminent danger and prepare for outpatient treatment. Patients in this level can tolerate and use full active milieu or therapeutic communities.	New Service
3.7	Medically Monitored Intensive Inpatient Services	Provides 24-hour nursing care with a physician's availability for significant problems in Dimensions 1, 2, or 3. Patients in this level of care require medication and have a recent history of withdrawal management at a less intensive level of care, marked by past and current inability to complete withdrawal management and enter continuing addiction treatment	New Service
4	Medically Managed Intensive Inpatient Services	Offers 24-hour nursing care and daily physician care for severe, unstable problems in ASAM Dimensions 1, 2 or 3. Counseling is available 16 hours a day to engage patients in treatment	New Service

B.4 Renewals, Amendments, and Major Operational Changes

There have been no changes to the Demonstration during the approval period. A request for an extension of the Demonstration is currently under review.

B.5 Population Groups Impacted

The population group affected by this Demonstration will be Kentucky Medicaid beneficiaries who have a substance use disorder.

The total population in the Commonwealth of Kentucky in 2020 was reported as 4,505,836 based upon counts by the US Census Bureau. As of June 2022, the unduplicated count for Medicaid beneficiaries in the Commonwealth was 1,694,2881, or 37.6% of the population based on the 2020 census. As depicted in Table B.5.1 below, 87% of these beneficiaries participate in managed care plans.

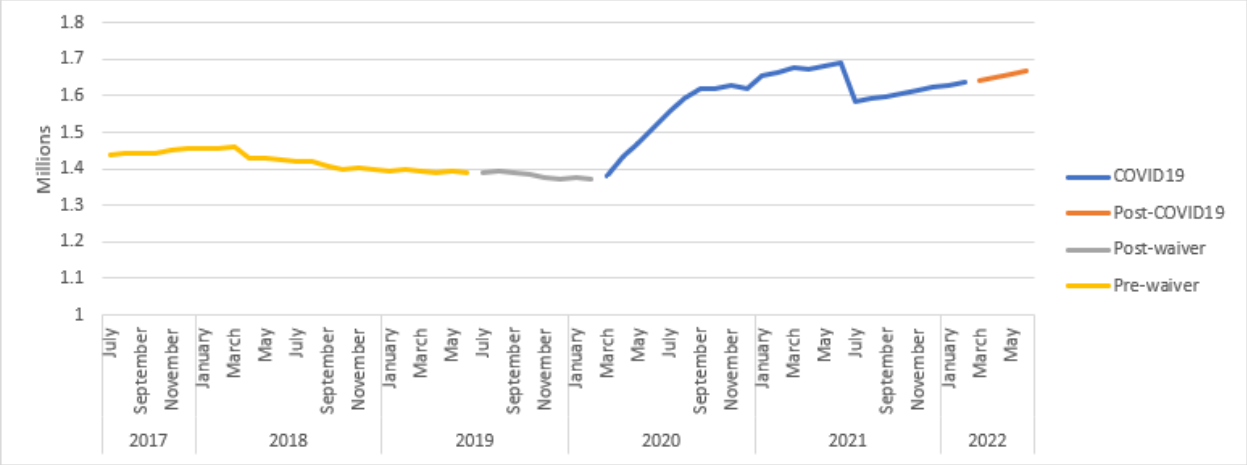
3. **Table B.5.1 Kentucky Medicaid Beneficiary Plans (December 2022)**

Plan Type	Unduplicated Member Count
Aetna Better Health of Kentucky	252,543
Anthem Blue Cross Blue Shield	181,571
Fee for Service	160,224
Humana Healthy Horizons in Kentucky	171,335
Passport Health Plan by Molina Health Care	339,356
United Healthcare Community Plan of Kentucky	93,305
WellCare of Kentucky	494,247
Grand Total	**1,694,881**

(Kentucky Department for Medicaid Services, 2022)

The chart below in Figure B.5.1 shows the four-year Medicaid enrollment trend in Kentucky from January 2017 to June 2022.

1. **Figure B.5.1 Medicaid Enrollment Trend January 2017 – June 2022**



While in 2017 there was little variation, 2018 and 2019 saw slight decreases and then between March 2020 and June 2021 there was a sharp increase by 20.6% to 1,666,692 beneficiaries. We note that this increase corresponds with the advent of COVID-19. Medicaid membership declined in the second half of 2021 as the pandemic waned but remains above the pre-pandemic levels. This report will attempt to highlight periods in which the pandemic might impact evaluation analysis.

Kentucky's Medicaid SUD population as of June 2018 consisted of 102,729 beneficiaries, or just over 7% of the enrolled Medicaid population (1,455,211); similarly, its SUD population as of June 2022 was 130,907 beneficiaries, or just over 7% of the enrolled Medicaid population (1,620,820).

SECTION C. EVALUATION QUESTIONS AND HYPOTHESES

C.1 Defining Relationships between Goals and Drivers

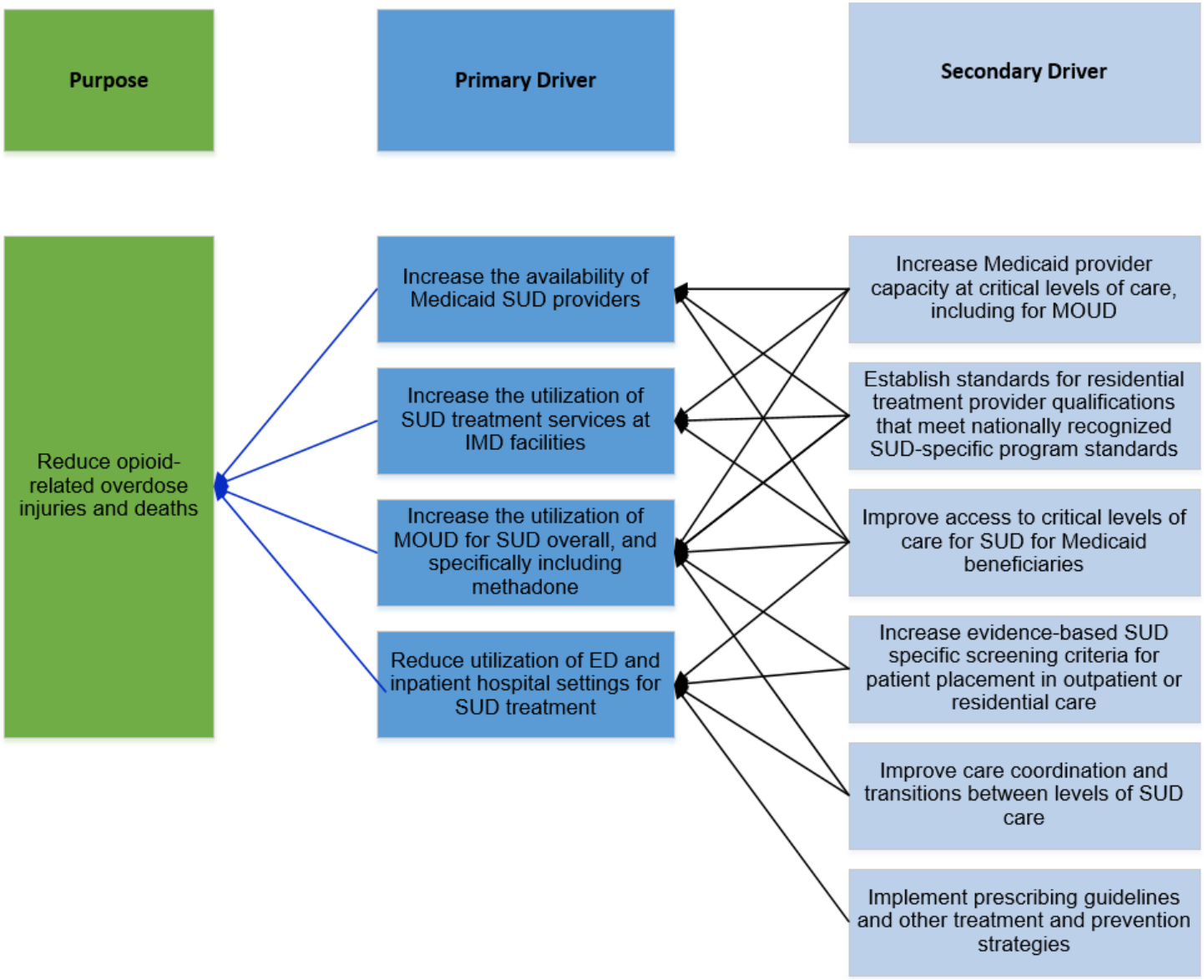
The overarching goal or purpose of Kentucky's 1115 SUD Waiver Demonstration is to reduce the impact opioids and other substances have on Kentucky Medicaid recipients, particularly injuries and deaths from accidental poisonings. To achieve this goal, the Commonwealth must achieve three primary objectives: increase the availability of SUD providers accepting Medicaid, increase utilization of Medicaid-supported SUD-related services, and increase the utilization of the best evidence-based treatment available: the use of medication for OUD (MOUD). To make these three objectives feasible, at the same time, the Commonwealth must also achieve a fourth goal; it must accrue cost savings by decreasing the usage of ED and inpatient hospital settings for SUD treatment, while increasing usage of other facilities.

To achieve the objectives, in its 1115 SUD Demonstration Waiver, the Commonwealth proposed to:

1. Increase Medicaid SUD provider capacity, especially for MOUD, which will increase the availability of providers, thus allowing for increased utilization of SUD treatment, including MOUD.
2. Improve standards for residential SUD treatment provider qualifications, which will expand the availability of successful residential providers, this allowing for increased utilization of SUD treatment, including MOUD.
3. Expand access to the levels of care for SUD, which will decrease the usage of ED and hospitals for SUD care, and increase the utilization of other providers, thus allowing for increased utilization of SUD treatment, including MOUD.
4. Improve SUD screening accuracy for patient placement in the appropriate service level of SUD treatment, which will increase the availability of providers, thus allowing for increased utilization of SUD treatment, including MOUD, as well as decreasing the usage of ED and hospitals for SUD care.
5. Improve coordination among the levels of care, which will increase the use of appropriate care and decrease the usage of ED and hospitals for SUD care
6. Improve SUD prevention practices, which will decrease the need for SUD treatment by decreasing the number of Kentucky citizens with SUD.

A driver diagram—depicting the relationship between the goal or purpose of the Demonstration, what the Commonwealth proposed to do, and how these "drivers" connect to the primary results that will achieve the overarching goal—is shown below in Figure C.1.

2. **Figure C.1 Driver Diagram**



C.2 Evaluation Hypotheses

C.2.1 Evaluation Goals

The following evaluation hypotheses were developed based on the primary drivers (PD) (the presumed results) and secondary drivers (SD) (what the Commonwealth proposed to do):

H1a: The Demonstration will increase the ratio of outpatient Medicaid SUD/OUD providers overall (PD1), and those specifically offering MOUD and methadone as part of MOUD, to beneficiaries in areas of greatest need (SD1).

H1b: The Demonstration will increase the ratio of SUD/OUD providers offering residential treatment, especially IMDs, to beneficiaries (PD1, SD1, SD2).

H1c: The Demonstration will increase the utilization of SUD/OUD services (PD1, PD2, SD1, SD3, SD4, SD5).

H1d: The Demonstration will decrease the rate of ED visits and inpatient admissions within the beneficiary population for SUD/OUD (PD4, SD1, SD2, SD3, SD4, SD5).

H2a: Among beneficiaries receiving care for SUD/OUD, the Demonstration will decrease the rate of ED visits for SUD/OUD (PD4, SD6).

H2b: Among beneficiaries receiving care for SUD/OUD, the Demonstration will reduce hospital readmissions for SUD/OUD care (PD4, SD5).

H3a: The Demonstration will decrease the rate of overdose deaths due to opioids (Purpose).

In addition, based upon CMS recommendations, additional hypotheses will be evaluated at three levels regarding the costs associated with the 1115 Waiver:

F1a: The Demonstration will decrease the total SUD/OUD expenditures.

F1b: The Demonstration will decrease SUD and OUD and non-SUD/OUD expenditures, with SUD/OUD expenditures disaggregated into IMD and non-IMD expenditures**.**

F1c: The Demonstration will decrease expenditures disaggregated by source of treatment—namely, inpatient expenditures, emergency department (ED) expenditures, non-ED outpatient expenditures, and pharmacy expenditures.

In Table C.2.1.1 below, specific evaluation questions are tied to the hypotheses above as well as to concomitant Demonstration goals. The table also lists the primary drivers, or that impact the Demonstration goals, along with a description of the measurements, their data sources, and the analytic approach answering each evaluation question.

4. **Table C.2.1.1 Summary of Key Evaluation Questions, Hypotheses, Data Sources, and Analytic Approaches**

Evaluation Question 1: Did access to SUD treatment services increase?

Demonstration Goal: Increase the ratio of outpatient Medicaid SUD providers offering MOUD, especially methadone, to beneficiaries in areas of greatest need.
Evaluation Hypothesis: The Demonstration will increase the ratio of outpatient Medicaid SUD providers overall, and those specifically offering MOUD and methadone as part of MOUD, to beneficiaries in areas of greatest need.

Driver	**Measure Description**	**Steward**	**Numerator**	**Denominator**	**Data Sources**	**Analytic Approach**
Primary Driver (Increase the availability of Medicaid SUD providers)	Providers offering SUD services	N/A	Number of providers billing for SUD treatment services	Total number of beneficiaries	Claims data Provider enrollment data	Descriptive statistics Interrupted time series without comparison group
	Providers offering MOUD	N/A	Number of providers prescribing any MOUD	Total number of beneficiaries		
	Providers offering methadone	N/A	Number of providers prescribing methadone	Total number of beneficiaries		
	Providers offering SUD services in areas of greatest need	CCBHC 2.a.3	Number of providers billing for SUD treatment services, by county	Total number of beneficiaries, by county	Claims data Provider enrollment data	Descriptive statistics
	Providers offering MOUD in areas of greatest need	CCBHC 2.a.3	Number of providers prescribing any medication that is part of MOUD, by county	Total number of beneficiaries, by county		
	Providers offering methadone in areas of greatest need	CCBHC 2.a.3	Number of providers prescribing methadone as part of MOUD, by county	Total number of beneficiaries, by county		

Demonstration Goal: Increase the ratio of SUD providers offering residential treatment, especially IMDs, to beneficiaries. *Evaluation Hypothesis*: The Demonstration will increase the ratio of SUD providers offering residential treatment, especially IMDs, to beneficiaries.						
Driver	**Measure Description**	**Steward**	**Numerator**	**Denominator**	**Data Sources**	**Analytic Approach**
Primary Driver (Increase the availability of Medicaid SUD providers)	Providers offering residential treatment for SUD	N/A	Number of providers billing for residential treatment for SUD	Total number of beneficiaries	Claims data Provider enrollment data	Descriptive statistics Interrupted time series without comparison group
	IMD facilities offering treatment for SUD	N/A	Number of IMD facilities billing for treatment for SUD	Total number of beneficiaries		
	Providers offering residential treatment for SUD in areas with greatest need	N/A	Number of providers billing for residential treatment for SUD, by county	Total number of beneficiaries, by county	Claims data Provider enrollment data	Descriptive statistics
	IMD facilities offering treatment for SUD in areas with greatest need	N/A	Number of IMD facilities billing for treatment for SUD, by county	Total number of beneficiaries, by county		

Demonstration Goal: Increase utilization of SUD services. *Evaluation Hypothesis*: The Demonstration will increase the utilization of SUD services.						
Driver	**Measure Description**	**Steward**	**Numerator**	**Denominator**	**Data Sources**	**Analytic Approach**
Primary Driver (Increase the utilization of MOUD for SUD, especially methadone)	Percentage of beneficiaries with newly initiated SUD treatment/diagnosis	N/A	Number of beneficiaries with SUD diagnosis and SUD-related service but not in 3 months preceding measurement period	Total number of beneficiaries	Claims data	Descriptive statistics Interrupted time series without comparison group
	Percentage of beneficiaries with SUD diagnosis who used outpatient services for SUD	N/A	Number of beneficiaries with SUD diagnosis who used outpatient services for SUD	Total number of beneficiaries		
	Percentage of beneficiaries with SUD diagnosis who used residential treatment services for SUD	N/A	Number of beneficiaries with SUD diagnosis who used residential treatment services for SUD	Total number of beneficiaries		
	Percentage of beneficiaries with SUD (OUD)	N/A	Number of beneficiaries with SUD diagnosis who used MOUD	Total number of beneficiaries	Claims data	Descriptive statistics

	diagnosis who used MOUD					
	Percentage of beneficiaries with SUD (OUD) diagnosis who received methadone	N/A	Number of beneficiaries with SUD diagnosis who received methadone as part of MOUD	Total number of beneficiaries		Interrupted time series without comparison group
	Continuity of pharmacotherapy for OUD*	NQF #3175	Number of beneficiaries who have at least 180 days of continuous pharmacotherapy for OUD without a gap of more than 7 days	Number of beneficiaries with a diagnosis of OUD and at least one claim for OUD medication		
Primary Driver (Increase the utilization of SUD treatment services at IMD facilities)	Percentage of beneficiaries with SUD diagnosis who used SUD services at IMD facility	N/A	Number of beneficiaries with SUD diagnosis who used SUD services at IMD facility	Total number of beneficiaries		

*Denotes a metric that is also part of the Monitoring Plan

Demonstration Goal: Reduce the preventable or medically inappropriate utilization of ED and inpatient hospital settings for SUD treatment *Evaluation Hypothesis*: The Demonstration will decrease the rate of ED visits and inpatient admissions within the beneficiary population for SUD.						
Driver	**Measure Description**	**Steward**	**Numerator**	**Denominator**	**Data Sources**	**Analytic Approach**
Primary Driver (Reduce utilization of ED and inpatient hospital settings for SUD treatment)	ED visits for SUD (OUD) related diagnosis*	N/A	Number of ED visits for SUD (OUD) related diagnosis	Total number of beneficiaries	Claims data	Descriptive statistics Interrupted time series without comparison group
	Inpatient admissions for SUD and specifically OUD*	N/A	Number of beneficiaries with an inpatient admission for SUD and specifically for OUD	Total number of beneficiaries		

*Denotes a metric that is also part of the Monitoring Plan

Evaluation Question 2: Did beneficiaries receiving SUD services experience improved health outcomes?

Demonstration Goal: Reduced utilization of ED services for SUD for beneficiaries receiving SUD care.
Evaluation Hypothesis: Among beneficiaries receiving care for SUD, the Demonstration will decrease the rate of ED visits for SUD.

Driver	Measure Description	Steward	Numerator	Denominator	Data Sources	Analytic Approach
Primary Driver (Reduce utilization of ED and inpatient hospital settings for SUD treatment)	ED visits with primary SUD (OUD) related diagnosis for individuals receiving SUD (OUD) treatment	N/A	Number of ED visits with primary SUD (OUD) related diagnosis among beneficiaries who used SUD (OUD) services within 30 days	Number of beneficiaries who used SUD (OUD) services within 30 days	Claims data	Descriptive statistics Interrupted time series without comparison group
	ED visits with primary SUD (OUD) related diagnosis for individuals receiving outpatient SUD (OUD) treatment	N/A	Number of ED visits with primary SUD (OUD) related diagnosis among beneficiaries receiving outpatient SUD (OUD) services within 30 days	Number of beneficiaries who used outpatient SUD (OUD) services within 30 days		
	ED visits with primary SUD (OUD) related diagnosis, following ED discharge for SUD (OUD)	NQF #2605	Number of ED visits with primary SUD (OUD) related diagnosis within 7 days ED discharge for SUD (OUD) Number of ED visits with primary SUD (OUD) related diagnosis within 30 days ED discharge for SUD (OUD)	Number of beneficiaries discharged from ED with primary diagnosis of SUD (OUD)		

Demonstration Goal: Fewer hospital readmissions for SUD for beneficiaries receiving SUD care.
Evaluation Hypothesis: Among beneficiaries receiving care for SUD, the Demonstration will reduce hospital readmissions for SUD care.

Driver	Measure Description	Steward	Numerator	Denominator	Data Sources	Analytic Approach
Primary Driver (Reduce utilization of ED and inpatient hospital settings for SUD treatment)	30-day readmission rate following hospitalization with SUD (OUD) related diagnosis	N/A	Number of beneficiaries readmitted to the hospital within 30 days of an index hospitalization with SUD (OUD) related diagnosis	Total number of beneficiaries who were admitted to the hospital with SUD (OUD) related diagnosis	Claims data	Descriptive statistics Interrupted time series without comparison group

Demonstration Goal: Improved physical and mental health for beneficiaries receiving SUD care. *Evaluation Hypothesis*: Among beneficiaries receiving care for SUD, the Demonstration will improve physical and mental health.						
Driver	**Measure Description**	**Steward**	**Numerator**	**Denominator**	**Data Sources**	**Analytic Approach**
Primary Drivers (Increase the availability of Medicaid SUD providers) (Increase the utilization of SUD treatment services at IMD facilities) (Increase the utilization of MOUD for SUD, especially methadone)	Self-reported health in past 6 months	N/A	Rating on 5-point Likert-like scale of overall health	N/A	KTOS KORTOS Patient interviews	Descriptive statistics Interrupted time series without comparison group Thematic analysis
	Self-reported days of poor physical health within past 30 days	N/A	Number of days of poor physical health within past 30 days	N/A		
	Self-reported days of poor mental health within past 30 days	N/A	Number of days of poor mental health within past 30 days	N/A		
	Self-reported attendance at AA, NA, MA, or other self-help group meetings within past 30 days	N/A	Number of times attended AA, NA, MA, or other self-help group meetings within past 30 days	N/A		
	Self-reported use of prescription opiates/ opioids within past 6 (KORTOS) / 12 (KTOS) months / 30 days (KTOS)	N/A	Use of prescription opiates/opioids within past 6 months	N/A		
	Self-reported use of heroin within past 6 (KORTOS) / 12 (KTOS) months / 30 days (KTOS)	N/A	Use of heroin within past 6 months	N/A		
	Self-reported continued substance misuse within past 6 months (KORTOS) / 12 months (KTOS)	N/A	Substance use within past 6 months	N/A		

Evaluation Question 3: Did rates of opioid-related overdose deaths decrease?

Demonstrated Goal: Reduction in opioid-related overdose deaths.
Evaluation Hypothesis: The Demonstration will decrease the rate of overdose deaths due to opioids.

Driver	**Measure Description**	**Steward**	**Numerator**	**Denominator**	**Data Sources**	**Analytic Approach**
Primary Drivers (Increase the availability of Medicaid SUD providers) (Increase the utilization of SUD treatment services at IMD facilities) (Increase the utilization of MOUD for SUD, especially methadone) (Reduce utilization of ED and inpatient hospital settings for SUD treatment)	Use of opioids at high dosage in persons without cancer*	NQF #2940	Number of beneficiaries with opioid prescription claims for a morphine equivalent dose of greater than 120 mg for 90 consecutive days	Number of beneficiaries with 2+ prescription claims for opioids filled on at least 2 separate dates, for which the sum of days' supply ≥ 15	Claims data	Descriptive statistics Interrupted time series without comparison group
	Rate of overdose deaths, specifically overdose deaths due to any opioid*	N/A	Number of overdose deaths	Number of beneficiaries	Claims data Administrative data [vital statistics]	
	Rate of overdose deaths, specifically overdose deaths due to any opioid	N/A	Number of overdose deaths, by county	Number of beneficiaries	Claims data Administrative data [vital statistics]	

In addition, changes in total costs associated with the care provided through MCOs to Medicaid beneficiaries with a substance abuse diagnosis will be analyzed in the evaluation using descriptive statistics, categorical data analyses, and interrupted-time-series-without-comparison-groups

C.2.2 Earlier Evaluation Findings

In April 2021, a Midpoint Assessment (refer to Appendix ??) was performed to provide an early assessment of the implementation of the Demonstration and a foundation for longer-term evaluation activities (attached in Appendix J). This evaluation was conducted in direct collaboration with the stakeholders to ensure that the findings will influence subsequent implementation and enhance longer-term assessment activities.

Two complimentary frameworks were used in this evaluation. Given the wide variety of SUD/OUD-focused initiatives underway in the Commonwealth of Kentucky a Cascade of Care Model framework was used to provide insights into Kentucky's global response to SUD/OUD and how the 1115 Demonstration is embedded into these activities. A crosswalk analysis using the Cascade of Care Model framework was applied to organize and understand the SUD/OUD initiatives in Kentucky and more precisely evaluate the 1115 Demonstration. Second, SWOT (Strength, Weakness, Opportunity, Threats) analyses were applied to mechanisms used to implement the 1115 Demonstration. These were used to evaluate the positioning of the 1115 Demonstration relative to the program goals. This positioning encompassed performance, competition, risk, and potential.

The focus for these analyses within the Midpoint Assessment was to identify common themes and issues across the mechanisms being used to implement the Demonstration for the purpose of considering any mid-course corrections, enhancements, or resource reallocations. That is, its goal was to inform decision-making about how to improve Kentucky's response to the opioid epidemic through more effectively exploiting available 1115 Demonstration mechanisms. Importantly, the analyses also provided a conceptual and evidenced-based foundation for this Interim Evaluation.

Relevant to the Interim Evaluation, the Midpoint Assessment revealed that the implementation of the Demonstration activities and the collection of data concerning performance under the waiver were constrained by the COVID-19 pandemic. There was also evidence that behaviors during this period changed, which will complicate the longitudinal analyses and other comparisons across time periods. For example, the rate of accidental poisoning deaths significantly increased during the pandemic in 2020, both in Kentucky and across the nation. As a result, the mechanisms of the 1115 Demonstration project could perform exactly as intended and yet the opioid-related deaths might still have increased due to the challenges of isolation and economic distress during the pandemic. This Interim Evaluation is sensitive to these potentially confounding factors.

The Midpoint Assessment also indicated that providers understood the 1115 Demonstration as set of tools that they can use to enact broad-based and multi-disciplinary efforts to combat SUD/OUD. Additionally, all MCOs reported that provider capacity had increased. These data

suggest that the 1115 waiver improved the Commonwealth's SUD infrastructure. The Interim Evaluation builds upon this insight and expands the evidence base available to the Commonwealth and CMS to determine appropriate next steps in their efforts to combat the impact and outcomes of SUD in Kentucky residents.

Due to the Midpoint Assessment, the Statement of Work for evaluation was amended to reflect new information and methodological enhancements that approved plan. These encompass:

1. New analyses focused on the findings of the midpoint evaluation
2. Refinement of qualitative analysis
3. Refinement of research questions
4. Tables providing direct explication of research hypotheses to required CMS metrics
5. Discussion of challenges related to data gathering and analysis.

Additions to the qualitative analysis included the following activities:

1. Inclusion as a topic area in qualitative instruments used in gathering data and information from providers
2. Interviews with the Managed Care Organizations (MCOs)
3. Interviews with Kentucky Department for Medicaid Services
4. Analysis of any changes in provider engagement or patient encounters associated with responses to the Mid-Point findings based upon claims data measures.

Refinements to the research questions informed by the Midpoint Assessment and designed to provide improved inference from the analyses are proposed below. The original research question in the approved plan is listed followed by the proposed revisions.

Evaluation Question 1: Did access to SUD treatment services increase?
Revision: Evaluation Question 1. To what extent has access by Medicaid beneficiaries for SUD treatment services increase based on:

a. Changes in the ratio of outpatient Medicaid SUD hospital and residential providers offering MOUD to beneficiaries under at least stage 6 (treatment) of Cascade of Care?
b. Changes in ratio of SUD Medicaid providers offering residential treatments, especially referrals to Institutions of Mental Disease (IMD), to beneficiaries at any Cascade level of care?
c. Changes in utilization of SUD services provided by all types of Medicaid providers by Medicaid beneficiaries at all levels of Cascades of Care?
d. The beneficiaries' response re: actual use of SUD treatment services and/or predisposition in the use of services based on information materials from providers and/or DMS?

Evaluation Question 2: Did beneficiaries receiving SUD services experience improved health outcomes?
Revision: Evaluation Question 2. To what extent did the quantity and quality of health outcomes for beneficiaries receiving SUD services with the 1115 Medicaid Demonstration project improve as evidenced by:

a. The report on preventable or medically inappropriate ED use of Medicaid

beneficiaries for SUD treatment?

b. The report on preventable and medically inappropriate inpatient hospital admission of Medicaid beneficiaries for SUD care?
c. The degree to which Medicaid beneficiaries in each CC stage met their goals within their CC stages improving the quality of their health outcomes and reducing the likelihood of use of ED and admission to hospitals?

Evaluation Question 3: Did rates of opioid-related overdose deaths decrease?
Revision: Evaluation Question 3. To what extent did the opioid-related overdose deaths decrease because of the 1115 Medicaid Demonstration project?

The qualitative analysis was enhanced through the addition of a mix of longitudinal cohort within a single case design using semi-structured interviews with initially identified populations, as well as one-time interviews. A thematic analysis technique was used to better understand how beneficiaries learn about and engage in new treatment options. Interviews also explore a narrative of the person's SUD vis-à-vis a Cascade of Care framework; (cf., Mid-point Evaluation for the 1115 SUD Demonstration Waiver, p. 4 ff.); its impact on daily life over time; transitions between stages of care, with a particular focus on transitions between diagnosis, engagement with care, withdrawal, treatment, remission, and retention; current medical needs and health status; past and current experiences with Medicaid, both for overall health and SUD; access to SUD treatment through any means of payment (including Medicaid); barriers to SUD treatment services; and any SUD treatment needs not currently covered by Medicaid or other insurance.

C.2.3 Meeting Title XIX Objectives

(Title XXI, which established the State Children's Health Insurance Program (CHIP), does not apply to Kentucky's 1115 SUD Waiver Demonstration.)

The purpose of Title XIX is to "[enable] each State, as far as practicable under the conditions in such State, to furnish (I) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care." As such, an important objective of the Medicaid program is to provide medical assistance and other services to vulnerable populations. A second important objective is to advance the health and wellness needs of beneficiaries in virtue of providing these services.

The first primary evaluation question:

1. To what extent has access by Medicaid beneficiaries to SUD treatment services increased?

will answer whether Kentucky provided more medical assistance and other services to its vulnerable residents.

The evaluation hypotheses being tested under this question, that the Demonstration:

1. increased the ratio of outpatient Medicaid SUD providers overall, and those specifically offering MOUD and methadone as part of MOUD, to beneficiaries in areas of greatest need
2. increased the ratio of SUD providers offering residential treatment, especially IMDs, to beneficiaries
3. increased the utilization of SUD services

explore the validity of the primary and secondary drivers associated with the evaluation question. Affirmative answers to all three suggest that the answer to the primary question is also yes, and therefore, will show that the proffered drivers resulted in Kentucky providing more medical assistance and other services to its vulnerable residents.

The second evaluation question:

1. To what extent did the quantity and quality of health outcomes for beneficiaries receiving SUD services with the 1115 Medicaid Demonstration project improve?

answers whether these services advanced the health and wellness of the vulnerable residents of Kentucky.

The evaluation hypotheses being tested under this question, that, among beneficiaries receiving care for SUD, the Demonstration:

1. decreased the rate of ED visits for SUD
2. reduced hospital readmissions for SUD care
3. improved physical and mental health

explore the validity of the fourth primary driver. Affirmative answers to the first two questions suggest that the driver is valid. An affirmative answer to the third question indicates that there is at least a correlation between the fourth primary driver and advancing the health and wellness of the vulnerable residents of Kentucky.

The third evaluation question:

1. To what extent did the opioid-related overdose deaths decrease?

answers whether lives were saved by advancing the health and wellness of the vulnerable residents of Kentucky.

The evaluation hypothesis being tested under this question, that the Demonstration:

1. decreased the rate of overdose deaths due to opioids

will obviously answer the same question, whether lives were saved by advancing the health and wellness of the vulnerable residents of Kentucky.

SECTION D. INTERIM EVALUATION METHODOLOGY

The approved Evaluation Design Plan is a mixed-methods approach, drawing from a range of data sources, measures, and analytics to best produce relevant and actionable study findings. Owing to the limited data points, no statistical testing is included in this Interim Evaluation and the principal metrics are percent change over time. Statistical testing will be included in the Summative Evaluation as it will contain a longer period of post-waiver data that will be appropriate for statistical testing.

Two principal analytic methods are used to achieve the goals in the Interim report:

- Longitudinal analysis of descriptive statistics
- Thematic analysis of provider and beneficiary interviews.

D.1 Evaluation Design

As has been approved, this project employs a mixed-methods research design. This design is in the tradition of Creswell & Plano-Clark (2011), where quantitative and qualitative data are integrated. Doing so reflects not only results in terms of numbers (i.e., the claims data, provider portal data and vital statistics data- with pre-post comparison design), but perspectives that enhance quantitative results when triangulated or integrated to answer the evaluation questions.

Although the broader objective of Kentucky's opioid strategy is to reduce the number of opioid-related injuries and deaths, the sheer magnitude of SUD challenges in the state and the many ongoing federal, state, and privately funded initiatives directed towards the state's SUD crisis mean that the incremental effect of the 1115 SUD Demonstration will be challenging to detect using population-level quantitative health measures, such as opioid-related deaths or aggregate costs. This is because these injuries and deaths and their associated treatments are the result of the co-occurrence of complex and overlapping demographic, social, economic, disease, health care, public health, and institutional factors. For this reason, the quantitative evaluation focuses primarily on monitoring and evaluating outcome measures that are most directly affected by the central features of the Demonstration and primary drivers of the waiver:

1. availability of provider service and capacity to Medicaid beneficiaries with a SUD diagnosis
2. utilization of SUD services in residential facilities, particularly those subject to the IMD waiver exclusion
3. utilization of MOUD for SUD treatments, especially methadone
4. utilization of ED and inpatient hospital settings for SUD treatment.

The ability to establish a control group for parallel analyses is not an option. The SUD Demonstration has been implemented statewide; therefore, it is not possible to have an internal comparison group within the Commonwealth**.** Likewise, other potentially matching populations for use in control groups from other states are not options due to SUD initiatives also being launched within those regions and differences in policies. For these reasons, ultimately, we will use an interrupted time series analysis without comparison group approach to evaluate the effect of the SUD Demonstration. For the Summative Evaluation, multiple techniques will be applied

to analyze these longitudinal data owing to complexities in their interrelationships. Here, however, we are limited in our analysis due to incomplete data sets.

In addition, based upon CMS recommendations, analyses will also be conducted to evaluate related costs, including:

1. total SUD/OUD expenditures
2. SUD/OUD and non-SUD/OUD expenditures, with SUD/OUD expenditures disaggregated into IMD and non-IMD expenditures
3. expenditures disaggregated by type of treatment.

What was planned initially for the qualitative aspect of this study was to allocate the provider and beneficiary interviews into four case study groups with multiple probes across participants with a time-lagged implementation. In this connection, four quadrants were chosen based on the density of the overdose death as published in the 2020 KPRIC report. The DMS list of provider types was used as the basis for the sampling of provider institutions within the four quadrants:

1. Central Quadrant, which includes Health District 5 (with 31% of the sample group)
2. North Quadrant, which includes Health Districts 3 and 6 (29% of the sample group)
3. Southeast Quadrant, which includes Health Districts 7, and 8 (26% of the sample group)
4. Southwest Quadrant, which includes Health Districts 1,2, and 4 (14% of the sample group).

However, anticipating challenges with contacting beneficiaries and potential attrition of respondents, and given the pandemic situation at the time the interviews were started, the initial sampling plan was augmented to include one-time interviews of beneficiaries and at least one representative provider from what our Project classified as small (< 100 beneficiaries served), medium (>100 to 300 beneficiaries served), and large (> 300 beneficiaries served) SUD service organizations from each from the four quadrants.

Additional enhancements to the qualitative evaluation plan following the Mid-Point Assessment are as follows:

1. inclusion as a topic area in qualitative instruments used in gathering data and information from providers
2. interviews with the Managed Care Organizations (MCOs)
3. interviews with Kentucky Department for Medicaid Services
4. analysis of any changes in provider engagement or patient encounters associated with responses to the Mid-Point findings based upon claims data measures

Results from these activities will be provided in the Final Summative Report. In the Summative Report, detailed thematic analysis of interview results will be presented as grouped responses from the four quadrants earlier identified, which embedded Health Districts overlaid on corresponding counties.

D.2 Target Population

The target population is any Kentucky Medicaid beneficiary with an SUD diagnosis during the study period. The analysis follows the procedures specified in Metric #3 in the *1115 Substance Use Disorder Demonstrations: Technical Specifications for Monitoring Metrics*, Version 4, dated September 2021 *(Technical Specifications Manual)*, to identify the target population, which consists of Kentucky Medicaid beneficiaries with a substance use disorder or who have used SUD services as defined by diagnostic codes. Individuals without an SUD diagnosis or any record of SUD treatment after these 12 months will be considered not to have an active SUD. They will be excluded from the target population in subsequent months unless there is another triggering SUD diagnosis or care visit.

The quantitative analysis uses a pre/post design with monthly or annual comparisons made for the administrative data analyzed. For the reasons described in the Evaluation Design in Section D.1 above, there is no comparison or control population.

For the qualitative analysis, interviews are being conducted with beneficiaries with active SUD and SUD treatment providers. As of December 20, 2022, 107 beneficiaries and 76 providers had been interviewed. These were divided into two data sets: Batch 1 and Batch 2. Batch 1 data, included in this report, comprises the one-time interview responses for 50 beneficiaries and 23 providers.

The case study interviews have been initiated and contact with these case study groups continue. As of December 20, 2022, Time 1 interviews have been completed for the Central, Southeast, and Southwest Quadrant case study groups; the North Quadrant case study group T1 interviews are in progress but currently incomplete. We anticipate continued contact with the identified study groups, including the T2 an T3 contacts as feasible.

D.3 Evaluation Period

Data for the period July 2017 to September 2023 will be used for the Summative Evaluation of the Demonstration. The state fiscal years of July 2017 to June 2018 (Baseline Year 1) and July 2018 to June 2019 (Baseline Year 2) are used for baseline comparisons. This Interim Evaluation compares these baseline years to data from June 2019 to July 2022, consisting of Demonstration Years 1 through 3. Adjudicated administrative data may have a three-to-six-month lag relative to their availability, therefore this timeline is appropriate, though data for Demonstration Year 3 (ending June 30, 2022) have a risk of being less complete than other years.

D.4 Evaluation Measures

Evaluation measures are included for both the quantitative and qualitative components of this report. For the quantitative component, the study adopted CMS-defined metrics used in quarterly and annual monitoring reports (see Tables D.4.1, D.4.2., D.4.3, D.4.4, and D.4.5 below.). Metrics from the *Technical Specifications Manual* were used to operationalize the variables where possible. Additionally, some hypotheses required specifications unique to Kentucky (see Table D.4.6). Refinements stemming from the Mid-Point Assessment are included and noted below as

indented measures. Measures that will be addressed only in the Summative Evaluation are in italics.

5**. Table D.4.1 Evaluation Measures – SUD Treatment Services**

SUD Treatment Services

• Percentage of beneficiaries with newly initiated SUD treatment/diagnosis (#2)
  • Beneficiaries with an SUD diagnosis by month
  • Beneficiaries with an SUD diagnosis by year
  • *Beneficiaries who initiated SUD Treatment within 14 days of diagnosis*
  • Beneficiaries receiving any SUD treatment by month
  • Beneficiaries who initiated treatment and engaged with two or more SUD services, including MOUD, with 34 days of initiation
• Percentage of beneficiaries with SUD diagnosis who used outpatient services (#8)
  • Beneficiaries using outpatient services by month
  • Beneficiaries using intensive outpatient or partial hospitalization services by month
• Beneficiaries treated in an IMD for SUD by year (#5)
  • *Average length of stay for beneficiaries*
  • Beneficiaries receiving residential or inpatient services by month
  • *Beneficiaries using withdrawal management services by month*
• Number of beneficiaries with SUD diagnosis who used MOUD (#12)
  • Beneficiaries with a claim for MOUD by month
• Percentage of beneficiaries with SUD diagnosis who used SUD services at IMD facility (#6)
• Number of beneficiaries who have at least 180 days of continuous pharmacotherapy for OUD without a gap of more than 7 days (#NQF3175)

6. **Table D.4.2 Evaluation Measures – Provider-Related**

Provider-Related Measures
• SUD Provider Availability (#13) • SUD Provider Availability – Buprenorphine (#14)

7. **Table D.4.3 Evaluation Measures – ED and Readmission**

ED and Readmission
• ED utilization for SUD per 1,000 Medicaid beneficiaries (#23) • Inpatient stays for SUD per 1000 Medicaid beneficiaries (#24) • Readmissions for Beneficiaries with SUD (#25) • ED visits with primary SUD-related diagnosis, following ED discharge for SUD (#NQF 2605)   • Percentage of ED visits with a primary SUD diagnosis who follow up with treatment • 30-day readmission rate following hospitalization with SUD-related diagnosis (#25)

8. **Table D.4.4 Evaluation Measures – Overdose Death**

Overdose Death
• *Use of opioids at high dosage in persons without cancer* (#18, NQF 2940)* • *Overdose deaths (#27)*

9. **Table D.4.5 Evaluation Measures – SUD Spending**

SUD Spending
• SUD Spending (#28) • SUD Spending within IMDs (#29) • SUD Spending on non-IMDs • SUD Spending inpatients • SUD Spending in ED • SUD Spending in non-ED • *SUD Spending in pharmacy* • *SUD Spending in long-term care*

10. **Table D.4.6 Evaluation Measures – Kentucky-Specific SUD Metrics**

Kentucky-Specific Metrics
• Providers offering SUD services in areas of greatest need • Providers offering MOUD in areas of greatest need • Providers offering methadone • Providers offering methadone in areas of greatest need • Number of beneficiaries with SUD or OUD diagnosis who received methadone as part of MOUD • *IMD facilities offering treatment for SUD in areas with greatest need* • Providers offering residential treatment for SUD • Providers offering residential treatment for SUD in areas with greatest need • ED visits with a primary SUD or OUD-related diagnosis for individuals receiving any SUD treatment • ED visits with a primary SUD or OUD-related diagnosis for individuals receiving outpatient treatment • *Overdose deaths due to any opioid*

Counties with greatest need were determined using metrics beyond rates of fatal overdose, with a specific focus on access to treatment (cf., Schneider et al., 2020; Katcher & Ruhm, 2021; Davis et al., 2022). As such, counties with greatest need were determined using three primary indicators related to the overall goals of the evaluation: fatal overdoses, availability of SUD treatment in county, and poverty levels. Fatal overdoses were calculated using publicly available data (KIPRC.ky.edu), in which <5 incidence is suppressed per Kentucky policy. Counties with the highest percent poverty were determined by the U.S. 2020 Census Bureau data. To determine prevalence of SUD treatment facilities, counties without SUD treatment facilities were ranked by population count, calculated using publicly available SAMHSA facilities data and 2021 Census estimates. The top 10 counties for each of these indicators, as well as a comparison with Kentucky as a whole, are displayed in Tables D.4.7-9 below.

11. **Table D.4.7 Counties with Highest Rates of Fatal Overdoses per 100K Residents**

Need Ranking	County	Quadrant	Rate
1st	Estill	Central	155.07
2nd	Gallatin	North	136.99
3rd	Perry	Southeast	133.25
4th	Rowan	Southeast	110.05
5th	Montgomery	Central	106.98
6th	Knott	Southeast	106.38
7th	Boyd	Southeast	99.24
8th	Lawrence	Southeast	96.13
9th	Pendleton	North	95.98
10th	Carroll	North	93.54
Kentucky Rate	**49.896**		

12. **Table D.4.8 Counties with Largest Populations with No SUD Treatment Facility**

Need Ranking	County	Quadrant	Population
1st	Meade	North	28,379
2nd	Henry	North	15,999
3rd	Trigg	Southwest	14,569
4th	Todd	Southwest	12,334
5th	Martin	Southeast	11,421
6th	McLean	Southwest	9202
7th	Livingston	Southwest	9172
8th	Crittenden	Southwest	8940
9th	Trimble	North	8528
10th	Lyon	Southwest	8226

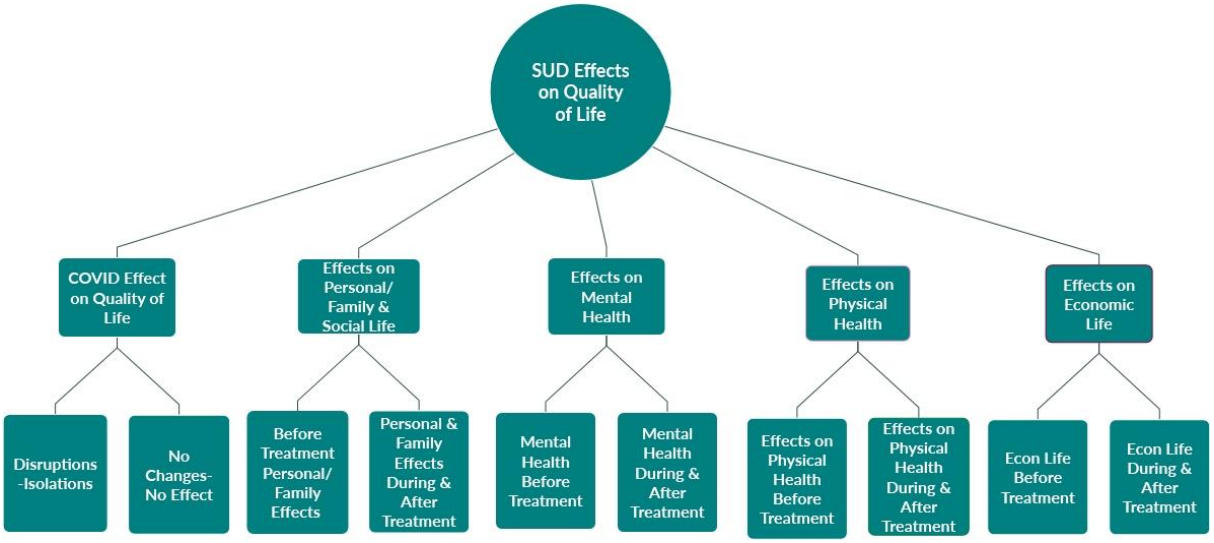
13. **Table D.4.9 Counties with the Highest Percentage of Population in Poverty**

Need Ranking	County	Quadrant	Percentage
1st	Wolfe	Southeast	36.10%
2nd	Clay	Southeast	34.94%
3rd	Harlan	Southeast	34.24%
4th	Knox	Southeast	33.47%
5th	Lee	Southeast	32.23%
6th	Magoffin	Southeast	31.69%
7th	Leslie	Southeast	31.53%
8th	Jackson	Central	31.02%
9th	Knott	Southeast	30.98%
10th	Letcher	Southeast	29.67%
Kentucky Comparison	**33.39%**		

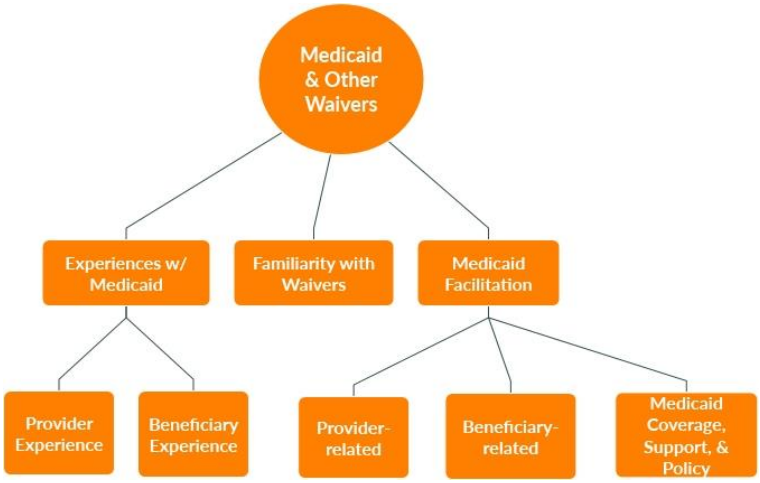
There are no discernable patterns regarding individual counties and their representation in each of the indicators. Indeed, only one county appears in all three metrics (Knott), and no counties appear even twice. Even when we compare the quadrants defined for this Interim Evaluation (color-coded above), specific needs vary among them. The Southwest has substantial populations lacking access to SUD treatment facilities. The North does as well, and it has high rates of fatal overdoses. The Southeast has high rates of fatal overdoses as well as high rates of poverty. Consequently, no further attempt at defining greatest need will be made.

The qualitative component included measures that were used for data coding as indicated by the following five mind maps representing the five major categories with related themes for each (see Figures D.4.1, D.4.2, D.4.3, D.4.4, D.4.5 below).

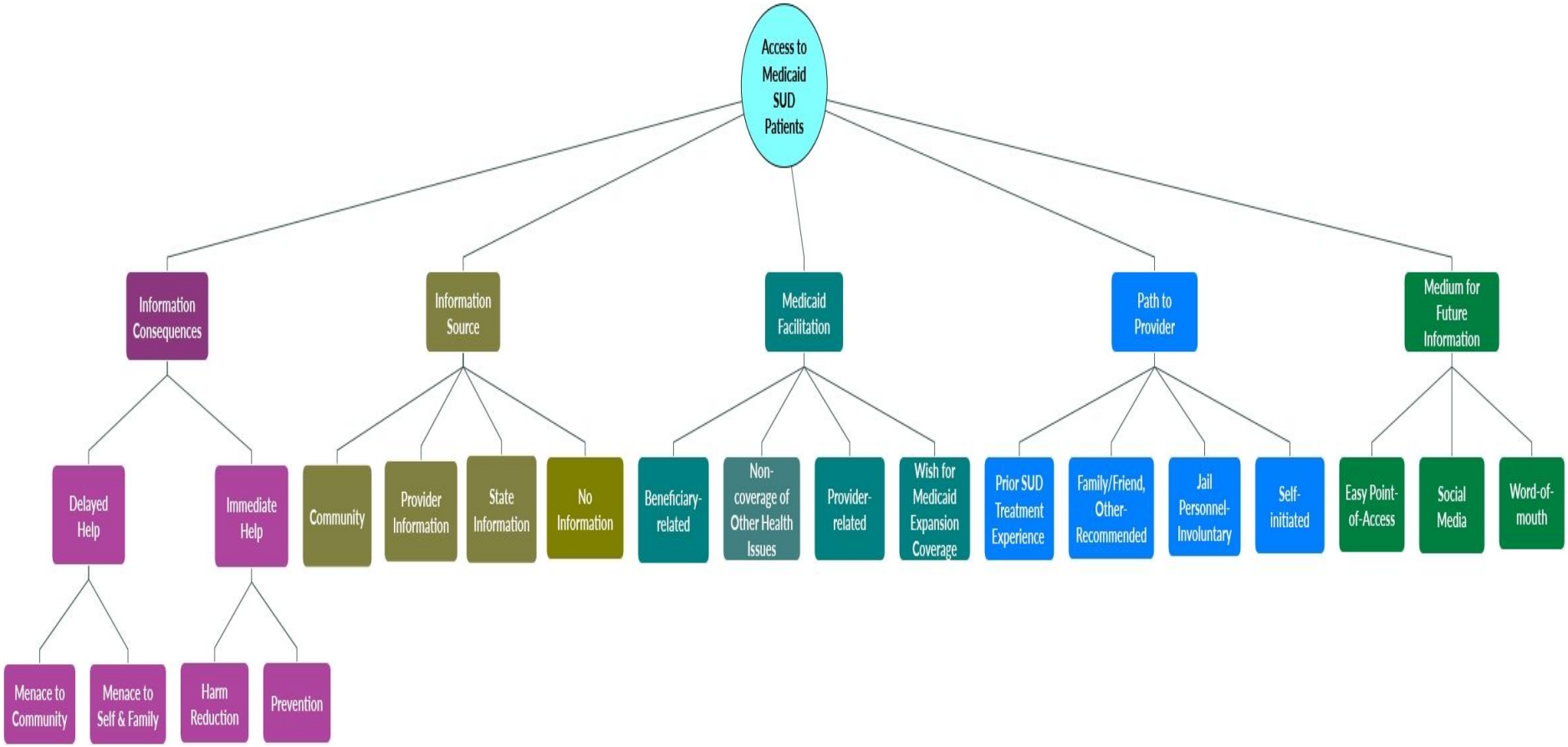
3. **Figure D.4.1 Quality of Life**



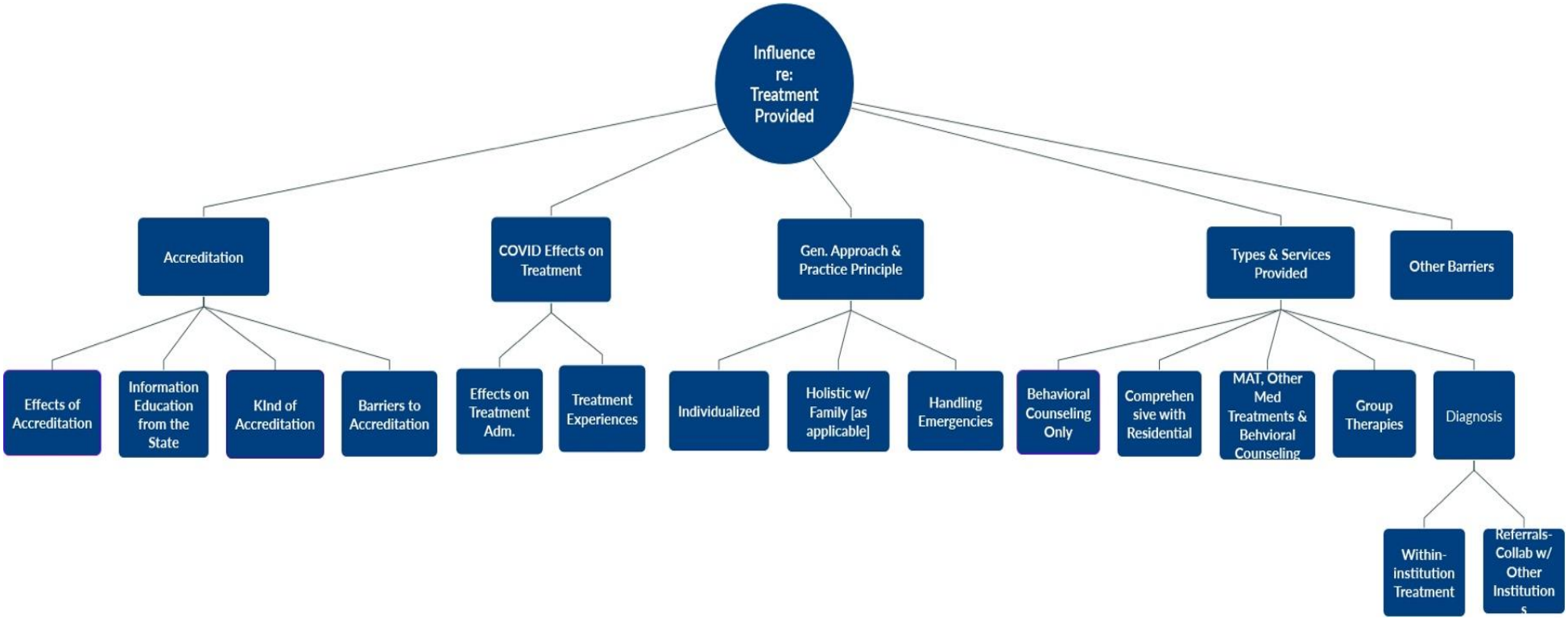
4. **Figure D.4.2 Medicaid**



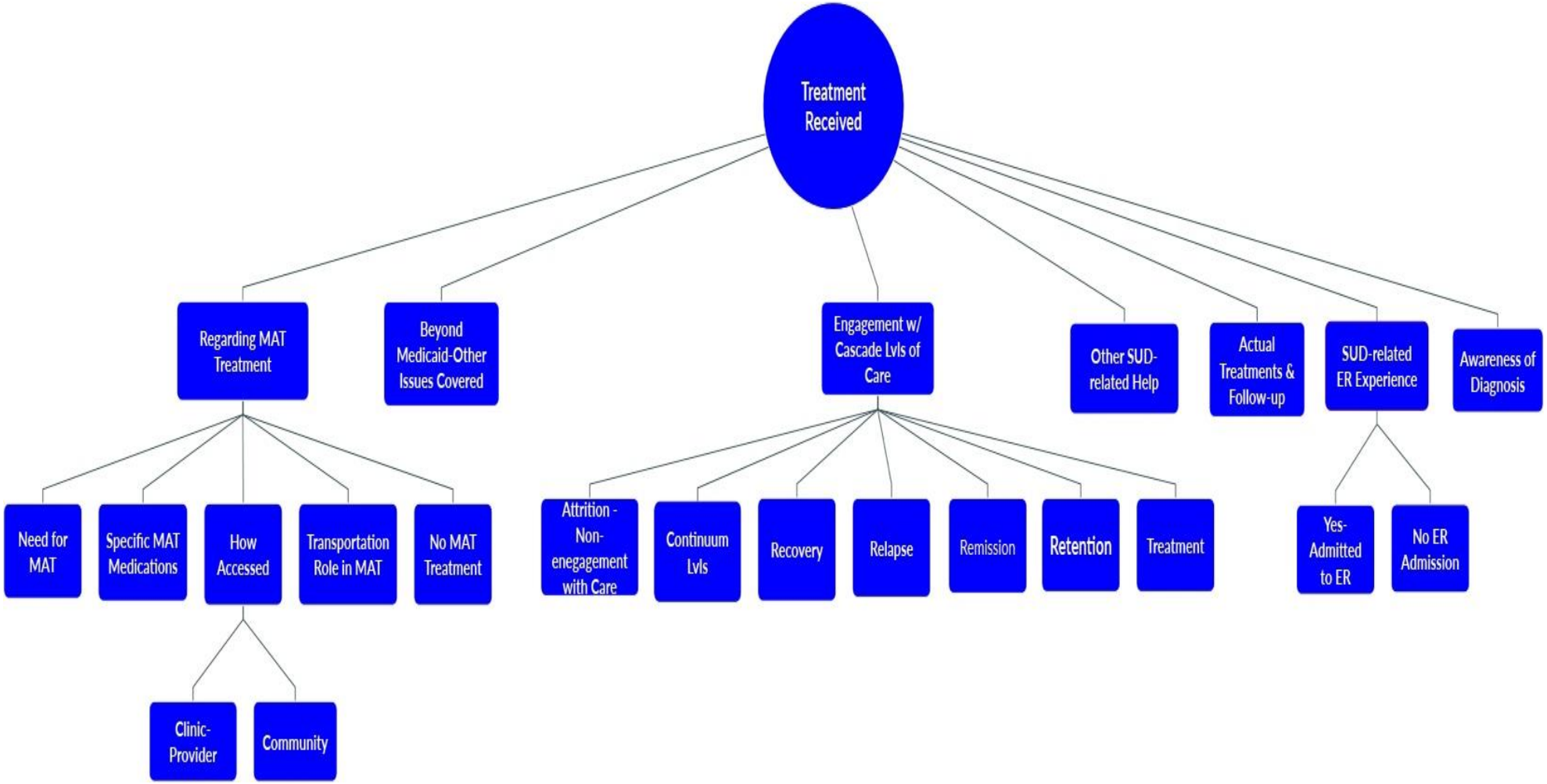
5. **Figure D.4.3 Access to Medicaid**



6. **Figure D.4.4 Treatment Provided**



7. **Figure D.4.5 Treatment Received**



D.5 Data Sources

The core data for this Interim Evaluation are Medicaid encounter data. These data are supplemented with data from administrative vital statistics; a provider enrollment database; SUD-related expenditures; qualitative interviews with Medicaid beneficiaries with SUD; and qualitative interviews with providers.

D.5.1 Medicaid encounter data

Most of Kentucky's Medicaid beneficiaries receive benefits administered by managed care organizations (MCOs), therefore the quantitative analysis will primarily rely on Kentucky Medicaid encounter data (e.g., claims) reported by these MCOs. These encounter data contain records of outpatient, emergency department, and inpatient services provided for SUD, as well as prescription drugs dispensed. They also include information on billing providers (facilities and physicians) and on payments made to these providers by the MCOs.

In submitting its encounters to the state Medicaid Management Information System (MMIS), each MCO is required to submit data that follow a consistent format and that must pass a range of edits and audits. These validated encounter data then undergo state review for quality—including completeness/missingness assessments, internal consistency checks, and other data validation reviews—prior to submission by the state to the federal Transformed Medicaid Statistical Information System (T-MSIS). According to the state, "these processes… ensure a high level of confidence in the quality of the encounter data." Encounter data are available on a quarterly basis with a six-to-nine-month lag. Limitations of these data are that they do not include direct measures of health status or substance misuse, nor do they provider reliable counts of billing or prescribing providers.

D.5.2 Administrative vital statistics data

Vital statistics data capture deaths attributable to accidental poisonings. These data are available on a quarterly basis with a nine-to-twelve-month lag. Limitations of these data are the measurement error in the attribution of overdose deaths to opioids.

D.5.3 SUD-related expenditure data

SUD-related expenditure data reflect health care services provided to beneficiaries and payments made to providers by MCOs for these services. Although these data do not reflect contemporaneous costs incurred by Medicaid for care provided to beneficiaries — because Medicaid pays a capitated rate to the MCOs— they are used by the state Medicaid program, in combination with other factors, to determine capitated MCO rates. For this reason, they do provide a useful if imperfect measure of costs incurred by the Medicaid program.

As described in Appendix C of the *SMI/SED Evaluation Design Guidance* document, capitated contracts, such as those covering more than 90% of the beneficiaries in Kentucky, provide a challenge to measuring costs. As recommended by the guidance, calculating total costs appears

to be the most accurate and feasible approach to calculating expenditure data. That is the approach used in this analysis.

More granular approaches such as assigning costs based upon the FFS schedule and shadow pricing does not appear reliable due to incomplete data and the arbitrary nature of applying them to Kentucky claims within a capitated model. As suggested in the *Guidance* document using the payments derived from the claims data appears the most reliable way of calculating costs.

D.5.4 Provider enrollment data

Kentucky Medicaid launched the Kentucky Medicaid Partner Portal Application (MPPA), a Medicaid provider enrollment system, in mid-2019. Data from MPPA were to be made available with a 6-month lag and used to cross-validate provider and facility information obtained from Medicaid claims when possible. Prior to the MPPA, provider enrollment was done through a manual reporting process. One limitation of this data source is that data on provider enrollment prior to implementation could be inaccurate. A more significant limitation is that provider reporting to the portal allows for the aggregation of multiple providers under a single billing provider and the aggregation of multiple physical locations under a single billing location. These limitations are described in detail in Appendix A.

D.5.5 Beneficiary and Provider Interviews

Beneficiaries and providers were randomly recruited from the rosters of treatment facilities as identified according to treatment type and facility size per defined Quadrant using a cross-sectional design. All interviews were voice-recorded and then machine transcribed and manually checked for accuracy. The clean transcripts provided the basis for an applied thematic analysis.

More specifically, the beneficiary and provider interviews were conducted with the distribution in the designated four Quadrants listed below in Table D.5.5.1. We note that several beneficiaries lived outside of the health districts and even the defined Quadrants where they were receiving treatment. The qualitative data reports by Quadrants include all those served by providers located in the target Quadrant.

14. **Table D.5.5.1 Interview Distribution for Interim Evaluation**

Quadrant	Beneficiaries (N=50)			Providers (N=23)		
	Health District	Number of Beneficiaries	Percentage by Quadrant	Health District	Number of Providers	Percentage By Quadrant
Central [N=17]	5	17	34.00%	5	12	52.17%
North [N=10]	3	4	20.00%	3	1	8.70%
	6	5		6	1	
	5*	1				
Southeast [N=16]	7	4	32.00%	7	1	30.44%
	8	6		8	6	
	5**	2				
	4**	1				
	3**	3				
Southwest [N=7]	1	1	14.00%	1	1	8.07%
	2	1		2		
	4	2		4	1	
	6***	1				
	3***	2				

*Beneficiary who lives in Health District 5 but was served in Health District 3 in the North Quadrant
**Beneficiaries who live in Health Districts 5, 4, or 3, but were served in Health District 8 in the Southeast Quadrant.
***Beneficiaries who live in Health Districts 6 or 3 but were served in Health District 4 in the Southwest Quadrant. (Additionally, one beneficiary lives in Health District 3 in the Southwest Quadrant but was served in Health District 1 in the same Quadrant.)

D.6 Analytic Methods

The quantitative analyses consisted in a longitudinal approach using descriptive statistics and pre-post (as applicable) analyses to assess the impact of the Demonstration using administrative data. The qualitative analyses consisted of semi-structured interviews, using a priori themes based on the mind maps described in a previous section with flexibility to explore unexpected responses.

D.6.1 COVID-19 Impact on the Evaluation

COVID-19 has had a profound impact on people's life. Because COVID interfered with the Demonstration, it is meaningful to classify the evaluation into four periods: pre-waiver (January 1, 2017– December 31, 2017), post-waiver (January 1, 2018 – February 29, 2020), COVID (March 1, 2020- February 28, 2022), and post-COVID (March 1, 2022 – June 30, 2023).[3] We

[3] We recognize that the classification divisions do not correspond to CMS-, CDC-, or Kentucky-specified dates; instead, these dates reflect when COVID-19 first appeared in Kentucky and then

analyzed the metrics and compared the differences in the impact of the waiver based on four periods. This approach was particularly useful in understanding Metric #2 (Medicaid beneficiaries with a new SUD diagnosis or newly initiated treatment). We anticipate that this approach will also be helpful in analyzing demographic differences for newly enrolled beneficiaries during the pandemic period as well as beneficiary service utilization.

D.6.2 Descriptive Statistics

CMS-defined metrics are computed annually or monthly. Steps outlined in the *Technical Specification Manual* were used to produce reports. Pre-post analyses were performed to find trends associated with a given metric. For year-to-year comparison, line charts were used.

Interrupted time-series analysis modeling was applied to specific measures (e.g., provider capacity and utilization). There were insufficient data for this Interim Evaluation to power a meaningful time-series analysis as evidenced by the result. In addition, data during the collection period were substantially perturbed by the COVID epidemic. The expectation that the Final Summative Analysis will provide sufficient data elements to apply this methodological approach more successfully.

When performing the analysis, the evaluation followed the instructions in the *Technical Specifications Manual*. There are some instances where modifications were made to expand the use of the procedure codes available in the claims data, to wit:

- The AOD Medication Treatment Value Set for MOUD does not contain two methadone-related codes, (J1230 and 80358) and three buprenorphine-related codes (J2310, J0592, and 80348). Therefore, we added five additional procedure codes when retrieving records.
- For OUD-related questions, we modified the methodologies to be specific to the OUD population.
- For ED-related questions, we made minor changes to the definition of the denominator. We defined the numerator as the number of beneficiaries who were diagnosed and used SUD (OUD) services within 30 days and as the number of beneficiaries who were diagnosed in an outpatient setting and used SUD (OUD) services in an outpatient setting within 30 days.
- Claims data were used to count the number of performing providers and billing providers. When counting the methadone providers, procedure codes H0020, H0033, S0109, J1230 were used.

We were not able to identify “counties of greatest need” using established methods.

To assess the number of providers at IMDs, data were provided by DMS from the MPPA Partner Portal. This use of claims data was not practical owing to the previously discussed billing provider vs performing provider issues.

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when the number of cases dropped significantly and have remained at essentially those same low levels through the remainder of the reporting period.

D.6.3 Qualitative Data Analysis

An applied thematic analysis technique (Clarke & Braun, 2017; Guest, MacQueen, and Namey, 2012), was used as part of the main analytical approach. Guest et al. (2012) referred to this technique as used for "solving practical problems" (p. 11) by the "bounding of the analysis" (p. 35.). Thematic analysis as a flexible non-research design well suited to this evaluation.

Applied themes were chosen deductively (*a priori),* which were primarily gleaned from this Project's Mid-Term Assessment. These *a priori* themes were then used to develop a codebook for thematic analysis. Inter-rater analysis was conducted with a Kappa coefficient value of 0.94 (k=.94), which suggests a very good agreement between the raters (McHugh, 2012; O'Connor & Joffe, 2020), attesting to the robust coding leading to the qualitative results.

The Batch 1 data set was coded using NVivo software for qualitative data analysis. The major categories and applied themes used were based on the five *a priori* major categories that paralleled the evaluation goals: (1) Medicaid & Waivers, (2) Access to Provider Institutions, (3) Influence re: Treatment Provided, (4) Treatment Received, and (5) Quality of Life. Within each category are *a priori* themes (parent and child codes) that were used in coding the Batch 1 data set (Figures D.4.1, D.4.2, D.4.3, D.4.4, D.4.5 above represent these applied themes and codes). Results were integrated with the quantitative components of this report as applicable.

SECTION E. METHODOLOGICAL LIMITATIONS

An important limitation of this evaluation is the absence of a comparison group. This is due to the statewide nature of the SUD Demonstration and the lack of a comparable state not implementing similar SUD policies. The lack of a comparison group could generate bias in our estimate of the effect of the evaluation because we might be erroneously attributing changes in SUD-related outcomes to the Demonstration. We will attempt to minimize this bias by including a set of covariates when appropriate within the time series analysis, but there remains a chance of bias due to factors we are unable to include in our model. There are insufficient data available in the current set to undertake time-series multi-variate analysis allowing for control variables for this Interim Analysis.

A second limitation, specific to the cost analysis, is the potential heterogeneity in the quality of the financial measures in the MCO encounter data. CMS's experience has been that Medicaid MCOs vary in the quality and completeness of their reporting; consequently, inference of expenditure effects could be confounded because of variation in financial data quality across plans and over time. If there is a measurement error in the expenditure fields, standard errors will be inflated, and analyses may vary from the actual expenditure effects of the Demonstration.

Another limitation is the length of time of the evaluation period. The Kentucky waiver implementation started in July 2018; however, COVID-19 became endemic in March 2020. While a total of 21 months of waiver implementation data are available for analysis, this period is likely not sufficient to observe changes introduced by the waiver with COVID-19 serving as a potential confounding variable. It is expected that not all metrics included in the study will show a reliable trending direction.

Findings from this Interim Evaluation are tentative; we anticipate more longitudinal data availability and the ability to do reliable time series analysis for the Final Summative Report. Careful interpretation of findings is especially important because best practices for isolating Demonstration effects in the context of the pandemic are not settled; therefore, isolating Demonstration effects from other impacts may not be feasible for all data sources.

E.1. Special Interim-Specific Evaluation Limitations

The SUD population under study is complex and presents numerous challenges to researchers. These include medical complexity, comorbidities, and data-related issues (accuracy, reliability, and completeness). We note the following four evaluation limitations specific to this report.

1. It is possible that the provider-related data may be under-reported. The current provider enrollment portal does not capture SUD type. Anecdotal evidence suggests that a small number of SUD providers may perform over 50% of MOUD prescribing. Some providers are eligible to prescribe MOUD, but they are choosing not to.

2. Since the initiation of the qualitative study, there have been at least five sample replacements from the initial sample drawn from each of the quadrants due to provider and beneficiary non-participation. More importantly, following up on the case study

interviewees for T2, and T3 is proving to be challenging. While T1 interviews were conducted in a closed facility, the facilities were unable to provide support for the T2 interviews. When interviewing within a facility, there is perceived credibility to those approved by the providers/management to enter and conduct interviews or programming. The follow-up interviews were conducted outside of these facilities and therefore may be missing that perceived credibility. This situation will affect our case study design; however, despite the anticipated attrition of case study participants, the plan to include one-time interviews from each of the quadrants should still provide "representativeness" of the quadrant participants**.**

3. The MMPA was used to identify provider enrollment, facility-type, and provider affiliations. For the period under measurement the MPPA had several limitations due to an absence of regulatory reporting requirements and the build-out of the application. Consequently, data from the MPPA are insufficient to address some of the research questions for this Interim Evaluation. These limitations to the MPPA are summarized below:
    - Limitations to 7/01/2019: DMS is unable to determine whether specific residential programs were operating more than one residential program under the same Medicaid ID through April 1, 2020.
    - DMS undertook a baseline assessment in Spring 2019 to ascertain residential programs using licensure, enrollment information, and direct outreach to organizations. This assessment uses these data for the baseline years for residential/IMD facilities.
    - Limitations to MPPA Upgrade Effective 7/01/2019: State Plan Amendments, regulations and system upgrade allowed for greater data capture including bed counts. Principal limitations are the inability to distinguish IMD between and residential facilities; inability to determine if an organization is operating at more than one location under the same Medicaid ID.
    - Limitations to MPPA Upgrade Effective 4/1/20: Specific program and location information of specific licensure and certification are now being captured. Limitations include the inability to determine when the program/location was first enrolled, as all locations fall under the same billing contract with a single effective date; providers may not complete billing information specifying the location (if multiple) thus invalidating the use of claims data.
    - XDEA prescriber data limitations: The system was initially improperly configured so the prescriber's information was only captured if linking to a BH provider type. This may result in an undercounting of providers with the XDEA waiver.

4. An interrupted time series analysis is provided to assess the multiple policy interventions related to SUD during the period July 2017 to June 2022. The model represents these multiple interventions and relevant control variables to the best of our knowledge. This is only a preliminary analysis of time series data. Given multiple change points in our data, our analysis has a few limitations. First, while we identified three covariates for the

SUD service rate, it is possible there are other covariates that need to be controlled. Second, seasonality was not modeled in our analysis given the limitation of sample size. We will include seasonality in the Final Summative Report

~~5.~~ This Interim Evaluation Assessment is unable to report overdose deaths by Medicaid patients or overdose deaths by Medicaid patients by county. These data have not been supplied to the research team by the Kentucky Office of Vital Statistics. The expectation is that these data will be provided for the Final Evaluative Summary~~.~~

SECTION F. RESULTS

F.1 Introduction

The Interim Evaluation Report contains both quantitative and qualitative analyses. The quantitative analysis focuses on testing research questions using administrative (e.g., medical claims) data, while qualitative analysis explores themes, experiences, and outcomes using the provider and beneficiaries' interviews. We integrate the qualitative results with the quantitative below to provide a nuanced portrait of the impact that Kentucky's Medicaid 1115 SUD waiver has had on beneficiaries.

Note that analyses related to Evaluation Question #3: "Did rates of opioid-related overdose deaths decrease?" will be presented in the Final Summative Report, as the data related to overdose deaths and overdose deaths by county were not made available for this report.

F.2. Access to Care

We developed ten questions about access to care to address the provider capacity issues. Specific questions are designed to examine the trend in the number of enrolled providers, the number of MOUD providers, the number of billing providers, and the service capacity variation at the county level. For all the questions, the Interim Evaluation reports the results based on the data available to us. In the Final Summative Report, we will have a more extended period of data to perform a longitudinal analysis and identify patterns.

The two primary hypotheses that are addressed by the ten questions are:

H1a: The Demonstration will increase the ratio of outpatient Medicaid SUD providers overall, and those specifically offering MOUD and methadone as part of MOUD, to beneficiaries in areas of greatest need.

H1b: The Demonstration will increase the ratio of SUD providers offering residential treatment, especially IMDs, to beneficiaries.

F.2.1 Provider-Related Questions

Figure F.2.1.1 below lists the ten provider-related questions developed to test H1a and H1b.

Specific hypotheses were developed based upon the characteristics and activities of providers. These hypotheses are operationalized and analyzed below. Variables were developed from *Medicaid Section 1115 Substance Use Disorder Demonstrations: Technical Specifications for Monitoring Metrics, Version 4.0, September 2021* (*Technical Manual* #4) when applicable.[4] At

[4] Metrics related to providers in the technical manual version 4 are Metric #13 and Metric #14. We largely followed the steps outlined in the technical manual when producing Metric #13 and Metric #14. Additional filtering criteria were applied to answer our specific research questions shown in section F.2.2.1.

this point in the measurement cycle, there are insufficient data points to conduct interrupted time series analyses and tests of statistical significance. The Final Summative Report will provide sufficient data points to support statistical testing. Therefore, only longitudinal data are presented, and the analyses are based upon direct comparisons and trends.

8. **Figure F.2.1.1 Provider-Related Questions**

1. Does the number of providers billing for SUD treatment services increase after the waiver implementation?
2. Does the number of providers prescribing any MOUD increase after the waiver implementation?
3. Does the number of providers dispensing methadone increase after the waiver implementation?
4. Which counties have the increased number of providers billing for SUD treatment services after the waiver implementation?
5. Which counties have the increased number of providers prescribing any MOUD after the waiver implementation?
6. Which counties have the increased number of providers dispensing methadone after the waiver implementation?
7. Does the number of providers billing for residential treatment for SUD increase after the waiver implementation?
8. Does the number of IMD facilities billing for treatment for SUD increase after the waiver implementation?
9. Does the number of providers billing for residential treatment for SUD, by county, increase after the waiver implementation?
10. Does the number of IMD facilities billing for treatment for SUD, by county, increase after the waiver implementation?

F.2.2 Provider-Related Results

There are data sources limitations in counting the number of providers who offer SUD treatment and services. Provider counts on SUD treatment are complicated owing to variability in the administrative processes tied to reimbursements. Specifically, the performing provider, who is the individual personally delivering care to the patient, and the billing provider, who is the individual or organization billing Medicaid for the service and receives payment for the service rendered, are not same. Table F.2.2.1 indicates the number of the variety of providers associated with SUD treatment services in Kentucky from baseline year through 2022. The counts are

derived from a combination of claims data analysis and data from the MPPA. Coverage for methadone for SUD was not effective until 7/1/19, and methadone facilities were enrolled as they qualified for Medicaid reimbursement with this enrollment date used for the count.

15. **Table F.2.2.1 Provider Statistics**

Year	Performing Providers	XDEA Waiver Prescribers	Methadone Treatment Facilities
2017BY	9,467	270	N/A
2018BY	10,268	295	N/A
2019DY	10,681	320	18
2020DY	11,062	356	24
2021DY	11,660	411	32

Counts derived from Medicaid claims data

1. *Did the number of providers billing for SUD treatment services increase after the waiver implementation?*

Based upon an analysis of Medicaid claims data, the number of performing providers, as defined as any individual personally delivering SUD-related service, has increased from a baseline of 9,467 in 2017BY to 11,660 in 2021DY. This represents an increase of 23.2%. Thus, the number of performing providers did increase from 2017 to 2022.

Provider interviews suggested that being reimbursed at a higher rate because of ASAM accreditation, which is part of the Kentucky Medicaid 1115 Demonstration waiver, may have influenced the number of providers billing for SUD treatment. From providers: "3.5 is actually ASAM accredited, so we actually get paid a higher rate for Medicaid because we are an ASAM facility" and "The rate for our residential program is nice because we do have that accreditation."

2. *Did the number of providers prescribing MOUD increase after the waiver implementation?*

There is not a reliable way to measure specific MOUD prescribing providers through claims data owing to the centralized billing either through billing providers or multiple locations billing through a central facility. A proxy measure is the number of providers licensed with an XDEA designation, which was a waiver issued by the Department of Drug Enforcement (DEA) allowing the prescription of medications like buprenorphine.[5] The number of providers with the XDEA designation increased 76.4% from the 2017BY to the 2021DY.

Almost 40% of interviewees mentioned receiving or prescribing MOUD. From a beneficiary: "But this right here is the first time I've ever had buprenorphine prescribed though, or suboxone,

[5] Section 1262 of the Consolidated Appropriations Act, 2023 (also known as Omnibus bill), removes the federal requirement for practitioners to submit a Notice of Intent (have a waiver) to prescribe medications, like buprenorphine, for the treatment of opioid use disorder (OUD) effective January 12, 2023.

or whatever." From a provider: "We did have, you know, not as many clients on suboxone and Vivitrol, but now, you know, that's become a more common occurrence."

3. *Did the number of providers dispensing methadone increase after the waiver implementation?*

Methadone was not reimbursable, except for pain, by Kentucky Medicaid until July 1, 2019. A proxy measure of the number of methadone clinics are used for dispensing providers, defined here as an NTP. Under Kentucky law, only NTPs dispense methadone. The NTP count shown in Table F.2.2.1 is derived from the MPPA and represent an approximation of the number of providers trend owing to the administrative issues of billing versus prescribing providers and what anecdotal evidence indicates is a slow conversion from a client-paid service to billing an MCO. Thus, the number of licensed NTPs is used as the best approximation for trends in the number of providers dispensing methadone. The fact that the number of facilities started nearly doubled since the start of the waiver provides evidence that it is likely that the number of methadone prescribers have increased during the Demonstration.

There appears to be a clear preference for suboxone over methadone treatment across stakeholders as evidenced in the parallel interviews conducted with beneficiaries and providers. We note that only 26% (13/50) of beneficiaries interviewed received methadone; most commonly suboxone was mentioned as the medication received.

4. *Did each county have an increased number of providers' billing for SUD treatment services after the waiver implementation?*

Analysis at the county level provides specific challenges. Kentucky has 120 counties with the majority being rural. Many consist of a small geographic area and lack a medical office within that political boundary. As well, many patients seek care outside their home counties; some for convenience and others due to a lack appropriate service within their county. As a unit of analysis, counts at the country level therefore do not provide specific insight into efficacy of the Demonstration. A more appropriate unit of analysis are Kentucky Health Districts, which form the foundation for the geographic quadrants used for sampling in the qualitative analysis portion of this evaluation.

In addition, owing to the billing provider vs performing or prescribing provider confounds, Medicaid claims cannot be used to measure county-level data. Data from the MPPA are not available at the county level for this assessment. It is anticipated that for the Final Summative Report data will be available for provider counts at the Health District level which can then be overlaid on counties.

5. *Did each county have an increased number of providers prescribing any MOUD after the waiver implementation?*

As discussed in Question #4, owing to the billing provider vs performing or prescribing provider confounds, Medicaid claims cannot be used to measure this question. Data from the portal are not available at the county level for this assessment. It is anticipated that for the Final Summative

Report data will be available for provider counts at the Health District level which will be overlaid on the county data.

6. *Did each county have an increased number of providers dispensing methadone after the waiver implementation?*

As described in the discussion of Question #4, owing to the uncertainty of billing provider vs performing/ prescribing provider and centralized geographic billing Medicaid claims cannot be used to reliably measure this question. As identified by the MPPA, licensed methadone treatment facilities may be used as a proxy for the location of providers dispensing methadone. Table F.2.2.2 summarizes the timeline of the introduction of facilities, the counties served, the geographic quadrant, and the population within the county.

16**. Table F.2.2.2 Counties and Populations Served by Methadone Treatment Facilities**

Year	County	Quadrant	New Facilities	Population
2019DY	Boyd	Southeast	2	19,956
	Christian	Southwest	1	73,955
	Daviess	Southwest	1	96,656
	Fayette	Central	1	295,803
	Jefferson	North	2	741,096
	Johnson	Southeast	1	23,356
	Kenton	North	3	159,720
	Laurel	Southeast	1	58,849
	Madison	Central	1	82,916
	McCracken	Southwest	1	65,565
	Perry	Southeast	1	28,712
	Pike	Southeast	1	65,024
	Pulaski	Southwest	1	63,063
	Shelby	North	1	42,074
	Running Total		**18**	**1,816,745**
2020DY	Franklin	Central	1	49,285
	Hardin	North	1	105,543
	Jefferson	North	2	*
	Madison	Central	1	*
	Warren	Southwest	1	113,792
	Running Total		**24**	**2,085,365**
2021DY	Bourbon	Central	1	19,985
	Boone	North	2	*
	Jefferson	North	2	*
	Jessamine	Central	1	*
	Kenton	North	1	*
	Running Total		**32**	**2,105,350**

As depicted in the Table F2.2.2, methadone treatment facilities are located in the more populous counties. A total of 22 of 120 counties in Kentucky or 18.3% have a methadone treatment facility. The populations in these counties represent 46.7% of the total population of Kentucky.

The geographic dispersion of the facilities is relatively even by location of county. There are six in the central quadrant, eight in the north, six in the southeast, and five in the southeast.

Medicaid reimbursement for methadone was not available until the 7/01/19, which coincided with the initial phase of the Demonstration. Thus, all methadone treatment facilities were opened after the implementation of the waiver.

7. *Did the number of providers billing for residential treatment for SUD increase after the waiver implementation?*

As described in the limitations in Section E.1, owing to an absence of specific regulations, DMS requirements, and MPPA technical capabilities, DMS was unable to capture bed counts by facility, which prevents distinguishing residential facilities from IMDs. In addition, DMS was unable to determine whether an entity was operating more than one residential program prior to April 1, 2020. Thus, a residential facility that operated in multiple locations was not required to report location specific information if it used centralized licensing and billing. Consequently, it is not possible to differentiate between a single residential or IMD facility and multiple facilities operating under a single Medicaid ID. They also were not required to provide provider counts.

In April 2020 new regulations and a technological upgrade allowed for increased reporting requirements, including bed counts. While now providing a location and bed count, data identifying the date of first enrollment are still not available. In addition, individual billing providers are associated with a specific location only if they provide optional information in the claim. Therefore, the number of facilities billing for treatment cannot be reliably determined and the number of licensed facilities cannot be derived from claims data. Consequently, this evaluation must use proxy measures of patient encounters and billing data to ascertain trends through the analyses #8 below and trends in Medicaid reimbursement expenditures.

8. *Did the number of IMD facilities billing for treatment for SUD increase after the waiver implementation?*

As described in the limitations in Section E.1, claims data do not provide a reliable measure of facilities due to centralized billing across multiple locations. Also, the other potential source of data, the DMS MPPA has additional limitations. Regulation did initially require specific information concerning residential facilities and the application not allow for the distinction between residential and IMD facilities (e.g., bed count >15) until April 2020.

The data in Table F.2.2 are from two sources, baseline year measures are from licensure information and outreach undertaken by DMS to establish counts of residential services and residential facility counts are ascertained from MPPA data. The effective enrollment data of some facilities with multiple locations may be brought forward in this analysis as all locations falling under one billing contract were assigned the initial enrollment date for the contract. This issue was addressed in a 9/1/22 MPPA upgrade.

Even with these data limitations, trends are clear that IMD facilities increased during the Demonstration years. New facilities introduced during the Demonstration all consisted of 16 or more beds and therefore were IMDs. There is also evidence in the claims data that several residential facilities began billing as IMDs during the Demonstration.

17**. Table F.2.2.3: Residential, IMD, and Narcotic Treatment Program Facility Count**

Year	Residential & IMD Facilities	IMD Facilities (Beds>15)	Methadone Treatment Facilities
2018BY	75	N/A	N/A
2019DY	115	N/A	18
2020DY	123	N/A	24
2021DY	142	119	32

Counts derived from Kentucky Medicaid Partners Portal Application (MPPA)

Based upon adjudicated claims, payments made to residential and IMD facilities increased 94% between 2017BY to 2021DY to more than $194 million as depicted in Table F.6.2.2 in a following section. This increase parallels the near doubling of facilities depicted in the table.

1. *Did the number of providers billing for residential treatment for SUD by county increase after the waiver implementation?*

As discussed in the responses to Research Questions #4 and #7, there are inadequate data to provide an independent evaluation of this question based upon the data reported to the state and available to the evaluation team.

In sum, relative to provider availability and access to care, the results show overwhelmingly positive trends. While we cannot determine whether particular counties have experienced increased provider availability and access, nor whether have they increased treatment options, it is clear that, overall, beneficiaries now have greater access to providers and care, as reflected in use trends.

F.3 Service Utilization

We developed seven questions about utilization of services to address beneficiary SUD/OUD needs. Specific questions are designed to examine the trend in the number of diagnosed beneficiaries, the types of services they utilize, and the use of MOUD. .

The two primary hypotheses that are addressed by the seven questions are:

H1c: The Demonstration will increase the utilization of SUD/OUD services.

H1d: The Demonstration will decrease the rate of ED visits and inpatient admissions within the beneficiary population for SUD/OUD.

F.3.1 Service-Related Questions

Figure F.3.1.1 below lists the seven service-related questions developed to test H1c and H1d.

9. **Figure F.3.1.1 Service Utilization Questions**

1. Does the number of beneficiaries with a new SUD diagnosis or newly initiated SUD-related service increase after the waiver implementation?
2. Does the number of beneficiaries with an SUD diagnosis who used outpatient services for SUD increase after the waiver implementation?
3. Does the number of beneficiaries with an SUD diagnosis who used residential treatment services for SUD increase after the waiver implementation?
4. Does the number of beneficiaries with an OUD diagnosis who used MOUD increase after the waiver implementation?
5. Does the number of beneficiaries with an OUD diagnosis who received methadone as part of MOUD increase after the waiver implementation?
6. Does the number of beneficiaries with continuous pharmacotherapy for OUD increase after the waiver implementation?
7. Does the number of beneficiaries with an SUD diagnosis who used SUD services at IMD facility increase after the waiver implementation?

F.3.2. SUD Service Utilization Results

Specific hypotheses were developed based upon the characteristics and activities of beneficiaries. These hypotheses are operationalized and analyzed below. Variables were developed from *Technical Manual* #4 when applicable. Data to evaluate question #6, which concerns continuous pharmacotherapy, will not be available until the Summative Report. Table F.3.2.1 provides a summary of the counts of beneficiaries accessing care.

18**. Table F.3.2.1 Access to Care: SUD-Diagnosed Individuals**

Year	Number of beneficiaries with an SUD diagnosis who used outpatient services	Number of beneficiaries with an SUD diagnosis who used residential/ IMD treatment services	Number of beneficiaries with an OUD diagnosis who used MOUD	Number of beneficiaries with an OUD diagnosis with a claim for methadone reimbursement
2017BY	72,167	13,333	33,074	N/A
2018BY	81,516	16,748	38,722	N/A
2019DY	85,479	19,185	43,506	3,148
2020DY	90,976	21,408	48,647	7,487
2021DY	96,457	22,600	51,080	8,884

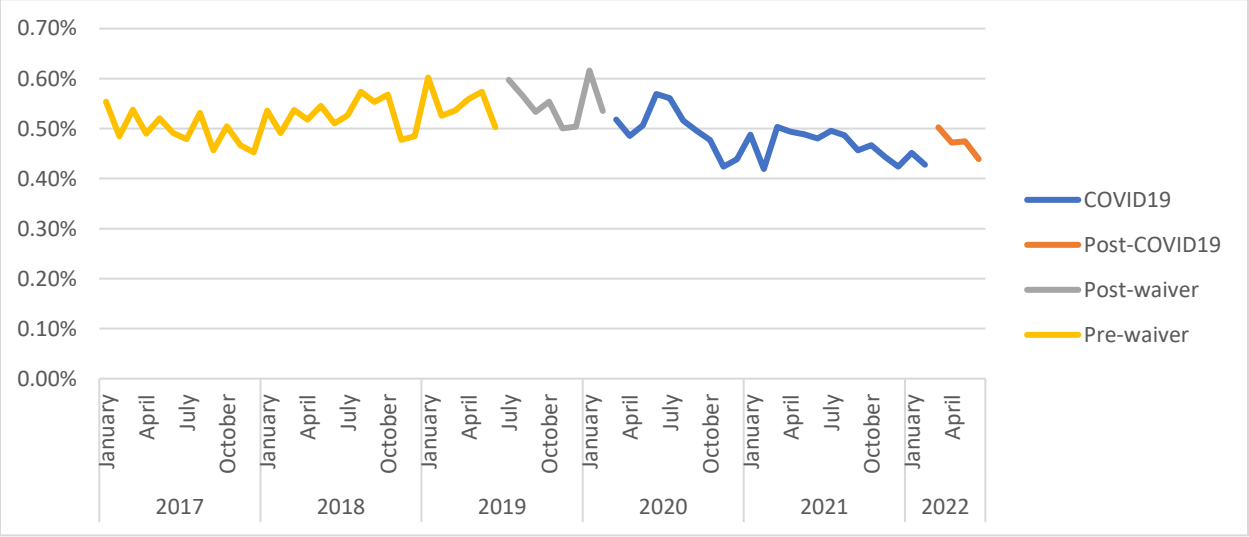
Source: Metric #9, Metric #10, Metric #12, Metric #11 (modified), respectively

1. *Did the number of beneficiaries with a new SUD diagnosis or newly initiated SUD-related services increase after the waiver implementation?*

There has been an overall increase over the years for number of beneficiaries with a new SUD diagnosis or newly initiated SUD service, but on a percentage basis of the Medicaid population, the rate of new SUD diagnosis and treatment has been flat. For normalization, Figure F.3.2.1 below depicts the number of beneficiaries with a new SUD diagnosis or who initiated treatment for the first time as a percentage of the Medicaid beneficiary population. Because access to Medicaid was relaxed during the initial COVID-19 period, variance in the denominator is to be expected. Figure F.3.2.2 breaks out the data into four periods: Pre-Waiver, Post-Waiver, COVID-19, and post-COVID-19. There appears to be increased initiation of SUD services that coincides with the initiation of the waiver, but with the shutdown from the pandemic, these gains were almost immediately lost.

We also note that only 28.0% (14/50) of beneficiaries in treatment who were interviewed as part of this evaluation project had a new SUD diagnosis. Over 70% (36/50) had had this diagnosis for some time. These figures are in alignment with those above for number of persons receiving treatment as compared to those who were newly diagnosed/in treatment.

10. **Figure F.3.2.1 Percentage of Total Beneficiaries with New SUD Diagnosis/ Treatment**



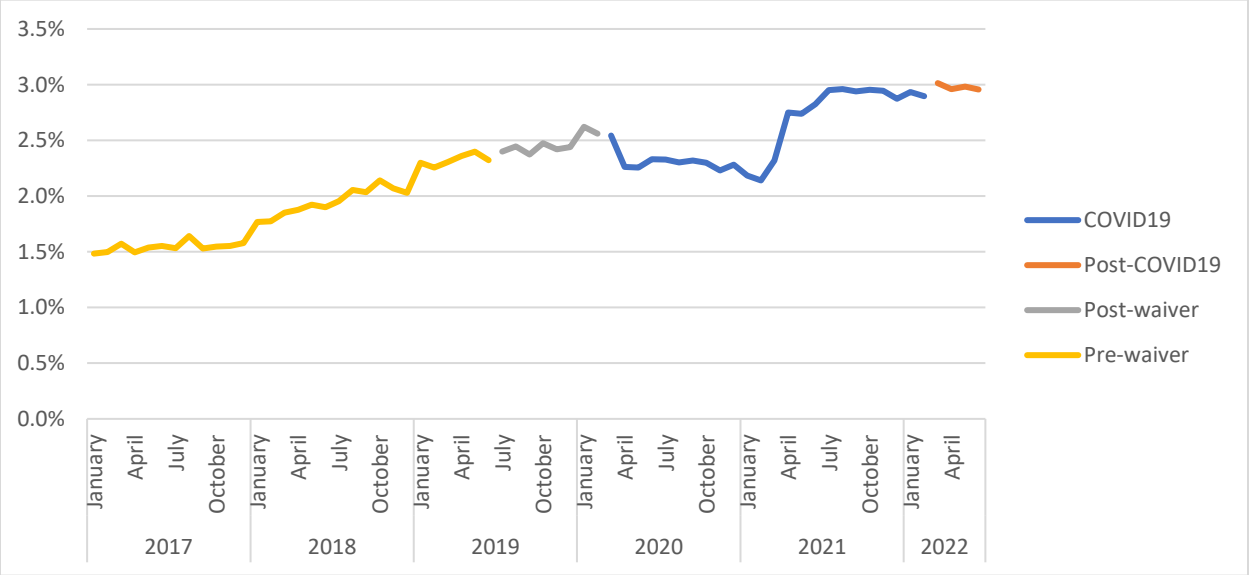
Numerator: Monthly count of beneficiaries with new SUD diagnosis during the monthly measurement period but not in the three months before the measurement month (Metric #2)
Denominator: Monthly count of all Medicaid beneficiaries

2. *Did the number of beneficiaries with an SUD diagnosis who used non-ED outpatient services for SUD increase after the waiver implementation?*

There has been an overall increase across 2017-2022 for outpatient SUD services, from 72,167 beneficiaries to 96,457, or a 33.7% increase. Figure F.3.2.2 below shows the SUD diagnoses rate trends pre-waiver, post-waiver, during COVID-19, and post-COVID between 2017 and 2021. There was a steady increase starting in the pre-waiver period, and it continued at the beginning of the post-waiver period. But with the onset of COVID, in March 2020, there was a downturn

that reversed starting in January of 2021 and continued through 2022. Relative to the beneficiary population, the rate of those receiving outpatient services has increased.

11. **Figure F.3.2.2 Non-ED Outpatient Service Use for SUD as a Percentage of Total Beneficiaries**



Numerator: Monthly count of beneficiaries with SUD diagnosis who used non-ED outpatient SUD services (Metric #8)
Denominator: Monthly count of all Medicaid beneficiaries

There has been an overall increase across 2017-2022 for outpatient SUD services, from 72,167 beneficiaries to 96,457, or a 33.7% increase. Figure F.3.2.2 above shows the SUD diagnoses rate trends pre-waiver, post-waiver, during COVID-19, and post-COVID between 2017 and 2021. There was a steady increase starting in the pre-waiver period, and it continued at the beginning of the post-waiver period. But with the onset of COVID, in March 2020, there was a downturn that reversed starting in January of 2021 and continued through 2022. Relative to the beneficiary population, the rate of those receiving outpatient services has increased.

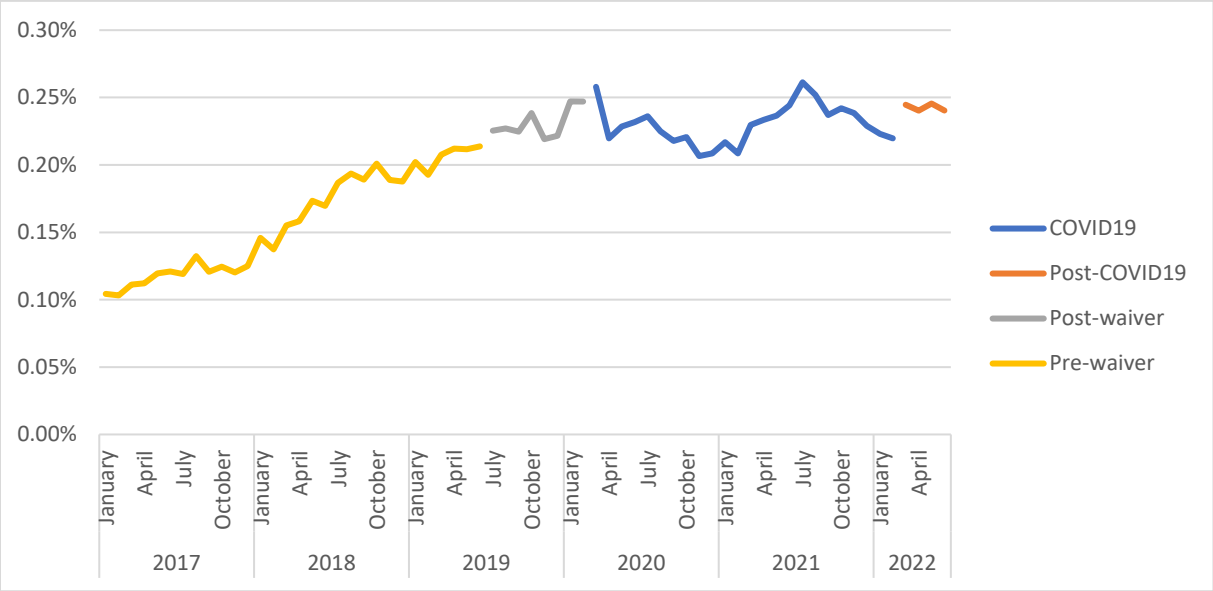
Providers are clearly working to transition beneficiaries to outpatient care. As a provider for the Southeast Quadrant commented, "If they start at a 3.5, we'll work to transition them down through the levels of care as they get better…..We're looking weekly….And so we just continue to assess them and see where they need to be and work them down through the process."

3. *Did the number of beneficiaries with an SUD diagnosis who used residential treatment services for SUD increase after the waiver implementation?*

As depicted in Table F.3.2.1 above, the number of individuals with a primary SUD diagnosis using residential services increased from 13,333 to 22,600 from 2017 to 2021, an increase of 69.5 %. We note that in our interviews all but one of the 50 beneficiaries used SUD services through an IMD. Almost a third (64%) of those were referred to IMDs by a court or through the Department of Corrections. (The remainder were referred by family, friends, social workers, or themselves.) Over half of those referred were in the Northern Quadrant.

Figure F.3.2.3 below controls for the changes in the number of Medicaid beneficiaries by showing the proportion using residential services as a percentage of the total number of beneficiaries. The results show an overall increase from January 2017 to June 2022 in a month-by-month comparison. The timeframe between August and December 2019 outperforms all other periods in a month-by-month comparison. Then, rates sharply decreased in March and April 2020, right at the start of the pandemic, but rebounded in early 2022.

12. **Figure F.3.2.3 Beneficiaries with SUD Diagnosis Using IMD/Residential Services as a Percentage of all Beneficiaries**



Numerator: Monthly count of beneficiaries with SUD diagnoses using IMD/residential services (Metric #10)
Denominator: Monthly count of all Medicaid beneficiaries

4. *Did the number of beneficiaries with an OUD diagnosis who used MOUD increase after waiver implementation?*

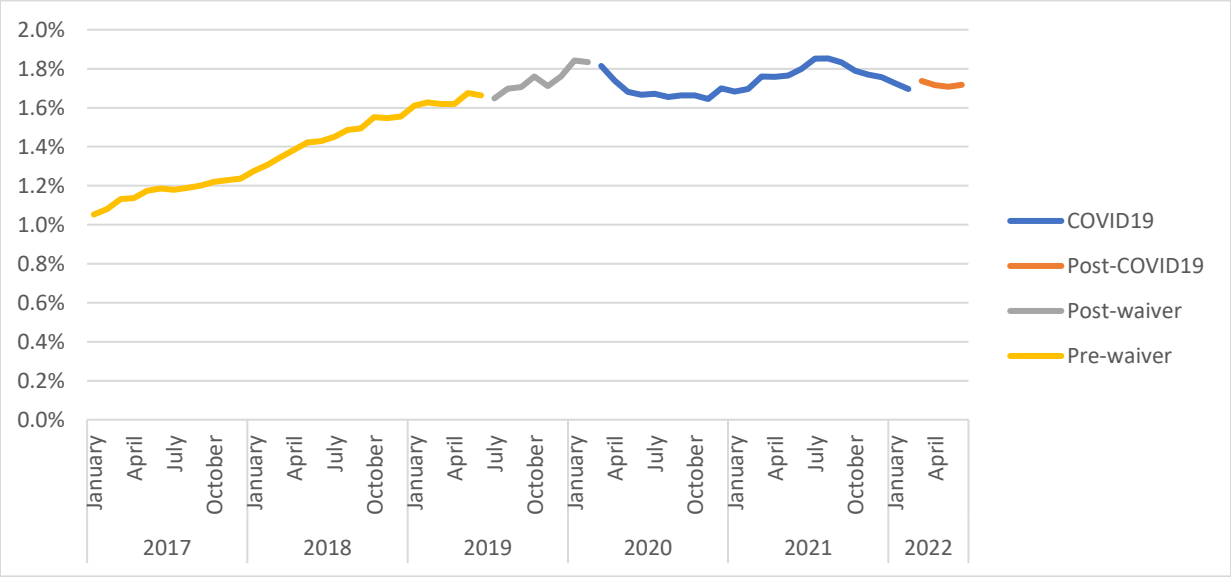
As depicted in Table F.3.1.1 above, the number of individuals with a primary OUD diagnosis who used MOUD increased from 33,074 to 51,080 from 2017 to 2021, an increase of about 54.4%.

Figure F.3.2.4 below controls for the changes in the number of Medicaid beneficiaries by showing the proportion of beneficiaries diagnosed with OUD using MOUD as a percentage of the total number of beneficiaries. It shows a relative increase in medication for OUD from 2017 to 2021. There is an overall increase in the rate during post-waiver, with a slight decrease in utilization from March through November 2020, again corresponding to the advent of COVID-19 in the region, and then a trend recovery in December 2020, with continued fluctuation through June 2022.

Those on MOUD expressed a belief that taking Suboxone or buprenorphine would be a part of their lives for the foreseeable future: "…I might be on Suboxone for the rest of my life" (a beneficiary from the Central Quadrant); "I've took them [referring to Suboxone and

buprenorphine], and not in the matter or sense of recovering or coming off" (beneficiary from the Southeast Quadrant). Some stop MOUD on their own, without medical supervision: "I've done Suboxone when I was here [before], and then I just quit taking it" (a beneficiary from the Southwest Quadrant).

13. **Figure F.3.2.4 Percentage of Total Medicaid Beneficiaries Using MOUD**



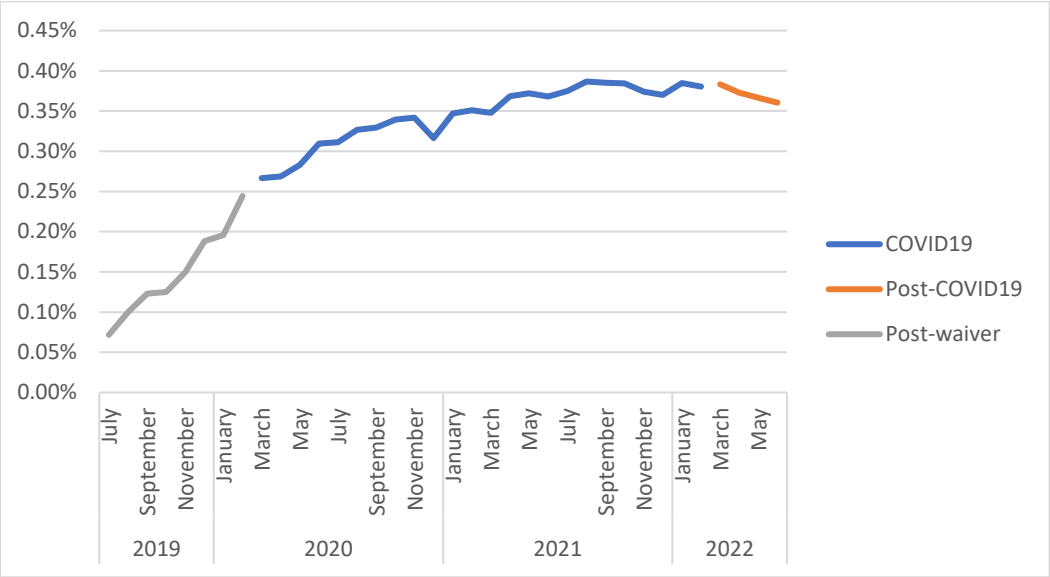
Numerator: Monthly count of beneficiaries with OUD diagnoses who used MOUD (Metric #12)
Denominator: Monthly count of all Medicaid beneficiaries

5. *Did the number of beneficiaries with an OUD diagnosis who received reimbursement for methadone increase after waiver implementation?*

As depicted in Table F.3.2.1 above, the number of individuals with a primary OUD diagnosis who received reimbursement for methadone increased from 5,576 to 9,096 from 2018DY to 2021DY. The year 2019 represents only 6 months of data, due to the timing of the start of Medicaid covering methadone treatments. Some treatment facilities may have been slow to convert to Medicaid reimbursement requiring direct payments by patients. This suggests that the number of beneficiaries receiving treatment may be greater than indicated in the table.

Figure F.3.2.5 below controls for the changes in the number of Medicaid beneficiaries by showing the proportion of beneficiaries diagnosed with OUD getting reimbursed for methadone as a percentage of the total number of beneficiaries. It shows a steady increase in the percentage of beneficiaries who accessed methadone through November 2020 and then a slight downturn.

14. **Figure F.3.2.5 Beneficiaries with OUD Diagnosis and a Claim for Methadone as a Percentage of Total Beneficiaries**



Numerator: Monthly count of beneficiaries with OUD Diagnoses with a methadone claim
Denominator: Monthly count of all Medicaid beneficiaries

F.4 Hospital Utilization

We developed two questions about utilization of hospitals to address beneficiary SUD/OUD needs. The questions are designed to examine the trends in the usage of the ED for SUD-related services and in hospital readmission rates.

For both questions, the Interim Evaluation reports the results based on the data available to us. In the Final Summative Report, we will have a more extended period of data to perform a longitudinal analysis and identify patterns.

The two primary hypotheses that are addressed by the two questions are:

H2a: Among beneficiaries receiving care for SUD, the Demonstration will decrease the rate of ED visits for SUD

H2b: Among beneficiaries receiving care for SUD, the Demonstration will reduce hospital readmissions for SUD care.

Figure F.4.1 below lists the two hospital utilizations questions developed to test H2a and H2b.

15. **Figure F.4.1 Hospitalization Utilization Questions**

1. Does the rate of ED visits for SUD-related diagnoses decrease after the waiver implementation?
2. Does the rate of hospital admissions for SUD-related diagnoses decrease after waiver implementation?

F.4.1. Hospital Utilization Results

Specific hypotheses were developed based upon the characteristics and activities of beneficiaries. These hypotheses are operationalized and analyzed below. Variables were developed from *Technical Manual* #4 when applicable. At this point in the measurement cycle, there are insufficient data points to conduct interrupted time series analyses and tests of statistical significance. The Final Summative Report will provide sufficient data points to support statistical testing. Therefore, only longitudinal data are presented, and the analyses are based upon direct comparisons and trends.

19. **Table F.4.1.1 Hospital Utilization: SUD-Diagnosed Beneficiaries**

Year	Number of ED visits for an SUD-related diagnosis	Number ED visits with a primary SUD diagnosis with SUD service follow-up within 30 days	Number of hospital admissions with an SUD diagnosis
2017BY	73,492	26,776	31,339
2018BY	85,231	27,846	35,680
2019DY	82,525	28,294	36,507
2020DY	88,831	30,612	41,478
2021DY	75,143	27,014	36,279

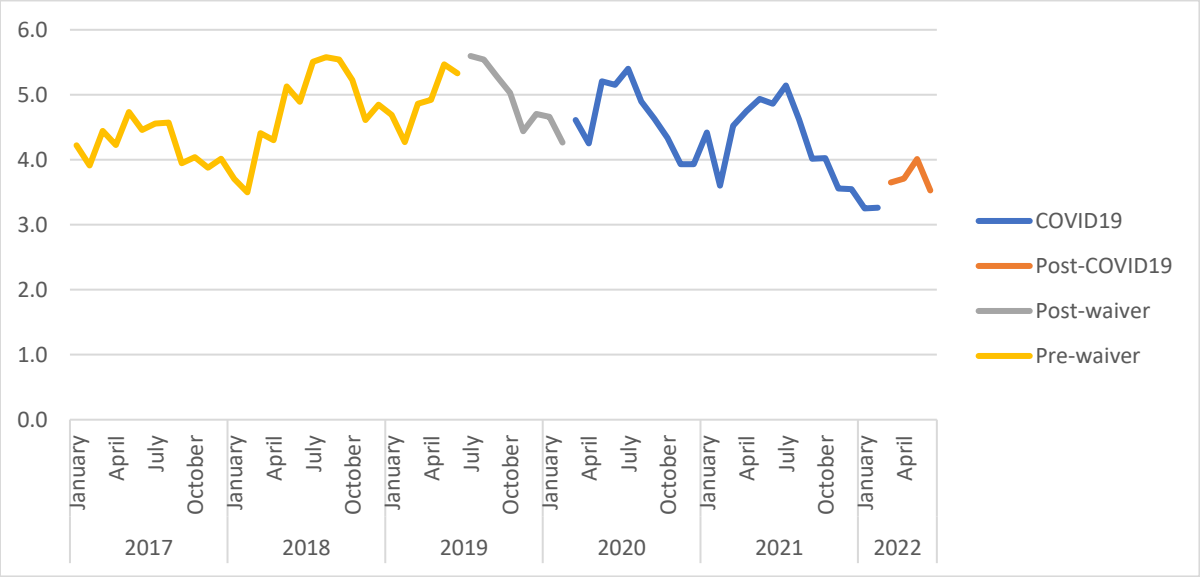
Source: Administrative Claims

1. *Did the rate of ED visits for SUD-related diagnoses decrease after the waiver implementation?*

As depicted in Table F.4.1.1 above, the number of ED visits for an SUD-related diagnosis did decrease from 85,231 in 2017BY to 75,143 in 2021DY. This is a decrease of 8.9% over the 3 years of the Demonstration and compares to non-COVID-19 effected years. This improvement in trend was an expectation of expanding services under the waiver.

There appears to be a seasonality associated with ED visits for beneficiaries with SUD-related diagnoses as shown below in Figure F.4.1.1. ED visits per 1,000 beneficiaries with an SUD diagnosis increased in the first half of the year and then decreased in the second. This pattern continued post-waiver and through the start of the pandemic. However, visits decreased in greater numbers from July to December in 2020, as compared to 2018 and 2019. This is not the case in comparison with July to December of 2017, but we note that there has been a steady increase in the total number of beneficiaries with an SUD diagnosis over the past four years, which could account for the lack of decrease in ED usage relative to 2017.

16. **Figure F.4.1.1 ED Visits for SUD per 1,000 Medicaid Beneficiaries**



Numerator: Monthly count of emergency department visits by beneficiaries for SUD-related Diagnoses
Denominator: Monthly count of all Medicaid beneficiaries
Normalization: Quotient *1000 (Metric #23)

Half of the beneficiaries interviewed (25/50) in the qualitative portion of the study had been to the ED for SUD-related reasons, often more than once: "A lot of times I did go to the emergency room, I was hurt because I was hurt. And so, it's happening and, you know, addicts, they're like, Oh, well, we'll get pills, so it'll be OK. It's got all this started" (a beneficiary from the Central Quadrant); "I've overdosed before. I used to shoot up, so I've had abscesses" (a beneficiary from the Northern Quadrant).

Table F.4.1.2 below provides an analysis for beneficiaries with a primary SUD diagnosis seeking follow-up services after an ED visit. The rate for both 30 and 7-day follow-up showed slight improvement during the Demonstration period when compared to the 2018 baseline, but a decline when compared to the 2017 baseline. The trend is unclear and will be revisited in the Final Summative Report.

20**. Table F.4.1.2 Adult SUD Follow-up After ED Visit with Primary Diagnosis SUD**

Year	Beneficiaries with ED Visit	30 Day	7 Day	30 Day Rate	7 Day Rate
2017BY	10,213	2,408	1,567	23.6%	15.3%
2018BY	9,478	1,726	985	18.2%	10.4%
2019DY	9,514	1,756	975	18.5%	10.2%
2020DY	10,032	1,952	1,197	19.5%	11.9%
2021DY	10,767	2,097	1,261	19.5%	11.7%

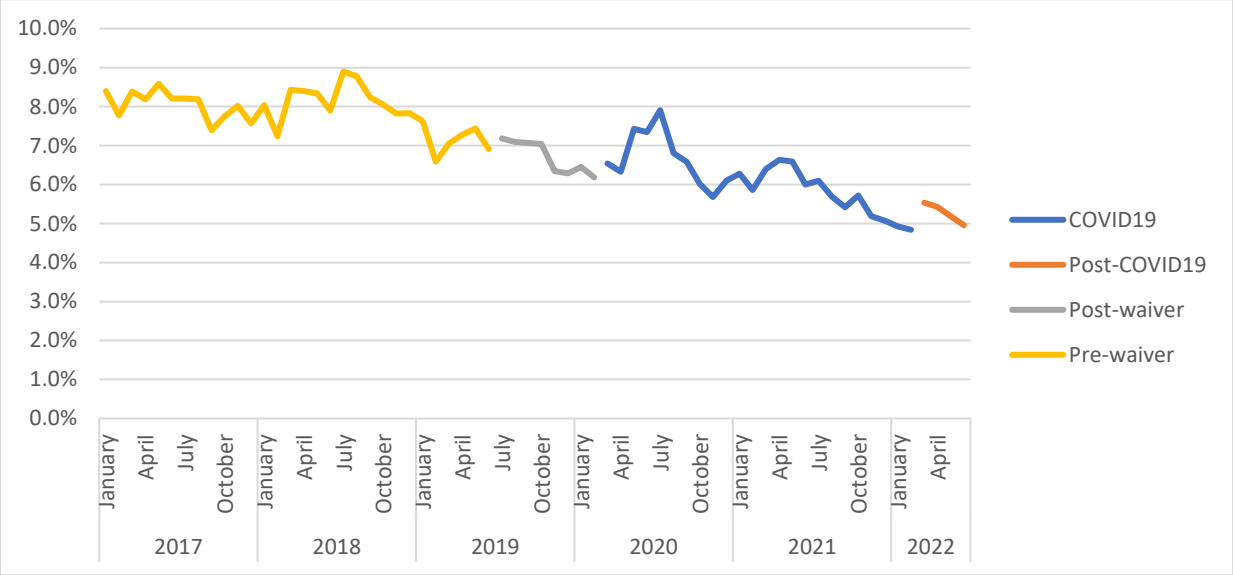
Computation: Metric #17

2. *Did the rate of hospital admissions for SUD-related diagnoses decrease after the waiver implementation?*

As shown in Figure F.4.1.3 below, the rate of admissions varies during the measurement period but shows a decline by June 2022 when compared to the rate at the initiation of the Demonstration. There is an increase in the rate of inpatient admissions from 2017 through the start of the waiver, then admissions fell slightly, but there was a surge of inpatient admissions between April to July 2020, at the start of the pandemic, followed by a relatively rapid decrease that is below the rate at the start of the waiver by June of 2022.

As depicted in Table F.4.1.1 above, the number of hospital admissions for SUD-related diagnoses increased from 31,339 to 36,279 from 2017 to 2021, an increase of 13.6%.

17. **Figure F.4.1.2 ED Visits with Inpatient Admission for Beneficiaries with SUD**



Numerator: Monthly count of inpatient admissions in conjunction with an ED visit for beneficiaries with an SUD diagnosis

Denominator: Monthly count of beneficiaries with an SUD diagnosis and ED visit

21. **Table F.4.1.4 30-Day Hospital Readmission Rates for Beneficiaries with SUD or OUD**

Year	SUD Readmissions	SUD Rate of Readmission	OUD Readmissions	OUD Rate of Readmission	Combined Readmissions	Combined Rate
2017BY	3,335	14.36%	896	9.90%	4,231	13.07%
2018BY	4,375	16.48%	1,129	11.27%	5,504	15.05%
2019DY	4,677	17.88%	1,186	11.98%	5,863	16.26%
2020DY	5,671	17.51%	1,352	11.97%	7,023	16.08%
2021DY	4,789	15.20%	1,175	11.79%	5,964	14.38%

Computation: Metric #25

The 30-day hospital readmission rates for beneficiaries with a diagnosis of SUD or OUD followed the patterns for ED use and hospital utilization relative to an increase during the initial two years of the Demonstration which are associated with the COVID pandemic followed by a decline in 2021 DY. The combined rate of readmission is in-line with the control years of 2017DY and 2018DY. With these confounded and limited data, it is not possible to ascertain at this time if there is a decrease of 30-Day readmissions under the Demonstration as hypothesized in this assessment.

F.5 Changes in Beneficiary Quality of Life: Improved Physical and Mental Health

We developed seven questions about improvement of physical and mental health to address beneficiary SUD/OUD needs. Specific questions are designed to examine the trend in the self-reported past 6-month health, self-reported past 30-day poor physical and mental health, self-reported self-help activities, and self-reported continued substance misuse. For all the questions, the Interim Evaluation reports the results based on the data available to us. In the Final Summative Report, we will have a more extended period of data over which to perform a time series analysis.

The primary hypothesis that is addressed by the seven questions is:

H2c: The Demonstration will improve the physical and mental health for beneficiaries receiving SUD care.

Figure F.5.1 below lists the seven health-related questions developed to test H2c.

18. **Figure F.5.1 Physical and Mental Health Questions**

1. **Did beneficiaries with an SUD diagnosis report improved health over the past 6 months?**
2. **Did beneficiaries with an SUD diagnosis report fewer poor physical health over the past 30 days?**
3. **Did beneficiaries with an SUD diagnosis report fewer poor mental health over the past 30 days?**
4. **Did beneficiaries with an SUD diagnosis report attending self-help group meetings in the past 30 days?**
5. **Did beneficiaries with an SUD diagnosis report use of opiates or opioids in the past 6 months, 12 months, or 30 days?**
6. **Did beneficiaries with an SUD diagnosis report use of heroin in the past 6 months, 12 months, or 30 days?**
7. **Did beneficiaries with an SUD diagnosis report continued substance use in the past 6 months, 12 months, or 30 days?**

The Department of Behavioral Health, Developmental and Intellectual Disabilities (DBHDID) in the Kentucky Cabinet for Health and Family Services utilizes University of Kentucky's Kentucky Treatment Outcome Survey (KTOS) and Kentucky Opiate Replacement Treatment

Outcome Survey (KORTOS) for analyzing outcomes data for publicly funded treatment programs. KTOS surveys program participants as they enter either outpatient or residential treatment and then after 12-months. KORTOS surveys program participants as they enter Kentucky licensed programs to treat OUD and then at the 6-month point after continuous program participation.
The major limitations of these surveys are the voluntary participation in the surveys, the 35%-40% attrition rates for Medicaid-insured respondents, extremely small sample sizes, and the use of self-reporting metrics, all of which may lead to selection/response bias, thus limiting the scope of inferences. Additionally, until 2022, persons who stopped engaging with treatment were excluded from follow-up interviews. Because of these limitations, evaluation of these measures should be viewed with caution. An additional limitation relative to this evaluation is the lag time between survey completion and final report.

As shown in Figure F.5.1 below, those participating in the survey showed improvement in all quality-of-life metrics, except for arrest rates for the 2020 cohort in the KORTOS survey and full-time employment and ability to meet basic health needs in the 2021 KORTOS. These differences are not significant, however. The number of participants is extremely small in the continuing evaluation (e.g., 16 in 2021/2), so it is questionable whether the survey represents the population of those participating in OUD treatment. At the same time, while improvements are shown regarding life outcomes, approximately a third still suffer from depression, anxiety, or both a year after treatment; a quarter still experience chronic pain; over a third have difficulty meeting basic life needs; and a fifth have difficulty meeting basic health needs. At 12 months, two-fifths report some sort of justice involvement, and a third report continued illicit drug usage. KTOS surveys show a modest self-reported improvement in quality of life (from 7.0 to 7.7 on a 10-point scale), but again sample size is extremely small; KORTOS indicated self-reported improvements in quality of life.

There are no significant changes in outcomes pre-waiver to post-waiver.

22. **Table F.5.1 KORTOS and KTOS Survey Results**

KTOS				
% Participants Reporting	**Intake 2018**	**Follow-up 2019**	**Intake 2020**	**Follow-up 2020**
depression	**56**	**33**	**54**	**33**
anxiety	**54**	**29**	**55**	**30**
co-morbid	**44**	**21**	**42**	**20**
suicidal ideation	**20**	**9**	**20**	**9**
chronic pain	**33**	**27**	**36**	**26**
#poor physical health days past 30 days	**7**	**4**	**6**	**4**
#poor mental health days past 30 days	**13**	**6**	**13**	**6**
self-reported good health	**17**	**41**	**21**	**38**
employed FT	**23**	**39**	**25**	**43**
homeless	**29**	**7**	**29**	**7**
difficulty meeting basic living needs	**46**	**31**	**46**	**34**
difficulty meeting basic health needs	**26**	**19**	**28**	**21**
arrested	**62**	**26**	**52**	**26**
incarcerated	**66**	**31**	**65**	**28**

under supervision	45	40	46	39
illicit drug use	89	33	91	31
opioid drug use	44	10	42	8
heroin usage	17	4	16	6
participation in mutual support group	34	49	35	48

KORTOS						
% Participants Reporting	**Intake 2018**	**Continuing 2019**	**Intake 2020**	**Continuing 2020/1**	**Intake 2021**	**Continuing 2021/2**
depression	71	28	67	14	44	19
anxiety	78	35	71	19	44	33
co-morbid	65	20	67	10	20	13
suicidal ideation	18	4	15	0	6	0
chronic pain	54	35	48	19	69	50
#poor physical health days past 30 days	14	8	5	2	8	3
#poor mental health days past 30 days	18	8	13	4	10	5
self-reported good health	9	39	24	43	0	44
employed FT	34	47	38	43	21	19
homeless	25	9	29	7	6	13
difficulty meeting basic living needs	54	35	48	48	69	44
difficulty meeting basic health needs	35	24	48	29	25	31
arrested	17	7	5	10	13	13
illicit drug use	96	37	100	62	100	38
opioid drug use	73	11	52	5	88	19
heroin usage	66	13	71	38	50	19

For the most part, these data dovetail with our qualitative interview results. Depression and anxiety were often mentioned: “I was definitely depressed when I was using, and I was definitely struggling with life in general,” and “That’s why one of the main things they’re focused on with me is like finding ways to cope and deal with, like them, trauma issues and certain things without drugs, because that’s what I’ve always used to call my anxiety …[and] my depression. So, it would make me feel better.”

Housing insecurity was also mentioned: “My grandparents kicked me out because of substance use and stuff, and I had a pretty rough time at one point there and I’ll bet I lived in the woods for about a month.”

Similarly, justice-involvement appeared common: “When I was using, I was committing a lot of crimes and ended up in jail quite a bit because of my drug use, really, because I was doing bad things to get money for drugs are just all kind of different things that got me in trouble.”

However, meeting basic needs appeared to be less of a challenge for our respondents: “So, it’s changed my life completely. I didn’t have a life before. I didn’t have clothes or shoes, or I didn’t have a lot of things that I have now. Now I have my own home. I have two vehicles; I have a family, you know; I’m pretty well-established,” and, “I sort of feel like I’m completely independent. I still feel like it’s a work in progress, but it’s this place is getting a lot of tools and

a lot of things. I needed to learn to move forward in the process and actually feel like I can be successful and actually do IT. So … [treatment] has made a difference."

F.6. SUD/OUD-Related Expenditures

We developed three questions about Medicaid SUD expenditures to address the Demonstration's impact on funding. Specific questions are designed to examine the trend in expenditures relative to total cost, SUD vs. OUD, IMD vs. non-IMD, and by each primary SUD expenditure source. For all the questions, the Interim Evaluation reports the results based on the data available to us. In the Final Summative Report, we will have a more extended period of data to perform a longitudinal analysis and identify patterns.

The three primary hypotheses that are addressed by the three questions are:

F1a: The Demonstration will decrease the total SUD/OUD expenditures.

F1b: The Demonstration will decrease SUD/OUD and non-SUD/OUD expenditures, with SUD/OUD expenditures disaggregated into IMD and non-IMD expenditures.

F1c: The Demonstration will decrease expenditures disaggregated by source of treatment—namely, inpatient expenditures, emergency department (ED) expenditures, non-ED outpatient expenditures, and pharmacy expenditures.

Figure F.6.1.1 below lists the three expenditure-related questions developed to test F1a, F1b, and F1c.

19**. Figure F.6.1. Expenditure Analyses**

1. **Did the Demonstration decrease the total SUD/OUD expenditures?**
2. **Did the Demonstration decrease SUD and OUD expenditures, with SUD/OUD expenditures disaggregated into IMD and non-IMD expenditures?**
3. **Did the Demonstration decrease expenditures disaggregated by source of treatment—namely, inpatient expenditures, emergency department (ED) expenditures, non-ED outpatient expenditures, and pharmacy expenditures?**

These questions are addressed below subject to the data limitations described. Overall, a pattern emerged across all categories for an increase in expenditures during 2020DY (ending 6/30/21) which was associated with the disruption of the health system by the COVID-19 pandemic. Key findings concerning the Demonstration are:

- Non-ED outpatient costs decreased for beneficiaries with an OUD diagnosis and the rate of growth in per capita outpatient expenses slowed for beneficiaries with a SUD diagnosis.

- ED visits, ED expenditures, and per capita ED costs decreased in 2021DY for both SUD and OUD diagnosed beneficiaries.
- There appears to be a trend of slowing in the rate of growth for most expenses and in some cases appears to be near the rate of healthcare inflation.

F.6.1 Expenditures Results

As described in Appendix C of the *SMI/SED Evaluation Design Guidance* document, capitated contracts, such as those covering more than 90% of the beneficiaries in Kentucky, provide a challenge to measuring costs. As recommended by the guidance, calculating total costs appears to be the most accurate and feasible approach to calculating the dollars per member per month (PMPM) metric. More granular approaches such as assigning costs based upon the FFS schedule and shadow pricing could also be considered. However, the availability of appropriate data and disclosure constraints exist owing to terms of the MCO contracts. This Interim Assessment uses total costs derived from claims data to calculate OUD/SUD payments and member counts to establish rates.

1. *Did the Demonstration decrease total SUD/OUD expenditures?*

Table F.6.1.1 below provides a summary of total SUD-related expenditures and the cost amortized over the total Medicaid population. SUD costs per member increased each of the years. The increase between the 2018BY (6/30/19) and 2021DY (6/30/22) was an increase of 59.2%. The rate of increase was slower in 2021DY compared to 2020DY.

23**. Table F.6.1.1 Total SUD Expenditures Per Total Beneficiary Population**

Year	Total ($)	Per Capita Cost of SUD Services Per Beneficiary	Percent Increase in Per Capita Costs Compared to Previous Year
2017BY	$415,216,288	$219.88	-
2018BY	470,822,039	249.88	14.0%
2019DY	544,224,739	280.26	12.2%
2020DY	753,280,318	362.53	29.4%
2021DY	802,873,322	397.94	9.8%

Numerator: Total SUD expenditures (Metric #28)
Denominator: Total number of Medicaid beneficiaries

SUD expenditures took a substantial jump during 2020, which corresponds to the COVID-19 pandemic and the initiation of programs associated with this waiver. The rate of change has significantly slowed in DY2021.This parallels the general findings of this assessment, that there was an increase during the initial introduction of the Demonstration that also corresponds to the start of the pandemic.

Table F.6.1.2 below provides an assessment of SUD expenditures analyzed within the context of the number of beneficiaries with an SUD diagnosis. Per-capita spending had a substantial increase during the 2020 Demonstration Year (ending 6/30/21), paralleling the encounter and treatment measures. The per capita increase appears to be an adjustment owing to an increase in

services covered during the initial post-Covid-19 period. The increase for the 2021DY (ending 6/30/22) Demonstration year shows an increase in line with the Baseline Years. We note that these costs are not inflation-adjusted.

24**. Table F.6.1.2 Aggregate and per Capita SUD Expenditures**

Year	Number of Diagnosed Beneficiaries	SUD Expenditures ($)	Per Capita SUD Spending ($)	Per Capita Percent Increase from Previous Year
BY2017	102,729	415,216,288	$4,042	-
BY2018	111,358	470,822,040	4,228	4.60%
DY2019	116,760	544,224,739	4,661	10.24%
DY2020	128,942	753,280,318	5,842	25.34%
DY2021	130,907	802,873,322	6,133	4.98%

Numerator: SUD Expenditures (Metric #28)
Denominator: Number of beneficiaries with an SUD diagnosis-annual (Metric #4)

There is no evidence of decreasing expenditures for SUD through 2021DY, but the rate of increase in spending may be declining.

2. *Did the Demonstration decrease SUD and OUD expenditures, with SUD/OUD expenditures disaggregated into IMD and non-IMD expenditures?*

Residential and IMD facility expenditures substantially increased. This is directly associated with the Demonstration waiver and the expansion of IMDs and reimbursable services. Also per capita expenditures increased for IMD and residential services during the evaluation period as shown in Table F.6.1.3. This increase appears associated with an increase in reimbursable service as well as general healthcare inflation.

25**. Table F.6.1.3 Aggregate and Per Capita IMD/Residential Expenditures**

Year	Beneficiaries IMD or Residential Services	Total IMD or Residential Expenditures	Per Capita Expenditures Beneficiaries Using IMD or Residential Services	Per Capita Increase from Previous Year	Per Capita Cost for Total Beneficiary Population
2017BY	12,902	N/A[6]	-	-	-
2018BY	15,957	102,019,134	6,393.38	134.3%	54.15
2019DY	17,679	125,042,578	7,072.94	10.6%	64.39
2020DY	19,106	175,225,405	9,171.22	29.7%	84.33
2021DY	20,811	194,202,980	9,331.75	1.8%	96.25

Numerator: IMD expenditures (Metric #29)
Denominator: Number of beneficiaries with a claim for a residential or IMD stay (Metric#10)

[6] DMS did not cover SUD residential stays in an IMD until January 2018. Therefore, data for the full 2017BY are unavailable.

IMD expenditures reflect the change in reimbursement and licensing policies associated with the Demonstration. Residential facility and new facility expansion resulted in an increase in the number of IMDs with an associated increase in spending. This began in anticipation and during the earliest months of the Demonstration during 2018BY (ending June 30, 2019) and continued in the following years. Of note is the rate of increase of per patient expenditures declined during 2021DY and the actual real increase would be negative if adjusted for inflation.

Table F.6.1.4 summarizes the non-IMD expenditures for beneficiaries with a SUD during the baseline and Demonstration years. These non-IMD costs parallel the IMD costs including the increase during 2020DY and the substantial decline in 2021DY.

26. **Table F.6.1.4 Non-IMD Expenditures for Beneficiaries with a SUD Diagnosis**

Year	Number of SUD Diagnosed Beneficiaries	Non-IMD SUD Expenditures	Non-IMD SUD Expenditures as a Percent of SUD Expenditures	Per Capita non-IMD SUD Costs	Per Capita Percent Increase from Previous Year
2017 BY	102,729	NA	-	-	-
2018BY	111,358	$368,802,905	73.3%	$3,312	-
2019DY	116,760	419,182,161	77.0%	3,593	8.5%
2020DY	128,942	578,054,913	76.7%	4,483	24.8%
2021DY	130,907	608,670,342	75.8%	4,650	3.7%

Numerator: The sum of non-IMD expenditures for beneficiaries with an SUD diagnosis (Metric #28, Metric #29)

Denominator: Number of beneficiaries with an SUD diagnosis (Metric #4)

As discussed in the data limitations, it was not possible to differentiate residential facilities from IMDs from claims data, and the MPPA was unable to provide the bed count differentiator until mid-2020. As described in Section F2.2, the number of residential and IMD facilities nearly doubled from the baseline to the last Demonstration year, with more than 90% of them IMD facilities. The rate of increase for per patient costs appears to be slowing, but if the costs ae amortized over the entire beneficiary population, IMD and Residential expenditures ae nearly doubled as the number of beneficiaries treated at IMDs increases.

3. *Did the Demonstration will decrease expenditures disaggregated by source of treatment—namely, inpatient expenditures, emergency department (ED) expenditures, non-ED outpatient expenditures, and pharmacy expenditures?*

Each of the expenditure categories are assessed below. Common to all are variances during 2020DY (ending 6/30/21), the period associated with the pandemic emergency. Most of the categories showed increased spending with an amelioration of the rate of growth during the post-COVID-19 Demonstration year. Both ED and non-ED outpatient spending for beneficiaries with an OUD diagnosis showed a per capita cost decline in the last Demonstration year when compared to the last baseline year.

Non-ED Outpatient: As indicated in Table 6.1.5, non-ED outpatient expenditures decreased during 2020DY, a period associated with the COVID-19 pandemic, then increased for 2021DY. This increase reflects the cumulative effect for beneficiaries with newly initiated treatments for OUD and SUD over the period, increased range of reimbursable services provided from both within and outside of the Demonstration, increased follow-up and engagement with beneficiaries, and overall healthcare cost trends.

Outpatient expenditures decreased during 2020DY, which paralleled healthcare in general during this pandemic emergency period. For the period between the 2018BY and 2021DY, per capita expenditures were up only 9.2% for the three-year period. This is a decrease in the rate of growth compared to the baseline years and below the rate of healthcare inflation. This slowing of the rate of growth could be associated with the Demonstration.

27**. Table F.6.1.5 SUD Non-ED Outpatient Expenditures**

Year	Beneficiaries with an SUD Diagnosis with non-ED Outpatient Claims	Total SUD Outpatient Expenditures	Per Capita Expenditures for Beneficiaries with a SUD Diagnosis with non-ED Outpatient Encounters	Per Capita Percent Increase from Previous Year
2017BY	72,167	$41,008,390	$568.24	_
2018BY	81,516	54,934,174	673.91	18.6%
2019DY	85,479	61,697,814	721.79	7.1%
2020DY	90,976	59,174,584	650.34	(9.9%)
2021DY	96,457	71,029,160	736.38	13.2%

Numerator: Expenditures for outpatient services excluding ED expenses for beneficiaries with an SUD diagnosis (Metric #8)
Denominator: Beneficiaries with an SUD diagnosis using non-ED outpatient services (Metric #8)

As indicated in Table 6.1.6, the per capita spending for OUD patients was lower for both the 2020DY and 2021DY for OUD diagnosed beneficiaries than the 2018BY. This is a predicted result of the Demonstration.

28**. Table F.6.1.6 OUD Non-ED Outpatient Expenditures**

Year	Beneficiaries with an OUD Diagnosis	Total OUD Outpatient Expenditures	Per Capita Expenditures	Per Capita Percent Increase from Previous Year
2017BY	42,757	$30,471,870	$712.68	_
2018BY	48,298	42,372,221	877.31	23.1%
2019DY	52,914	48,545,370	917.44	4.6%
2020DY	59,138	46,328,249	783.39	(14.6%)
2021DY	61,811	52,825,238	854.63	9.1%

Numerator: Expenditures for outpatient services excluding ED expenses for beneficiaries with an OUD diagnosis (Metric #8)

Denominator: Beneficiaries with an OUD diagnosis using non-ED outpatient services (Metric #8)

Inpatient Expenditures: F.6.1.7 below indicates the SUD inpatient treatment expenditures for beneficiaries with an SUD diagnosis. Expenditures increased by more than 22% during 2020DY, which is associated with the pandemic. Expenses continue to build from that higher level in 2021DY, albeit at a much lower rate, and would be negative in real terms with adjustments for healthcare inflation.

29**. Table F.6.1.7 SUD Inpatient Expenditures**

Year	Beneficiaries Using Inpatient Services	Total SUD Inpatient Expenditures	Per Capita Expenditures	Per Capita Percent Increase from Previous Year
2017BY	13,333	$83,080,168	$6,231.17	_
2018BY	16,748	109,793,500	6,555.62	5.2%
2019DY	19,185	135,055,793	7,039.66	7.4%
2020DY	21,408	184,135,707	8,601.26	22.2%
2021DY	22,600	201,407,706	8,911.85	3.6%

Numerator: Expenditures for inpatient services for beneficiaries with an SUD diagnosis
Denominator: Beneficiaries with an SUD diagnosis using inpatient services

As shown in Table 6.1.8, Inpatient Expenditures for beneficiaries with OUD paralleled those with a SUD diagnosis. The OUD per capita expenditures were lower than those with SUD. This appears to be a continuation of a trend rather than being associated with the Demonstration.

30. **Table F.6.1.8 OUD Inpatient Expenditures**

Year	Beneficiaries Using Inpatient Services	Total SUD Inpatient Expenditures	Per Capita Expenditures	Per Capita Percent Increase from Previous Year
2017BY	6,340	$33,496,777	$5,283.40	_
2018BY	7,299	41,080,178	5,628.19	6.5%
2019DY	8,343	49,021,002.	5,875.70	4.4%
2020DY	9,203	65,601,290	7,128.25	21.3%
2021DY	9,298	68,931,328	7,413.57	4.0%

Numerator: Expenditures for inpatient services for beneficiaries with an OUD diagnosis
Denominator: Beneficiaries with an OUD diagnosis using inpatient services

Emergency Department Expenditures: As depicted in Table 6.1.9 below, ED SUD-related expenditures paralleled the trends in the beneficiary encounters previously discussed with an increase during 2020DY. Relative to the Demonstration, we note that the ED visits, ED expenditures, and per capita costs decreased in 2021DY for both SUD and OUD diagnosed beneficiaries as depicted in Table 6.1.9 and Table 6.1.10 respectively. The decline in ED visits and expenditures during the most recent Demonstration year could be associated with the impact of the Demonstration and increased beneficiary access to care.

31**. Table F.6.1.9 SUD Emergency Department Spending**

Year	Beneficiary Count	Total SUD ED Expenditures	Per Capita SUD ED User Expenditure[7]	Per Capita Percent Increase from Previous Year
2017BY	31,635	$15,512,963	$490.37	-
2018BY	36,103	19,563,979	541.89	10.5%
2019DY	34,190	21,949,774	641.99	18.5%
2020DY	36,803	25,493,557	692.70	7.9%
2021DY	32,926	21,861,543	663.96	(4.1%)

Numerator: Expenditures for emergency services for beneficiaries with an SUD diagnosis
Denominator: Beneficiaries with an SUD diagnosis using emergency services

As shown in Table F.6.1.10, the relative decline in per capita expenditures for OUD was not as substantial as for SUD but had parallel trends.

32**. Table F.6.1.10 OUD Emergency Department Spending**

Year	Beneficiary Count	Total OUD ED Expenditures	Per Capita OUD User Expenditure	Per Capita Percent Increase from Previous Year
2017BY	7,669	$2,774,133	$361.73	_
2018BY	9,164	3,718,384	405.76	12.1%
2019DY	8,614	3,938,986	457.28	12.7%
2020DY	9,354	4,757,648	508.62	11.2%
2021DY	8,145	4,075,804	500.41	(1.6%)

Numerator: Expenditures for ED services for beneficiaries with an OUD diagnosis
Denominator: Beneficiaries with an OUD diagnosis using inpatient services

F.7 Interrupted Time Series Analysis on SUD Service Utilization

Between 7/1/2017 and 6/30/2022, there were multiple policy interventions related to SUD. We, therefore, model the time series analysis as a single-group segmented regression with multiple intervention points. Below is the full model to represent the reality of multiple intervention periods and possible controls between 7/2017 – 6/2022 to the best of our knowledge.

Below is a segmented regression model with four change points.

$$Y_t = \beta_0 + \beta_1 * \text{time} + \beta_2 * \text{intervention1}_t + \beta_3 * \text{time after intervention1}_t + \beta_4 * \text{intervention2}$$

[7] This level of expenditures tracks with national averages for ED overdose encounters. Admitted patients are tracked under inpatient expenses. E.g., https://revcycleintelligence.com/news/opioid-overdose-care-totals-1.94b-in-annual-hospital-costs.

$+ \beta_5 * \text{time after intervention2}_t$
$+ \beta_6 * \text{intervention3}_t$
$+ \beta_7 * \text{time after intervention3}_t$
$+ \beta_8 * \text{intervention4}_t$
$+ \beta_9 * \text{time after intervention4}_t$
+ controls
$+ \epsilon_t$

T_{1t}: time period 1: DMS IMD Reimbursement
X_{1t}: first intervention: DMS IMD Reimbursement
X_{2t}: time period 2: 1115 SUD Waiver Demonstration
X_{3t}: time period 3: COVID19
X_{4t}: time period 4: Post-COVID19

Controls: per thousand rate of Medicaid beneficiaries with a mental illness diagnosis, per thousand rate of performing providers, Kentucky monthly employment rate

Measures

The outcome was the per thousand proportion of the Kentucky Medicaid population receiving any SUD services. The monthly per thousand Medicaid population of SUD service rate was used as the dependent/outcome variable in our models. The controls include the Kentucky monthly unemployment rate, the per thousand proportion of providers (1000*total number of providers/Medicaid beneficiary population) and the per thousand proportion of beneficiaries with a mental illness diagnosis (1000*total number of beneficiaries with a mental illness diagnosis and treatment/total number of Medicaid population).

Data Source

De-identified data were extracted via the Kentucky Adjudicated Claims Database between 7/1/2017 – 6/30/2022 following the steps outlined in the technical manual V4 on metric 6 (any SUD services). Metric 6 represents service utilization in the residential, inpatient, pharmacy, and outpatient. This metric includes all SUD service utilization. Based on the policies implemented related to SUD and data behavior, for this Interim report we are considering the following intervention points: 1/1/2018, 7/1/2019, 3/1/2020, and 3/1/2021.

F.7.1 Data Analysis

All data analyses were completed using Stata 17 and SPSS 28. The ITS was conducted by using the ITSA package. Significance is defined as a p-value less than 0.05.

Table 7.1.1 below provides descriptive statistics on measures used in the ITS analysis.

33**. Table F.7.1.1: Descriptive Statistics for ITS Variables**

Measures	N	Mean	Median	SD	Min	Max
Per 1000 Medicaid population SUD service rate	60	30.59	32.11	4.37	21.49	36.01
Per 1000 Medicaid population SUD provider rate	60	3.30	3.29	0.20	2.88	3.79
Per 1000 Medicaid population mental health provider rate	60	0.67	0.67	0.04	0.56	0.77
Per 1000 Medicaid population beneficiaries with mental illness diagnosis	60	1.26	1.27	0.10	1.05	1.51
Unemployment rate	60	4.74	4.20	1.91	3.70	16.50

Tables F.7.1.2 and F.7.1.3 below shows descriptive statistics for the measures at specific intervention points in time.

34**. Table F.7.1.2 Descriptive Statistics for ITS Variables at Intervention Points**

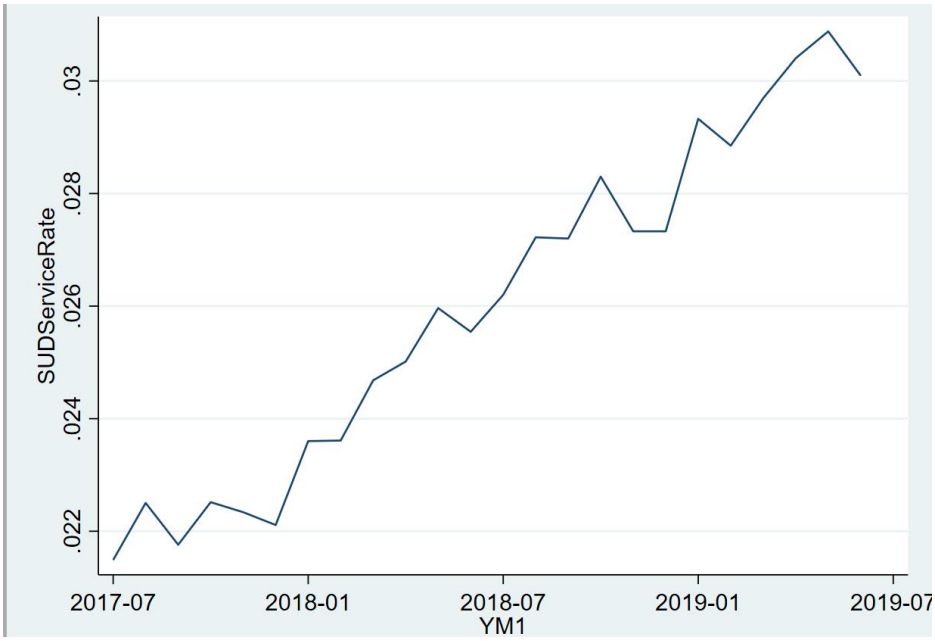
Measures	Periods	N	Mean	Std.dev	Deviation	95% CI	95% CI	Min	Max
Per 1000 population SUD service rate	7/1/2017 - 6/30-2019	24	26.00	3.02	0.62	24.72	27.28	21.49	30.88
	7/1/2019 - 2/29/2020	8	32.52	0.89	0.31	31.78	33.26	31.55	34.01
	3/1/2020 - 2/28/2021	12	32.57	0.59	0.17	32.20	32.94	31.68	34.03
	3/1/2021 - 6/30/2022	16	35.03	0.86	0.22	34.57	35.49	33.52	36.01
Per 1000 population SUD provider rate	7/1/2017 - 6/30-2019	24	3.23	0.20	0.04	3.14	3.31	2.88	3.59
	7/1/2019 - 2/29/2020	8	3.63	0.09	0.03	3.55	3.70	3.52	3.79
	3/1/2020 - 2/28/2021	12	3.22	0.15	0.04	3.12	3.31	2.99	3.57
	3/1/2021 - 6/30/2022	16	3.30	0.07	0.02	3.26	3.34	3.17	3.43
Per 1000 population mental health provider rate	7/1/2017 - 6/30-2019	24	0.67	0.04	0.01	0.65	0.68	0.56	0.73
	7/1/2019 - 2/29/2020	8	0.74	0.02	0.01	0.72	0.75	0.71	0.77
	3/1/2020 - 2/28/2021	12	0.67	0.02	0.01	0.66	0.69	0.63	0.72
	3/1/2021 - 6/30/2022	16	0.66	0.04	0.01	0.64	0.68	0.61	0.72
Per 1000 population rate for beneficiary with mental illness diagnosis	7/1/2017 - 6/30-2019	24	1.29	0.09	0.02	1.25	1.33	1.11	1.51
	7/1/2019 - 2/29/2020	8	1.36	0.04	0.02	1.33	1.40	1.32	1.44
	3/1/2020 - 2/28/2021	12	1.22	0.06	0.02	1.19	1.26	1.12	1.29
	3/1/2021 - 6/30/2022	16	1.17	0.10	0.02	1.12	1.23	1.05	1.35
Unemployment	7/1/2017 - 6/30-2019	Jul-19	24.00	4.27	0.20	0.04	4.19	4.36	4.10
	7/1/2019 - 2/29/2020	8	4.05	0.05	0.02	4.01	4.09	4.00	4.10
	3/1/2020 - 2/28/2021	12	6.54	3.85	1.11	4.10	8.99	4.10	16.50
	3/1/2021 - 6/30/2022	16	4.44	0.39	0.10	4.23	4.64	3.70	4.80

35**. Table F.7.1.3 Descriptive Statistics for ITS Variables Stratified by Intervention Points**

Measures	Periods	N	Mean	Std.	Std Error	95% CI		Min	Max
Per 1000 population SUD service rate	7/1/2017 - 12/31/2017	6	22.12	0.42	0.17	21.68	22.56	21.49	22.52
	1/1/2018 - 6/30/2019	18	27.29	2.29	0.54	26.15	28.43	23.60	30.88
	7/1/2019 - 2/29/2020	8	32.52	0.89	0.31	31.78	33.26	31.55	34.01
	3/1/2020 - 2/28/2021	12	32.57	0.59	0.17	32.20	32.94	31.68	34.03
	3/1/2021 - 9/30/2022	16	35.03	0.86	0.22	34.57	35.49	33.52	36.01
Per 1000 population SUD provider rate	7/1/2017 - 12/31/2017	6	2.98	0.08	0.03	2.90	3.07	2.88	3.12
	1/1/2018 - 6/30/2019	18	3.31	0.16	0.04	3.23	3.39	2.99	3.59
	7/1/2019 - 2/29/2020	8	3.63	0.09	0.03	3.55	3.70	3.52	3.79
	3/1/2020 - 2/28/2021	12	3.22	0.15	0.04	3.12	3.31	2.99	3.57
	3/1/2021 - 9/30/2022	16	3.30	0.07	0.02	3.26	3.34	3.17	3.43
Per 1000 population mental health provider rate	7/1/2017 - 12/31/2017	6	0.61	0.03	0.01	0.58	0.64	0.56	0.64
	1/1/2018 - 6/30/2019	18	0.68	0.03	0.01	0.67	0.70	0.63	0.73
	7/1/2019 - 2/29/2020	8	0.74	0.02	0.01	0.72	0.75	0.71	0.77
	3/1/2020 - 2/28/2021	12	0.67	0.02	0.01	0.66	0.69	0.63	0.72
	3/1/2021 - 9/30/2022	16	0.66	0.04	0.01	0.64	0.68	0.61	0.72
Per 1000 population rate for beneficiary with mental illness diagnosis	7/1/2017 - 12/31/2017	6	1.18	0.05	0.02	1.12	1.24	1.11	1.26
	1/1/2018 - 6/30/2019	18	1.33	0.07	0.02	1.29	1.36	1.24	1.51
	7/1/2019 - 2/29/2020	8	1.36	0.04	0.02	1.33	1.40	1.32	1.44
	3/1/2020 - 2/28/2021	12	1.22	0.06	0.02	1.19	1.26	1.12	1.29
	3/1/2021 - 9/30/2022	16	1.17	0.10	0.02	1.12	1.23	1.05	1.35
Unemployment	7/1/2017 - 12/31/2017	6	4.57	0.21	0.08	4.35	4.78	4.30	4.80
	1/1/2018 - 6/30/2019	18	4.17	0.05	0.01	4.15	4.20	4.10	4.20
	7/1/2019 - 2/29/2020	8	4.05	0.05	0.02	4.01	4.09	4.00	4.10
	3/1/2020 - 2/28/2021	12	6.54	3.85	1.11	4.10	8.99	4.10	16.50
	3/1/2021 - 9/30/2022	16	4.44	0.39	0.10	4.23	4.64	3.70	4.80

Figure 7.1.1 below displays an upward trend in the SUD service rate per thousand of Medicaid beneficiaries from 7/1/2017 – 6/30/2022. Based on the visual inspection, we conducted a Dfuller test to check the stationarity of our data. Dfuller test results in a p-value of 0.002, suggesting stationary data at level, lag 1.

20. **Figure F.7.1.1 SUD Service Rate per 1000 Medicaid Beneficiaries 7/1/2017 – 6/30/2022**



F.7.2 Pre-waiver Period 7/2017 -7/2019

Kentucky DMS implemented a new policy for SUD reimbursement for IMD starting January 2018. This policy could increase SUD service utilization. We conducted an ITS test using Stata with 1 lag. Figure F.7.2.1 below shows both the level change and slope change after the new policy was implemented. Table F.7.2.1 shows the Newey Test. All coefficients except time are statistically significant. The results confirm the positive impact of the Kentucky DMS IMD reimbursement intervention as both level and slope are positive and significant.

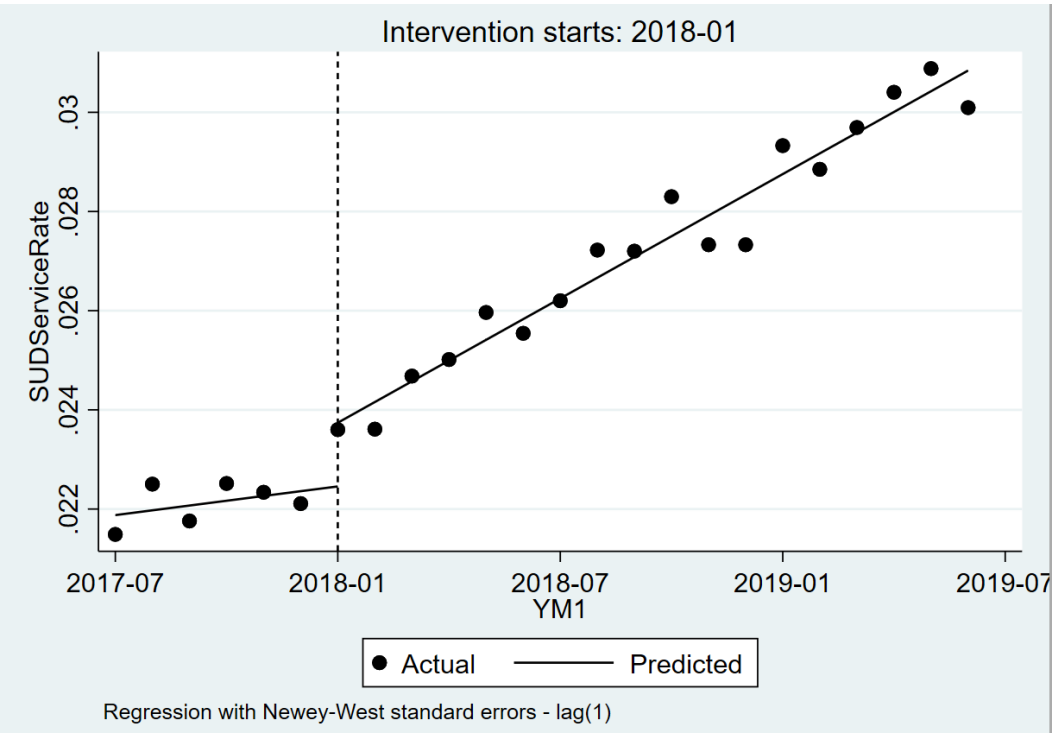
36**. Table F.7.2.1 Newey Coefficient Test IMD Waiver Intervention**

_SUDSR1000	**Coefficient**	**std.**	**P>|t|**	**95% CI**	
_t	0.10	0.07	0.18	-0.05	0.24
_x2018m1	1.33	0.35	0.00	0.58	2.08
_x_t2018m1	0.31	0.09	0.01	0.11	0.50
_cons	21.88	0.20	0.00	21.44	22.32
Post-intervention trend					
_b[_t]+_b[_x_t2018m1]	0.40	0.06	0.00	0.28	0.53

As shown in the regression table, the starting level of the per thousand population SUD service rate was estimated at 21.88, and the per thousand population SUD service rate appeared to increase slightly every month prior to Jan. 2018 by 0.10. However, the p value is not significant (p=0.18, CI=[−0.05, 0.23]). In the first year of the intervention (2018), there appeared to be a significant increase in per thousand population SUD service rate of 1.33 (p<0.0001, CI=[0.58, 2.08]), followed by a significant increase in the monthly trend of 0.31 per thousand population SUD service rate (relative to the pre-intervention trend) per month (p=0.01, CI =[0.11, 0.50]). We also see from the Post-intervention estimate that after the introduction of the SUD IMD

reimbursement policy, the per thousand population SUD service rate increased monthly at a rate of 0.4 (95% CI =[0.28, 0.53]). Figure F.7.2.1 provides a visual display of these results.

21. **Figure F.7.2.1 ITSA with Newey-West Standard Errors and one Lag**



To ensure that we fit a model that accounts for the correct autocorrelation structure, we used actest to test for autocorrelation (Baum and Schaffer 2013). Autocorrelation is not present at lags 1-6 with p values (0.21,0.54,0.89,0.28,0.91,0.88).

We further conducted a Prais–Winsten AR(1) regression. With one intervention variable, our model for the pre-waiver period resulted in 96.63% R square. With this background knowledge, we then proceeded to the model building using the entire time series available to us.

F.7.3. Period 7/2017-6/2022

Based on the pre-intervention analysis, we deemed it appropriate to treat January 2018, when Kentucky DMS implemented the IMD policy, as the first intervention for the evaluation period 7/2017-6/2022 for this Interim Report. We conducted ITS analyses using six models. The first three models do not treat January 2018 as an intervention point, whereas the last three models include January 2018 as an intervention point. Model 1 includes three intervention points with no controls; Model 2 includes Model 1 plus 1 control; Model 3 includes Model 2 plus 2 controls; Model 4 includes four intervention points with no controls; Model 5 includes Model 4 plus 1 control; Model 6 include Model 5 plus 2 controls. Model comparisons were conducted based on R square and residual analysis. We present the six models below.

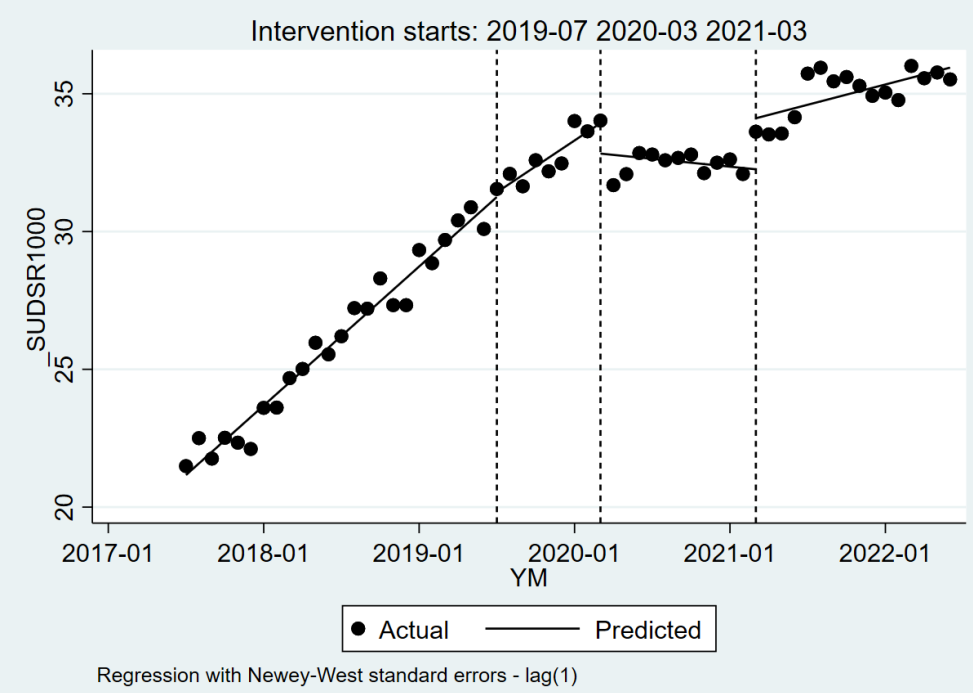
Model 1 (Three Intervention Points, No Controls): This model has three intervention points: 7/2019, 3/2020, and 3/2021. Table F.7.3.1 shows the Newey test. Among 11 estimated parameters, 9 were significant. The intervention point 7/2019 and the post-intervention slope

between 7/2019 and 3/2020 are not significant. R square is 97.8%. Figure F.7.3.1 provides a visual display of these results.

37. **Table F.7.3.1 Model 1: Three Intervention Points, No Controls**

_SUDSR1000	Coefficient	std.err	p	95% CI	
_t	0.42	0.02	0.00	0.38	0.46
_x2019m7	0.17	0.29	0.56	-0.42	0.76
_x_t2019m7	-0.11	0.05	0.05	-0.21	0.00
_x2020m3	-1.10	0.53	0.04	-2.17	-0.04
_x_t2020m3	-0.36	0.07	0.00	-0.51	-0.21
_x2021m3	1.85	0.51	0.00	0.83	2.87
_x_t2021m3	0.17	0.07	0.02	0.03	0.31
_cons	21.16	0.26	0.00	20.65	21.68
Post Intervention Trend					
_b[_t]+_b[_x_t2019m7]	0.31	0.05	0.00	0.21	0.41
_b[_t]+_b[_x_t2019m7]+_b[_x_t2020m3]	-0.05	0.05	0.39	-0.16	0.06
_b[_t]+_b[_x_t2019m7]+_b[_x_t2020m3]+_b[_x_t2021m3]	0.12	0.04	0.00	0.04	0.20

22. **Figure F.7.3.1 Model 1: ITSA with Newey-West Standard Errors and one lag**

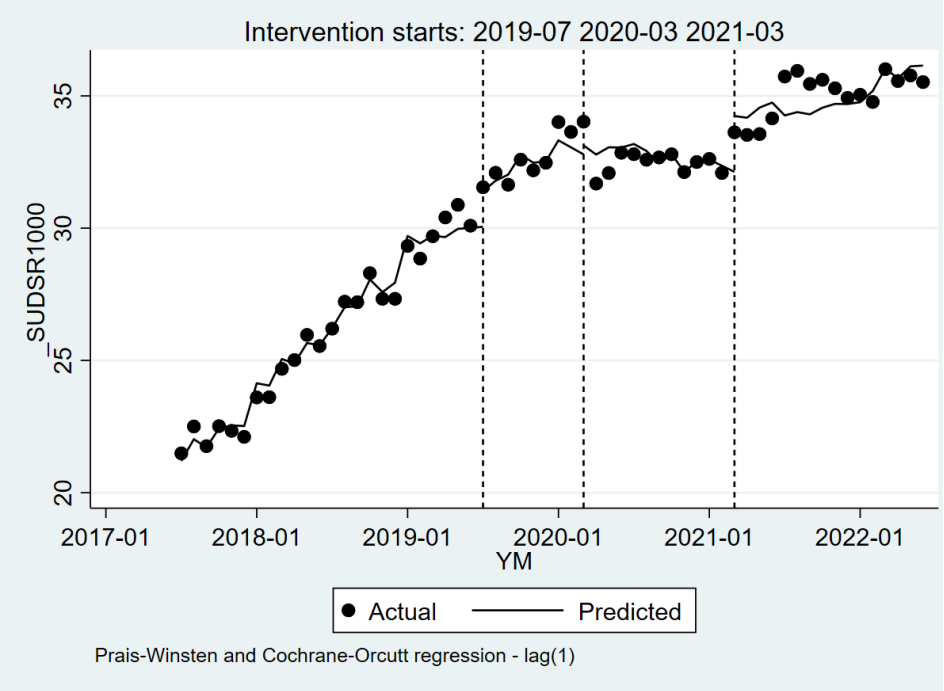


Model 2 (Three Intervention Points, One Control): This model has three intervention points: 7/2019, 3/2020, and 3/2021. The control variable used in the analysis is the per thousand rate of beneficiaries with a mental illness diagnosis. The Newey test is below in Table F.7.3.2. Prais–Winsten AR(1) regression with iterated estimates shows this model produced a R square of 94.02%. The post-intervention slope and intervention points are not significant between 7/2019 and 3/2020. The covariate is significant. Figure F.7.3.2 provides a visual display of these results.

38**. Table F.7.3.2 Model 2: Three Intervention Points, One Control**

_SUDSR1000	Coefficient	std.err	p	95% CI	
_t	0.39	0.02	0.00	0.35	0.44
_x2019m7	0.31	0.33	0.36	-0.36	0.97
_x_t2019m7	-0.09	0.06	0.14	-0.20	0.03
_x2020m3	-0.82	0.50	0.11	-1.83	0.18
_x_t2020m3	-0.32	0.08	0.00	-0.48	-0.15
_x2021m3	1.35	0.63	0.04	0.08	2.62
_x_t2021m3	0.19	0.07	0.01	0.04	0.33
PerMentalBenRatio1000	3.21	1.34	0.02	0.53	5.90
_cons	17.33	1.61	0	14.09	20.57
Post Intervention Trend					
_b[_t]+_b[_x_t2019m7]	0.31	0.05	0.00	0.20	0.42
_b[_t]+_b[_x_t2019m7]+_b[_x_t2020m3]	-0.01	0.06	0.86	-0.12	0.10
_b[_t]+_b[_x_t2019m7]+_b[_x_t2020m3]+_b[_x_t2021m3]	0.18	0.05	0.00	0.07	0.28

23. **Figure F.7.3.2 Model 2: 3 Intervention Points, 1 Control**

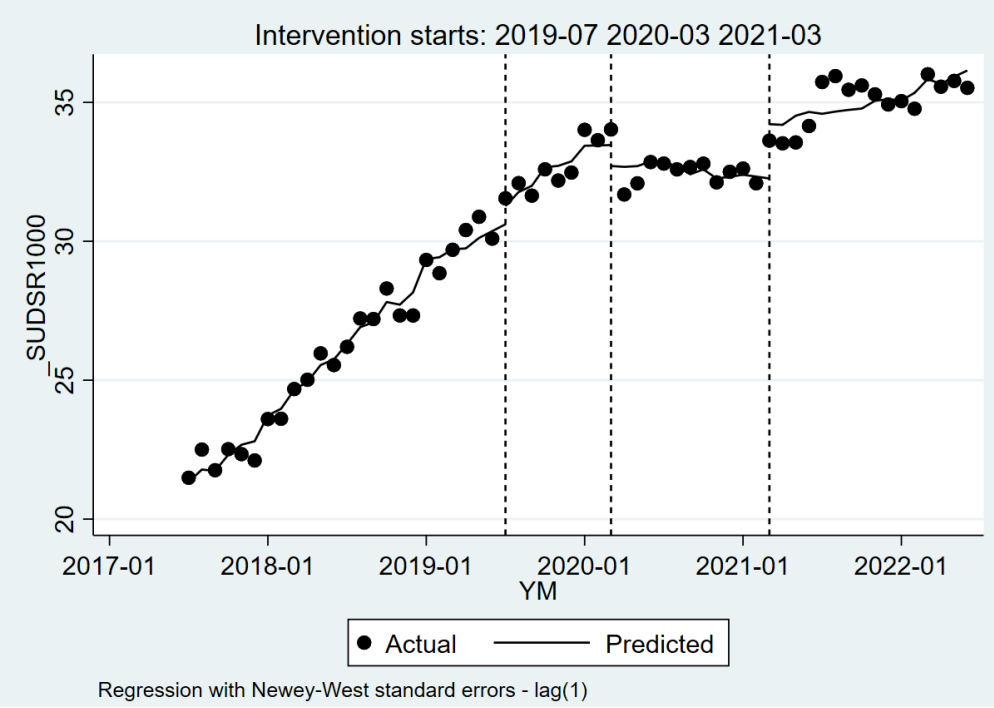


Model 3 (Three Intervention Points, Two Controls): This model has three intervention points: 7/2019, 3/2020, and 3/2021. The control variable used in the analysis is the per thousand rate of beneficiaries with a mental illness diagnosis. Prais–Winsten AR(1) regression with iterated estimates shows this model produced a R square of 94.19%. The control variables used in the analysis are the per thousand rate of beneficiaries with mental illness diagnosis I changed and per thousand population rate of mental health providers. Table F.7.3.3 shows the Newey test. Among 14 estimated parameters, 9 are significant. The parameters in the Covid period are not significant. Figure F.7.3.3 provides a visual display of these results.

39. Table F.7.3.3, Model 3: Three Intervention Points, Two Controls

_SUDSR1000	Coefficient	std.err	p	95% CI	
_t	0.41	0.03	0.00	0.35	0.46
_x2019m7	0.30	0.36	0.41	-0.43	1.03
_x_t2019m7	-0.08	0.06	0.25	-0.20	0.05
_x2020m3	-1.02	0.63	0.11	-2.29	0.24
_x_t2020m3	-0.35	0.09	0.00	-0.53	-0.17
_x2021m3	1.38	0.62	0.03	0.15	2.62
_x_t2021m3	0.19	0.07	0.01	0.05	0.34
PerMentalBenRatio1000	4.29	1.53	0.01	1.23	7.36
MentalProviderRate1000	-4.21	4.52	0.36	-13.30	4.88
PerMentalBenRatio1000	0.00				
_cons	18.59	2.33	0.00	13.91	23.28
PerMentalBenRatio1000	0				
_cons					
Post Intervention Trend					
_b[_t]+_b[_x_t2019m7]	0.33	0.06	0	0.20	0.46
_b[_t]+_b[_x_t2019m7]+_b[_x_t2020m3]	-0.02	0.06	0.79	-0.14	0.10
_b[_t]+_b[_x_t2019m7]+_b[_x_t2020m3]+_b[_x_t2021m3]	0.18	0.05	0.00	0.08	0.28

24. **Figure F.7.3.3. Model 3: Three Intervention Points, Two Controls**



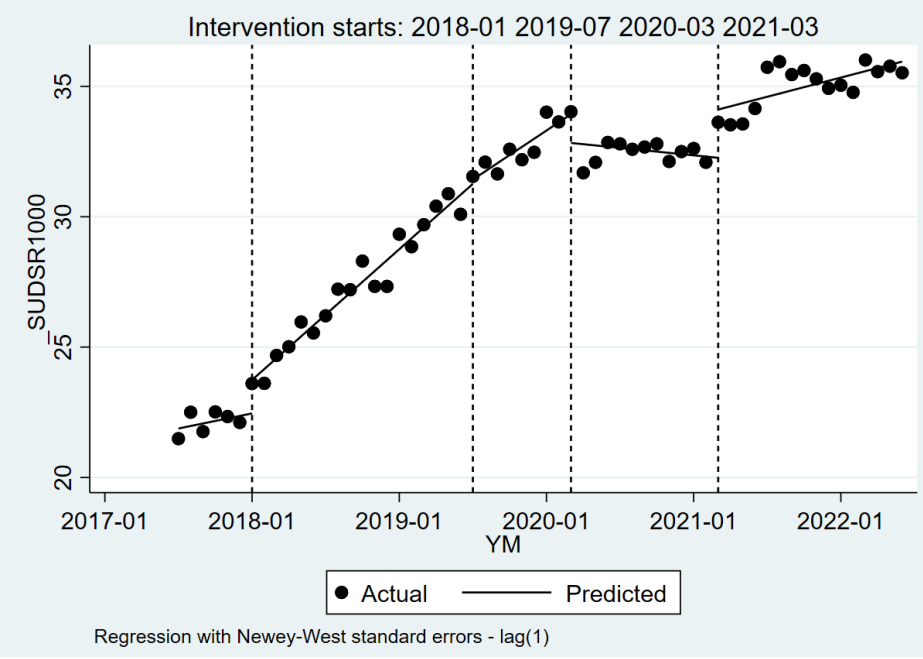
Model 4 (Four Intervention Points, No Controls): This model has four intervention points: 1/1/2018, 7/2019, 3/2020, and 3/2021. The control variable used in the analysis is the per thousand rates of beneficiaries with a mental illness diagnosis. Prais–Winsten AR(1) regression

with iterated estimates shows this model produced a R square of 98.32%. Table F.7.3.4 shows the Newey test. Among 14 parameters, 10 are significant. The COVID period and post-interventions slope are not significant. Figure F.7.3.4 provides a visual display of these results.

40**. Table F.7.3.4. Model 4: Four Intervention Points, No Controls**

_SUDSR1000	**Coefficient**	**std.err**	**p**	**95% CI**	
_t	0.10	0.07	0.15	-0.04	0.23
_x2018m1	1.28	0.29	0.00	0.70	1.86
_x_t2018m1	0.32	0.07	0.00	0.18	0.46
_x2019m7	0.17	0.32	0.60	-0.47	0.80
_x_t2019m7	-0.10	0.05	0.06	-0.21	0.00
_x2020m3	-1.10	0.54	0.05	-2.19	-0.01
_x_t2020m3	-0.36	0.08	0.00	-0.51	-0.21
_x2021m3	1.85	0.52	0.00	0.81	2.89
_x_t2021m3	0.17	0.07	0.02	0.03	0.31
_cons	21.88	0.20	0.00	21.48	22.27
Post Intervention Trend					
_b[_t]+_b[_x_t2018m1]	0.42	0.02	0.00	0.38	0.46
_b[_t]+_b[_x_t2018m1]+_b[_x_t2019m7]	0.31	0.05	0.00	0.21	0.42
_b[_t]+_b[_x_t2018m1]+_b[_x_t2019m7]+_b[_x_t2020m3]	-0.05	0.06	0.40	-0.16	0.06
_b[_t]+_b[_x_t2019m7]+_b[_x_t2020m3]+_b[_x_t2021m3]	0.12	0.04	0.00	0.04	0.20

25. **Figure F.7.3.4. Model 4: Four Intervention Points, No Controls**



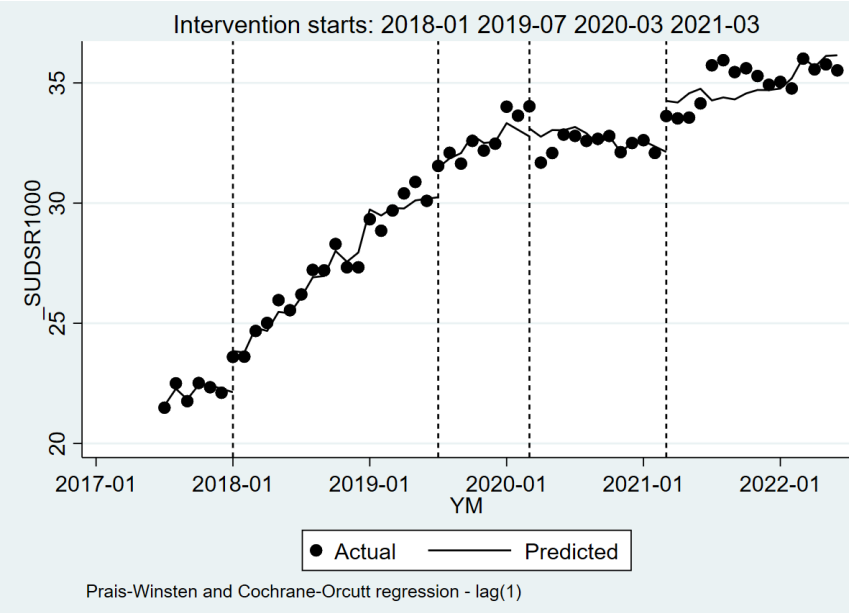
Model 5 (Four Intervention Points, One Control): This model has four intervention points: 1/1/2018, 7/2019, 3/2020, and 3/2021. The control variable used in the analysis is the per thousand rate of beneficiaries with a mental illness diagnosis and treatment. Prais–Winsten

AR(1) regression with iterated estimates shows this model produced a R square of 94.63%. Table F.7.3.5. shows the Newey test. The control is significant. All the post intervention slopes are significant, with 3 positive and one negative in year 2020. Between 7/2019 and 3/2020, intervention and slopes are not significant. Among 15 estimated parameters, 10 are significant. The covariate, intervention points 7/2019, 3/2020 and the intervention period, the slope of the post intervention 3/2020 are not significant. Figure F.7.3.5 provides a visual display of these results.

41**. Table F.7.3.5 Model 5: Four Intervention Points, One Control**

_SUDSR1000	**Coefficient**	**std.err**	**p**	**95% CI**	
_t	0.14	0.05	0.01	0.04	0.25
_x2018m1	0.81	0.34	0.02	0.14	1.49
_x_t2018m1	0.26	0.06	0.00	0.13	0.39
_x2019m7	0.20	0.34	0.56	-0.48	0.88
_x_t2019m7	-0.10	0.06	0.09	-0.21	0.02
_x2020m3	-0.87	0.52	0.10	-1.91	0.17
_x_t2020m3	-0.32	0.08	0.00	-0.49	-0.16
_x2021m3	1.43	0.64	0.03	0.14	2.72
_x_t2021m3	0.18	0.07	0.02	0.04	0.33
PerMentalBenRatio1000	2.69	1.45	0.07	-0.21	5.60
_cons	18.58	1.78	0.00	15.01	22.15
Post Intervention Trend					
_b[_t]+_b[_x_t2018m1]	0.41	0.02	0.00	0.36	0.45
_b[_t]+_b[_x_t2018m1]+_b[_x_t2019m7]	0.31	0.05	0.00	0.20	0.42
_b[_t]+_b[_x_t2018m1]+_b[_x_t2019m7]+_b[_x_t2020m3]	-0.02	0.06	0.79	-0.13	0.10
_b[_t]+_b[_x_t2019m7]+_b[_x_t2020m3]+_b[_x_t2021m3]	0.17	0.05	0.00	0.06	0.27

26. **Figure F.7.3.5: Model 5: Four Intervention Points, One Control**

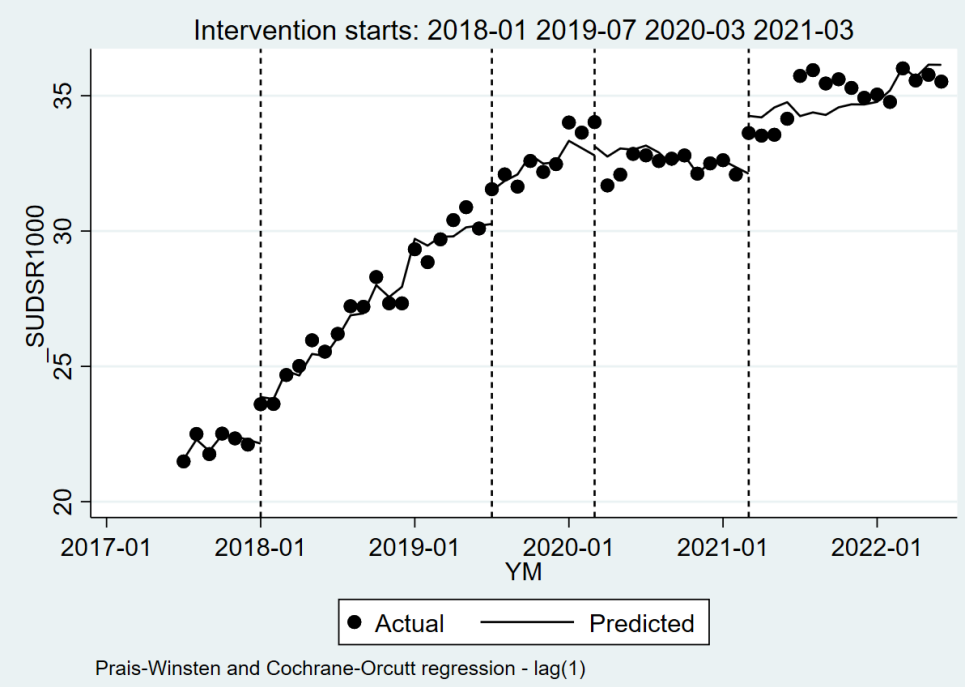


Model 6 (Four Intervention Points, Two Controls): This model has four intervention points: 1/1/2018, 7/2019, 3/2020, and 3/2021. The control variable used in the analysis is the per thousand rate of beneficiaries with a mental illness diagnosis and the per thousand population provider rate. Prais–Winsten AR(1) regression with iterated estimates shows this model produced a R square of 94.56%. Table F.7.3.6 shows the Newey test. Per thousand population provider rate is not significant. All the post intervention slopes are significant, with 3 positive and one negative in year 2020. Among 16 estimated parameters, 8 are not significant. The covariate, per thousand population mental health provider rate, is not significant. The intervention point 7/2019,3/2020, the intervention period 7/2019 -3/2020, and post-intervention slope (3/2021) are not significant. Figure F.7.3.6 provides a visual display of these results.

42**. Table F.7.3.6. Model 6: Four Intervention Points, Two Controls**

_SUDSR1000	**Coefficient**	**std.err**	**p**	**95% CI**	
_t	0.17	0.07	0.02	0.03	0.32
_x2018m1	0.76	0.32	0.02	0.12	1.39
_x_t2018m1	0.24	0.08	0.00	0.09	0.39
_x2019m7	0.21	0.36	0.57	-0.53	0.94
_x_t2019m7	-0.09	0.06	0.15	-0.22	0.03
_x2020m3	-0.97	0.64	0.14	-2.27	0.32
_x_t2020m3	-0.34	0.09	0.00	-0.52	-0.16
_x2021m3	1.44	0.64	0.03	0.16	2.73
_x_t2021m3	0.19	0.07	0.01	0.04	0.33
PerMentalBenRatio1000	3.32	1.50	0.03	0.31	6.33
MentalProviderRate1000	-2.32	4.77	0.63	-11.91	7.26
_cons	19.19	2.53	0.00	14.10	24.27
Post Intervention Trend					
_b[_t]+_b[_x_t2018m1]	0.41	0.02	0.00	0.36	0.46
_b[_t]+_b[_x_t2018m1]+_b[_x_t2019m7]	0.32	0.06	0.00	0.20	0.45
_b[_t]+_b[_x_t2018m1]+_b[_x_t2019m7]+_b[_x_t2020m3]	-0.02	0.06	0.75	-0.14	0.10
_b[_t]+_b[_x_t2019m7]+_b[_x_t2020m3]+_b[_x_t2021m3]	0.17	0.05	0.00	0.07	0.27

27. **Figure F.7.3.6 Model 6: Four Intervention Points, Two Controls**



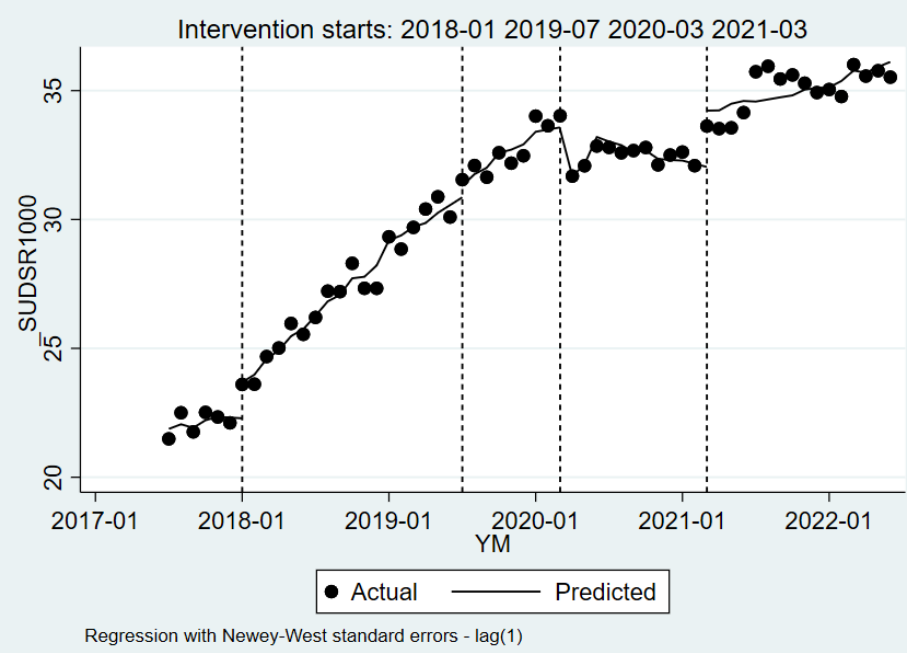
Model 7 (Four Intervention Points, Three Controls): This model has four intervention points: 1/1/2018, 7/2019, 3/2020, and 3/2021. The control variables used in the analysis are the Kentucky monthly unemployment rate, the per thousand rates of beneficiaries with a mental diagnosis and treatment, and per thousand population provider rate. Prais–Winsten AR(1) regression with iterated estimates shows this model produced a R square of 94.24%. Table F.7.3.7 shows the Newey test. Two covariates are significant, unemployment rate and per thousand rates of beneficiaries with a mental illness diagnosis. Per thousand population provider rate is not significant. All the post intervention slopes are significant, with 3 positive and one negative in year 2020. Among 17 estimated parameters, 4 are not significant. The covariate, per thousand population mental health provider rate, is not significant. The intervention points 7/2019 and 3/2020, and the intervention period 7/2019-3/2020 are not significant. Figure F.7.3.7 provides a visual display of these results.

43**. Table F.7.3.7 Model 7: Four Intervention Points, Three Controls**

_SUDSR1000	**Coefficient**	**std.**	**p**	**95% CI**	
_t	0.15	0.07	0.04	0.00	0.30
_x2018m1	0.83	0.34	0.02	0.15	1.50
_x_t2018m1	0.26	0.08	0.00	0.10	0.42
_x2019m7	0.20	0.37	0.59	-0.54	0.94
_x_t2019m7	-0.09	0.06	0.16	-0.22	0.04
_x2020m3	-0.28	0.55	0.61	-1.38	0.82
_x_t2020m3	-0.42	0.09	0.00	-0.60	-0.25
_x2021m3	1.79	0.64	0.01	0.50	3.08
_x_t2021m3	0.25	0.06	0.00	0.13	0.38
PerMentalBenRatio1000	3.03	1.48	0.05	0.05	6.02

MentalProviderRate1000	-2.94	4.14	0.48	-11.28	5.39
UnemploymentRate	-0.14	0.03	0.00	-0.20	-0.08
_cons	20.57	2.44	0.00	15.65	25.48
Post Intervention Trend					
_b[_t]+_b[_x_t2018m1]	0.41	0.02	0.00	0.37	0.46
_b[_t]+_b[_x_t2018m1]+_b[_x_t2019m7]	0.32	0.06	0.00	0.20	0.45
_b[_t]+_b[_x_t2018m1]+_b[_x_t2019m7]+_b[_x_t2020m3]	-0.10	0.05	0.05	-0.20	0.00
_b[_t]+_b[_x_t2019m7]+_b[_x_t2020m3]+_b[_x_t2021m3]	0.15	0.05	0.01	0.05	0.26

28. **Figure 9 Model 7: Four Intervention Points, Three Controls**



Discussion: We modeled the time series data using seven models with different intervention points and controls. Among all seven Models, Model 7 has the greatest number of significant parameters and is the most robust. In addition, this model shows that two covariates, the per thousand population rate of beneficiaries with a mental illness diagnosis and the monthly Kentucky unemployment rate are significant. Furthermore, all post-intervention slopes are significant.

This discussion focuses on Model 7**.** As shown in the regression Table 7, the starting level of the per thousand population SUD service rate was estimated at 20.57, and the per thousand population SUD service rate appeared to increase slightly every month prior to 2018m1 by 0.15 with a significant p value (0.04) (p=0.04, CI =[0, 0.30]). In the first month of the intervention (1/2018), there appeared to be a significant increase in per thousand population SUD service rate of 0.83 (p<0.02, CI =[0.15, 1.5]), followed by a significant increase in the monthly trend of 0.26 points per thousand population SUD service rate (relative to the pre-intervention trend) per month (p=0.00, CI =[0.1, 0.42]). We also see, from the post-intervention estimate, that after the introduction of the SUD IMD reimbursement policy, the per thousand population SUD service rate increased monthly at a rate of 0.41 (95% CI =[0.37, 0.46]). Compared to the first intervention, the second intervention (2018m7) has no evidence of a treatment effect. There was

evidence of a COVID treatment effect, however. In March 2020, the per thousand population SUD service rate appeared to decrease every month prior to 22020m3 by 0.28 with a non-significant p value (p=0.61, CI =[-0.38, 1.28]), followed by a significant decrease in the monthly trend of 0.42 points per thousand population SUD service rate (relative to the second intervention) per month (p=0.00, CI =[-0.6, -0.25]). Though the immediate Demonstration implementation was not significant, the post-intervention estimate after the introduction of 1115 SUD Demonstration of the per thousand population SUD service rate increased monthly at a rate of 0.32 (p=0; 95% CI =[0.32, 0.45]).

In March 2020 the per thousand population SUD service rate appeared to decrease every month prior to 22020m3 by 0.28 with a non-significant p value (p=0.61, CI =[-0.38, 1.28]), followed by a significant decrease in the monthly trend of 0.42 points of the per thousand population SUD service rate (relative to the second intervention) per month (p=0.00, CI =[-0.6, -0.25]). The post-intervention estimate after COVID19 shows a significant decrease by 0.1 (p=0.0, CI=[-0.2,0].

In March 2021 the per thousand population SUD service rate appeared to increase every month prior to 2021m3 by 1.79 with a non-significant p-value (p=0.02, CI =[0.5, 3.08]), followed by a significant increase in the monthly trend of 0.25 points per thousand population SUD service rate (relative to the second intervention) per month (p=0.00, CI =[0.13, 0.38]). The post-intervention estimate after COVID-19 shows a significant increase by 0.15 (p=0.05, CI=[0.05,0.26].

Conclusion: Regarding the 2018 DMS IMD policy, we find an increase in level, an immediate increase in monthly trend, and significant post-intervention trend. Our regression results show a non-significant negative effect of 2019m7, the 1115 Demonstration implementation month. The negative coefficient could be explained by the significant and improved employment rate; due economic conditions, the number of Kentucky Medicaid enrollees decreased in 2019. However, we do see evidence of a post-waiver increase trend of 0.32 points.

We conclude that policy changes, including the Demonstration, have contributed to an increase in the SUD service rate at level, an immediate increase or a gradual long-term increase, despite the unprecedented events that occurred in the past few years. Our analysis shows a positive impact of the interventional policies.

However, this is a preliminary analysis of the time series data. Given the multiple change points in our data, our analysis has some limitations. First, while we identified three covariates for SUD service rate, it is possible there are other covariates that need to be controlled for. Second, seasonality was not modeled in our analysis, given the limitation of sample size. We will include seasonality in the Final Summative Report.

SECTION G. CONCLUSIONS

Returning to the three primary evaluation questions and their attendant hypothesis analyzed in this report:

(1) To what extent has access by Medicaid beneficiaries to SUD treatment services increased?
- **H1a: The Demonstration will increase the ratio of outpatient Medicaid SUD providers overall, and those specifically offering MOUD and methadone as part of MOUD, to beneficiaries in areas of greatest need.**
- **H1b: The Demonstration will increase the ratio of SUD providers offering residential treatment, especially IMDs, to beneficiaries.**
- **H1c: The Demonstration will increase the utilization of SUD/OUD services.**
- **H1d/H2a: The Demonstration will decrease the rate of ED visits and inpatient admissions within the beneficiary population for SUD/OUD.**

(2) To what extent did the quantity and quality of health outcomes for beneficiaries receiving SUD services with the 1115 Medicaid Demonstration project improve?
- **H1d/H2a: Among beneficiaries receiving care for SUD, the Demonstration will decrease the rate of ED visits for SUD.**
- **H2b: Among beneficiaries receiving care for SUD, the Demonstration will reduce hospital readmissions for SUD care.**
- **H2c: Among beneficiaries receiving care for SUD, the Demonstration will improve self-reports of health and quality of life metrics.**

(3) Did SUD-related expenditures decrease, as analyzed by total expenditures, disaggregated by IMD and non-IMD expenditures, and disaggregated by source of treatment?
- **F1a: The Demonstration will decrease the total SUD/OUD expenditures.**
- **F1b: The Demonstration will decrease SUD/OUD and non-SUD/OUD expenditures, with SUD/OUD expenditures disaggregated into IMD and non-IMD expenditures.**
- **F1c: The Demonstration will decrease expenditures disaggregated by source of treatment—namely, inpatient expenditures, emergency department (ED) expenditures, non-ED outpatient expenditures, and pharmacy expenditures.**

(4) To what extent did rates of opioid-related overdose death decrease?

We draw the following interim conclusions based on the data available to us and using the analysis summarized above in Section F. Results.

H1a: The number of Medicaid billing providers for SUD treatments, the number of Medicaid providers prescribing MOUD, and the number prescribing methadone all increased from 2017 through 2020.

H1b: The number of Medicaid providers billing for residential SUD treatment increased from 2017 through 2020.

H1a and H1b county-by-county analysis: These hypotheses cannot be tested from the data available at this time. Owing to the billing provider vs performing or prescribing provider confounds, Medicaid claims cannot be used to measure county-level data. Data from the MPPA portal are not available at the county level nor are counts of performing providers are not available. In addition, analysis at the county level provides specific challenges. Kentucky has 120 counties, with the majority being rural. Many consist of a small geographic area and lack a medical office within that political boundary. As well, patients seek care outside their home counties. As a unit of analysis, counts at the country level do not provide specific insight into efficacy of the Demonstration. A more appropriate unit of analysis is Kentucky Health Districts, which are also the foundation for the geographic quadrants used for sampling in the qualitative analysis portion of this evaluation.

H1c: Based upon analyses of Medicaid claims data, there has been an increase in the utilization of services. However, while the number of beneficiaries newly diagnosed with SUD and those receiving treatment for the first time both increased from 2017BY through 2021DY, the rate as a percentage of beneficiaries did not show an increase. Relative to access to care, the number of beneficiaries using services increased across all categories measured: outpatient services, residential treatment, MOUD, and the expanded methadone services. Nevertheless, these interim outcomes suggest that there appears to be a foundation to meet the objectives of the Section 1115 Demonstration Waiver relative to access.

H1d/H2a: The number of ED visits for SUD-related diagnoses among beneficiaries decreased for the 2021DY compared to the baseline years, declining by 8.9%. ED visits increased during 2020DY, which we could have been driven by the COVID-19 pandemic and issues about access to care in other settings. For, the number of beneficiaries with a primary SUD diagnosis who then accessed SUD services within 30 days after visiting the ED the rate stayed relatively flat from 2018BY to the Demonstration years, 18.5% and 19.5%, respectively, but declined significantly from the 2017BY rate of 23.6%. The decrease in ED visits was an expectation of the expansion of services under the waiver. The 30-day follow-up SUD service rate for individuals with an ED visit was flat, although it was expected to increase under the waiver. Thus, there are currently mixed results for these hypotheses.

H2b: The rate of admissions varies during the measurement period but shows a decline by June 2022 when compared to the rate at the initiation of the Demonstration. There is an increase in the rate of inpatient admissions from 2017 through the start of the waiver, then admissions fell slightly, but there was a surge of inpatient admissions between April to July 2020, at the start of the pandemic, followed by a relatively rapid decrease that is below the rate at the start of the waiver by June of 2022 (2021DY). The more recent, post-pandemic, rate of admissions indicates a decline to about 5 percent of beneficiaries with a SUD diagnosis had an inpatient visit compared to almost 9 percent for 2018BY. This recent trend is in-line with the objectives of the waiver.

H2c: While significant improvements are shown regarding self-reported life outcomes by respondents to the KTOS and KORTOS surveys, approximately a third still suffer from depression, anxiety, or both a year after treatment; a quarter still experience chronic pain; over a third have difficulty meeting basic life needs; and a fifth have difficulty meeting basic health needs. At 12 months, two-fifths report some sort of justice involvement, and a third report

continued illicit drug usage. No changes were noted in self-reported outcomes from pre-waiver to post-waiver.

F1a/F1b/F1c: Based upon the claims data analyzed, expenditures across all categories showed a similar pattern of a substantial increase during 2020DY and then a slower rate of increase during 2021DY. The 2020DY is associated with both the expansion of services under the waiver and the COVID-19 pandemic and showed a 38.4% increase in SUD expenditures compared to the previous year. The rate of growth in expenditures for the most recent Demonstration year (ending 6/22) shows an increase in expenditures of 6.6%. Per capita expenditures for beneficiaries with a SUD diagnosis increased to $5,842 in 2020DY, a 25.34% increase from 2019DY and a 38.17% increase from 2018BY. The increase in per capita expenditures from 2021DY to 2021DY was only 4.98% to $6,133. The trend for 2021DY is promising and is below the rate of healthcare inflation for that period. This suggests following the initial jump in expanses linked to the expansion of services and the complication of COVID-19, costs are moderating relative to the rate of growth before the waiver.

For Evaluation Question 1: Access by Medicaid beneficiaries to SUD treatment services has increased as measured across all types of services. There is some indication the effect of the Demonstration in lowering the costs associated with emergency department use by beneficiaries with a SUD diagnosis.

For Evaluation Question 2: Whether the quantity and quality of health outcomes for beneficiaries receiving SUD services with the 1115 Medicaid Demonstration project has improved is undetermined at this time, due to the challenges of controlling for COVID-19's impact. We anticipate providing a definitive answer in the Final Summative Report.

For Evaluation Question 3: With the exception of ED expenses, all SUD-related Medicaid expenditures increased. For those increasing, a similar pattern of expenditures developed across the evaluation period, with a substantial increase in 2020DY from a surge in access and use associated with an increase in the availability of services and a relaxation of pandemic restrictions. This was followed by a slowing in the rate of increase in 2021DY as services and beneficiary demand normalized.

At this stage in the evaluation, we can conclude that, in general, the Commonwealth has been successful in increasing the availability of SUD-related services to Medicaid beneficiaries along several dimensions. Unfortunately, the immediate impact of these changes has been tempered by the COVID-19 pandemic, and results have been ambiguous with the data available thus far. As Kentucky moves into a normalized state related to COVID, more definitive conclusions should be able to be drawn.

SECTION H. INTERPRETATIONS, POLICY IMPLICATIONS, AND INTERACTIONS WITH OTHER STATE INITIATIVES

This evaluation activity is challenged in differentiating the direct impact of the 1115 Waiver mechanisms versus DMS's efforts to support those mechanisms as well as other state initiatives, as they occur concurrently and are directed toward similar goals. Moreover, with increased polysubstance use, increased contaminants in illicit substances (both level and types), and the multi-dimensional impact of the COVID-19 pandemic on mental health, substance misuse, and quality of life, Kentucky confronts even greater challenges in addressing SUD now than it did at the initiation of the waiver Demonstration. It is within this context that interpretations of the current data analysis are provided.

H.1. Interrelation with Kentucky's Medicaid Program

Concomitant with the initiation of the 1115 SUD Demonstration waiver, the Kentucky DMS 2019-2022 Managed Care Quality Strategy (MCQS) was released. It indicated that reducing the burden of SUD by engaging enrollees in improving behavioral health outcomes was its first goal. Relevant objectives under this goal included reducing the burden of SUD and improving outcomes, reducing substance misuse through engagement in recovery services, and increasing screening for SUD. Specific HEDIS measures of performance included Initiation of Treatment (IET), Use of Opioids at High Dosage (HDO) and Anti-Depressant Medication Management (AMM).

The External Quality Report (EQR) for the MCQS examined MCO performance on its stated goals. The rate for IET: Initiation of Treatment Total showed an improved benchmark rating at or above the national 75th percentile but below the 90th percentile, while the rate for IET: Engagement of Treatment Total continued to be greater than the national 90th percentile. The Use of Opioids at High Dosage (HDO) measure has a benchmark rate that met or exceeded the national 75th percentile but was below the 90th percentile.

The 2019-2020 KY MCQS pledges that enrollees shall retain the fullest control possible over their behavior health treatment; that behavioral health services will be responsive, organized, and accessible to those who need behavioral healthcare; and that behavioral health services are recovery- and resiliency-focused. In addition, MCOs maintain an emergency and crisis Behavioral Health Services Hotline staffed by trained personnel available 24 hours a day throughout the Commonwealth, as well as provide training to network PCPs on how to screen for behavioral health disorders, the referral process for Behavioral Health Services and clinical coordination requirements for those services.

KY DMS is in the process of updating the MCQS. The updated strategy reflects the complementarity of the 1115 Demonstration and considers the results and experiences associated with the Demonstration in establishing new goals and objectives. The 2019 Quality Strategy focused specifically on issues of substance use disorder within the domain of behavioral health. The proposed updated strategy broadens the behavioral health-related goals beyond SUD to include objectives targeting treatment retention and care coordination for individuals with serious mental illness (SMI) as well as SUD and the utilization of psycho-social treatments for adolescents on antipsychotic drugs.

Specific OUD measures included in the updated MCQS are:

- MOUD
- ED Utilization

Under the Quality Strategy, MCOs are scored on their annual performance relative to these measures and must bring interventions to bear to improve outcomes. That these two measures overlap with the 1115 Demonstration is positive, as likely more resources will be used to promote improvement.

H.2 Interactions with Other Kentucky Medicaid Demonstrations

Table H.2.1 below lists other Kentucky Medicaid Demonstrations relevant to this project.

44. **Table H.2.1 Medicaid Waivers Impacting the SUD 1115 Demonstration**

Waiver Type	Project Effective Date	Project Ending Date	Project Description
1915	7/2020	12/21	NEMT waiver renewal
1915	1/21	12/25	Managed care expansion

Excepting methadone treatment services for beneficiaries (excluding those under 20, former foster youth, and pregnant women), NEMT can be utilized by beneficiaries for SUD-related care. The Medicaid 1915 (b1), 1915 (b4) NEMT waiver renewal provided the structure for NEMT operations throughout the Commonwealth.

Qualitative interviews revealed that most of the beneficiaries who receiving methadone live in metropolitan areas with bus service; the few who do not indicated that they either have their own transportation (car) or access to family or friends who provide transportation to their clinic.

The Medicaid 1915 (b1) MCO waiver expanded the number of MCOs to its current total of six, thus expanding the availability of managed care to Kentucky Medicaid beneficiaries.

There are seven additional Medicaid 1915 waivers expanding support and services for beneficiaries with acquired brain injuries or physical, intellectual, or developmental disabilities that are tangentially related to this 1115 Demonstration.

H.3 Interactions with Other Federal Awards

The Commonwealth of Kentucky, along with regional and local organizations, have initiated multiple intervention activities to disrupt the drivers for the negative outcomes in SUD. Three important federally funded initiatives at the state level include the KORE programs, the HEALing Communities Study, and the Opioid Response Network.

Kentucky's initiative associated with SAMHSA's State Targeted Response to the Opioid Crisis grant (or the Opioid STR grant) is the Kentucky Opioid Response Effort (KORE). Guided by the Recovery-Oriented Systems of Care Framework, the purpose of KORE is to implement a comprehensive targeted response to Kentucky's opioid crisis by sustaining and expanding access

to a full continuum of high quality, evidence-based opioid prevention, treatment, recovery support services. Target populations include persons who have survived an opioid-related overdose, pregnant and parenting women, justice-involved individuals, children, transition-age youth, and families. KORE is aimed at addressing eight overarching goals:

(1) overdose prevention and naloxone distribution
(2) reducing opioid overprescribing and improving safe opioid use
(3) community-guided prevention
(4) harm reduction
(5) engagement and linkage to services
(6) access to FDA-approved medications for opioid use disorder
(6) reducing unmet treatment need
(7) recovery support
(8) provider education and training.

From 2017-2020, KORE has allocated $99.9 million to over 70 providers who then manage distribution of funds and program implementation. Relative to the goals of this Demonstration project, KORE serves as the payor of last resort for uninsured individuals needing SUD treatment and for those seeking methadone treatment. KORE also provides support to initiate SUD treatment, including MOUD, in ED and other hospital settings, as well as mobile units to provider SUD services to those in underserved rural areas. As such, KORE complements the activities of the Kentucky Medicaid 1115 SUD Demonstration waiver but does not duplicate them. It raises reduces stigma associated with SUD, allowing more beneficiaries to seek assistance, and it expands the availability of MOUD in the Commonwealth.

In 2019, the National Institutes of Health (NIH) launched the HEALing (Helping End Addiction Long Term) Communities Study. The University of Kentucky, in partnership with the Commonwealth, received one of the four HEAL grants and initiated a four-year, $87 million study aimed at reducing opioid overdose deaths by 40%. Kentucky HEAL seeks to address the opioid epidemic in a randomized study that includes 16 Kentucky counties acutely impacted by opioid abuse. The study leverages existing resources, initiatives, and community capacity to develop and implement SUD/OUD prevention, treatment, and recovery strategies and to develop evidence-based standards that can serve as a national model for reducing opioid mortality. As of 1 August 2022, selection of the particular strategies and full implementation for wave 1 counties have been completed, and the selection of strategies for wave 2 counties has been initiated (see HEALing Communities Study Consortium, 2020, for a fuller discussion of the methodology). Primary interventions in this project include community engagement to drive community change; health communication around stigma; and overdose reduction through education, naloxone distribution, increased use of MOUD, and decreased prescribing of opioids. Preliminary data analysis comparing wave 1 and wave 2 mid-point outcomes is only now beginning. Given the timing of the HEAL Communities Study and the fact that it only reaches 16 out of the 120 (13.3%) counties in Kentucky, its impact on the Kentucky Medicaid 1115 SUD Demonstration waiver is expected to be minimal. It may, however, influence future Kentucky Medicaid 1115 SUD Demonstration expansion requests.

The Substance Abuse and Mental Health Services Administration (SAMHSA) funded a large national coalition representing over 2 million stakeholders to create the *Opioid Response Network (ORN)* with representatives in each state to provide training and to help address the

opioid crisis. The ORN provides education and training for community members, health professionals, and justice personnel on evidence-based practices for treating opioid use disorder. As with the KORE grant, these interventions complement but do not duplicate the Kentucky Medicaid 1115 SUD Demonstration waiver's activities. It promotes interaction with SUD healthcare professionals and trains healthcare personnel in the best practices.

The Mid-point Assessment Table 2 in Section J below provides a deeper and more extensive analysis of the interrelation among program activities in Kentucky.

SECTION I. LESSONS LEARNED AND RECOMMENDATIONS

Recommendations for Medicaid policymakers, advocates, and stakeholders will be finalized upon the completion of the Final Summative Report. Particularly given current uncertainty around the impact of COVID-19 on data available for the Draft Interim Evaluation, it is premature to suggest substantial changes in policy, procedures, or services practices with the exception of data collection. This limitation in determining lessons learned and recommendations will be revisited in the Final Interim Evaluation to be submitted in January 2023.

However, it is possible at this juncture to recommend changes in DMS data collection to include MPPA requiring data reporting for each location and by individual provider as well as bed counts by date. The portal should also distinguish individual performing providers served by a single billing provider. Regulations and contracts governing Medicaid claims should also be reviewed to allow for the identification of performing providers and location specific information. Steps taken to improve the MPPA in September 2022 will allow for distinguishing between IMDs and residential facilities and location information for multiple-facility operators.

Relative to the analysis, assessments made at the county level are difficult to interpret and, in some cases, spurious, given small geographical size or population number. A more appropriate unit of analysis is at the Health District level.

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APPENDICES

Appendix A: Summary of All Planned Measures and Statistical Analyses

A summary of the status of all planned statistical measures described in the evaluation design is available in Table A-1 below. This includes a description and status of all measures in both this Interim Report and those delayed for inclusion in the Final Summative Report.

Table A-1: Status of All Planned Statistical Measures

Hypotheses and Research Questions Inclusions in the Evaluation Hypotheses	Research Questions	Interim Evaluation	Summative Evaluation
H1a: The Demonstration will increase the ratio of outpatient Medicaid SUD providers overall, and those specifically offering MAT and methadone as part of MAT, to beneficiaries in areas of greatest need	Does the rate of providers billing for SUD service per capita in the total number of beneficiary population increase in the post-waiver period?	Yes	Yes
	Does the rate of providers prescribing any MOUD for SUD service per capita in the total number of beneficiary population increase in the post-waiver period?	Yes	Yes
	Does the rate of providers prescribing Methadone for SUD service per capita in the total number of beneficiary population increase in the post-waiver period?	Yes	Yes
	Does the rate of providers billing for SUD service per capita per county in the total number of beneficiary population increase in the post-waiver period?	No	Yes
	Does the rate of providers prescribing any MOUD for SUD service per capita per county in the total number of beneficiary population increase in the post-waiver period?	No	Yes
	Does the rate of providers prescribing Methadone for SUD service per capita per county in the total number of beneficiary population increase in the post-waiver period?	No	Yes
H1b: The Demonstration will increase the ratio of SUD providers offering residential treatment, especially IMDs, to beneficiaries	Does the rate of providers billing for SUD residential service per capita in the total number of beneficiary population increase in the post-waiver period?	Yes	Yes
	Does the rate of providers billing for SUD IMD service per capita in the total number of beneficiary population increase in the post-waiver period?	Yes	Yes
	Does the rate of providers billing for SUD residential service per capita per county in the total number of beneficiary population increase in the post-waiver period?	No	Yes
	Does the rate of providers billing for SUD IMD service per capita per county in the total number of beneficiary population increase in the post-waiver period?	No	Yes
H1c: The Demonstration will increase the utilization of SUD services.	Does the rate of a beneficiary who was newly diagnosed with SUD per capita in the total number of beneficiary population increase in the post-waiver period?	Yes	Yes
	Does the rate of a beneficiary who was diagnosed with SUD and received SUD outpatient service per capita in	Yes	Yes

	the total number of beneficiary population increase in the post-waiver period?		
	Does the rate of a beneficiary who was diagnosed with SUD and received SUD residential service per capita in the total number of beneficiary population increase in the post-waiver period?	Yes	Yes
	Does the rate of a beneficiary who was diagnosed with SUD and received MOUD service per capita in the total number of beneficiary population increase in the post-waiver period?	Yes	Yes
	Does the rate of a beneficiary who was diagnosed with SUD and received Methadone per capita in the total number of beneficiary population increase in the post-waiver period?	Yes	Yes
	Does the rate of a beneficiary who received at least 180 days of continuous pharmacotherapy for OUD without a gap of more than 7 days per capita in the total number of OUD beneficiary population increase in the post-waiver period?	Yes	Yes
	Does the rate of a beneficiary with SUD diagnosis and used SUD services at the IMD per capita in the IMD facility increase in the post-waiver period?	Yes	Yes
H1d: The Demonstration will decrease the rate of ED visits and inpatient admissions within the beneficiary population for SUD.	Does the rate of a beneficiary with ED visits for SUD diagnosis per capita in the total beneficiary population decrease in the post-waiver period?	Yes	Yes
	Does the rate of a beneficiary with inpatient stays per 1000 beneficiaries per capita in the total beneficiary population decrease in the post-waiver period?	Yes	Yes
H2a: Among beneficiaries receiving care for SUD, the Demonstration will decrease the rate of ED visits for SUD.	Does the rate of ED visits with primary SUD (OUD) related diagnosis among beneficiaries who used SUD (OUD) services within 30 days per capita in the number of beneficiaries who used SUD (OUD) services within 30 days decrease in the post-waiver period?	Yes	Yes
	Does the rate of ED visits with primary SUD (OUD) related diagnosis among beneficiaries who used SUD (OUD) services within 30 days per capita in the number of beneficiaries discharged from ED with primary diagnosis of SUD (OUD decrease in the post-waiver period?	Yes	Yes
	Does the rate of ED visits with primary SUD (OUD) related diagnosis among beneficiaries who used SUD (OUD) services within 7 days per capita in the number of beneficiaries discharged from ED with primary diagnosis of SUD (OUD) decrease in the post-waiver period?	Yes	Yes
	Does the rate of ED visits with primary SUD (OUD) related diagnosis within 30 days ED discharge for SUD (OUD) per capita in the number of beneficiaries discharged from ED with primary diagnosis of SUD (OUD) decrease in the post-waiver period?	Yes	Yes
H2b: Among beneficiaries receiving care for SUD, the Demonstration will reduce	Does the 30-day readmission rate following hospitalization with SUD(OUD) related diagnosis decrease in the post-waiver period?	Yes	Yes

hospital readmissions for SUD care.			
H3a: The Demonstration will decrease the rate of overdose deaths due to opioids.	Does the rate of opioid-related overdose death decrease in the post-waiver period?	No	Yes
	Does the rate of opioid-related overdose death decrease by county in the post-waiver period?	No	Yes
	Does the rate of a beneficiary who use opioids at high dosage in persons without cancer* decrease in the post-waiver period?	No	Yes

Appendix B: Mid-Point Evaluation of Demonstration Waiver

MIDPOINT ASSESSMENT

Mid-Point Evaluation
Section 1115 Substance Use Disorder Demonstration
Kentucky Cabinet for Health & Family Services
Department for Medicaid Services

April 12, 2021

Center for Health Innovation
Northern Kentucky University
Highland Heights, KY 41076

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List of Acronyms

Acronyms	Name
ACA	Affordable Care Act
ASAM	American Society of Addiction Medicine
BH	Behavioral Health
BHSO	Behavioral Health Service Organization
CARF	Commission on Accreditation of Rehabilitation Facilities
CHFS	Cabinet for Health and Family Services
CMHC	Community Mental Health Center
CMS	Medicare and Medicaid Services
COA	Council of Accreditation
DEA	Drug Enforcement Administration
DMS	Department for Medicaid Services
ED	Emergency Department
HEALing	Helping End Addiction Long Term
IMD	Institutions for Mental Disease
KIPRC	Kentucky Injury Prevention Research Center
KORE	Kentucky Opioid Response Effort
LOC	Level of Care
MAT	Medication-assisted Treatment
MCO	Managed Care Organizations
MOUD	Medication for Opioid Use Disorder
MPE	Midpoint Evaluation
MSG	Multi-Specialty Group
NIH	National Institutes of Health
NTPs	Narcotic Treatment Programs
OUD	Opioid Use Disorder
PAs	Prior Authorizations
RCSU	Residential Crisis Stabilization Units
RTCs	Residential Treatment Centers
SAMHSA	Substance Abuse and Mental Health Services Administration
SBIRT	Brief Intervention and Referral to Treatment
SPA	State Plan Amendment
SUD	Substance Use Disorder
SWOT	Strength, Weakness, Opportunity and Threat

EXECUTIVE SUMMARY

The Department for Medicaid Services (DMS) within the Kentucky Cabinet for Health & Family Services (CHFS) proposed a Substance Use Disorder (SUD/OUD) Demonstration project as a Section 1115 Demonstration Waiver project to expand ongoing efforts to address the opioid crisis. The Centers for Medicare and Medicaid Services (CMS) approved the implementation plan on October 5, 2018 and an amended implementation plan on November 4, 2019.

The purpose of the SUD/OUD Demonstration project is to "ensure that a broad continuum of care is available to Kentuckians with a substance use disorder (including an opioid use disorder [OUD])," with the primary goal of reducing overdose injuries and deaths. To achieve this purpose, Kentucky Medicaid implemented a plan to (1) increase beneficiary access to SUD/OUD providers offering treatment services and (2) expand SUD/OUD treatment benefits available to enrollees, thereby increasing utilization of SUD/OUD treatment services.

The goals of the 1115 Demonstration are:

- Improve access to critical levels of care for OUD and other SUD/OUDs for Medicaid beneficiaries
- Increase the use of evidence-based SUD/OUD screening criteria for patient placement in outpatient or residential care
- Establish standards for residential treatment provider qualifications that meet nationally-recognized SUD/OUD-specific program standards
- Increase provider capacity at critical levels of care, including MOUD for OUD
- Implement prescribing guidelines and other treatment and prevention strategies
- Improve care coordination and transitions between levels of SUD/OUD care.

The purposes of this Midpoint Evaluation are to provide an early assessment of the implementation of the Demonstration and to lay a foundation for longer-term evaluation activities. This evaluation was conducted in direct collaboration with the stakeholders to ensure that the findings will influence subsequent implementation and enhance longer-term assessment activities.

Methodology

Two complimentary frameworks are used in this evaluation. Given the wide variety of SUD/OUD-focused initiatives underway in the Commonwealth of Kentucky, a Cascade of Care Model framework is used to provide insights into Kentucky's global response to SUD/OUD and how the 1115 Demonstration is embedded into these activities. A crosswalk analysis using the Cascade of Care Model framework is applied to organize and understand the SUD/OUD initiatives in Kentucky and more precisely evaluate the 1115 Demonstration.

Second, SWOT (Strength, Weakness, Opportunity, Threats) analyses are applied to mechanisms used to implement the 1115 Demonstration. These are used to evaluate the positioning of the 1115 Demonstration relative to the program goals. This positioning encompasses performance, competition, risk and potential. The focus for these analyses within this Midpoint Evaluation is to identify common themes and issues across the mechanisms being used to implement the Demonstration for the purpose of considering any mid-course corrections, enhancements, or resource reallocations. The SWOT analyses also provide a foundation of the Interim and Final Assessments of the Waiver activities.

Data were collected from four sources:

- Review of documents including reports and analyses of SUD/OUD activities across Kentucky
- Review of documents and data from departments within CHFS
- Two waves of stakeholder interviews
- Stakeholder reviews of early drafts of this Midpoint Evaluation

Results

The implementation of the Demonstration and the collection of data concerning performance under the waiver have been constrained by the COVID-19 pandemic. There is also evidence that behaviors during this period changed, which complicates longitudinal analyses and other comparisons across time periods. Common themes and issues that became apparent in evaluating the 1115 Demonstration within both the Cascade of Care Model and SWOT analysis frameworks are listed below, along with (where appropriate) accompanying recommendations for consideration for implementation:

1. *Policies and regulation* - the comprehensive response by the Commonwealth in addressing evidence-based treatment through public policies and evolving regulation was a consistent theme throughout the evaluation. This includes changes to prior authorization requirements, changes to regulations, policies supporting engagement and education, and standardization and coordination of actions across departments and cabinets. Kentucky should be applauded for thoroughness in which it has implemented complementary supports for the 1115 Demonstration. Resource constraints for the implementation of these supporting activities were the principal concern identified by stakeholders. However, it appears that at least some of these concerns have been addressed through additional DMS actions; hence, additional communication to providers around reimbursement and related changes might be advised.

2. *Justice-involved persons with SUD/OUD* - Key informants from multiple systems believe there is a gap for persons involved in the criminal justice system between the SUD/OUD services they need and those that are available. Since the inception of the Affordable Care Act (ACA), 15 states have applied to increase care for the justice-involved through the 1115 Waiver Initiative and 13 states are currently implementing plans. Kentucky has applied for a similar waiver but has yet to hear whether its application has been approved. However, its supportive actions, including reimbursement, intervention and treatment for pre-trial detainees, and increased services connecting to inmate's pre-release, go beyond what other states are implementing. However, no recommendations for change with the justice-involved population are possible until the status of the Demonstration amendment is resolved.

3. *Education and training* – Respondents consistently identified the need for both increased and targeted education for providers. Incenting the training programs remains a challenge, as does reaching those in rural regions – who are most in need of technical assistance.

4. *Reducing complexity* – An additional theme that emerged was the increased complexity that comes with adopting and other standards. A central issue is how these new criteria will be folded into current accreditations. Possible suggested solutions include coordinating DMS accreditations with those of Commission on Accreditation of Rehabilitation Facilities (CARF) and COA to reduce demands on providers and to subsidize a standardized ASAM consistent six-dimensional tool.

5. *Reimbursement* - A final theme that emerged was the issue of reimbursement for providers who serve large numbers of Medicaid clients. We appreciate that this is an on-going issue and not specific to this 1115 Demonstration project. However, several stakeholders did raise the possibility that reimbursement and payment challenges disincentivized providers from participating more fully. It might be worth investigating whether some small changes in reimbursement schedules might make wider adoption of these measures more palatable.

Conclusions

The goal of the midpoint evaluation is to inform decision-making about how to improve Kentucky's response to the opioid epidemic through more effectively exploiting available 1115 Demonstration mechanisms.

Importantly, our analyses do indicate that stakeholders understand the 1115 Demonstration as set of tools that they could use to facilitate broad-based, multi-disciplinary, overlapping efforts to combat SUD/OUD in the Commonwealth. Additionally, all Managed Care Organizations (MCOs) were unanimously of the opinion that provider capacity had increased. The primary areas of concern identified through this evaluation process could be leveraged for sharpening Kentucky's on-going response to substance misuse through (1) prioritizing communication to providers around changes to reimbursement schedules and similar activities; (2) increasing education and training opportunities for providers, especially those in rural regions; (3) coordinating DMS accreditations with other current accreditation activities; and (4) investigating the potential impact of small changes to the reimbursement schedule to further incentivize provider participation.

However, it also is important to place this evaluation in the context of the impact of COVID-19, especially as it has affected the rate of accidental poisoning deaths, both in Kentucky and across the nation. Already prior to the advent of the pandemic, opioid-related deaths had increased by 6.6% among Kentucky residents from January 1, 2017, to March 31, 2020; fentanyl- and fentanyl analog-related deaths increased by 19.3%. Official accidental poisoning death counts for the year 2020 are not complete yet, but preliminary analyses show significant percentage increases over the previous year: overdose deaths increased by 11.4% from the second quarter of through the third quarter of 2020. Consequently, the mechanisms of the 1115 Demonstration project could be performing exactly as intended and yet the opioid-related deaths might still have increased due to the challenges of isolation and economic distress during the pandemic.

BACKGROUND

The Department for Medicaid Services (DMS) within the Kentucky Cabinet for Health & Family Services (CHFS) proposed a Substance Use Disorder (SUD/OUD) Demonstration project as a Section 1115 Demonstration Waiver project to expand ongoing efforts to address the opioid crisis. The proposal for the 1115 SUD/OUD Demonstration project was approved by the Centers for Medicare and Medicaid Services (CMS) on January 12, 2018. The implementation plan for the Demonstration was initially approved on October 5, 2018 with an amendment granted on November 4, 2019.

The purpose of the SUD/OUD Demonstration project is to "ensure that a broad continuum of care is available to Kentuckians with a substance use disorder (including an opioid use disorder [OUD])," with the primary goal of reducing overdose injuries and deaths. To achieve this purpose, Kentucky Medicaid implemented a plan to (1) increase beneficiary access to SUD/OUD providers offering treatment services and (2) expand SUD/OUD treatment benefits available to enrollees, thereby increasing utilization of SUD/OUD treatment services.

The central features of this Demonstration are:

6. increased access to SUD/OUD providers by assessing Medicaid SUD/OUD provider capacity at critical levels of care and certifying residential treatment providers according to nationally recognized standards for SUD/OUD treatment.

7. waiver of the Medicaid Institutions for Mental Disease (IMD) exclusion, allowing reimbursement for SUD/OUD treatment, crisis stabilization, and withdrawal management during short-term residential stays at certified IMD facilities with more than 16 beds.

8. expanded coverage of medication-assisted treatment (MAT, below referred to as "MOUD," or Medication for Opioid Use Disorder) services to include methadone.

Figure 1 below depicts a driver diagram illustrating the relationship between the purpose of the Demonstration, the primary drivers that contribute directly to realizing that purpose, and the secondary drivers necessary to achieve the primary drivers. This evaluation is focused on the mechanisms established with 1115 Demonstration as the methods to implement the secondary drivers. Later assessments will focus on the efficacy of the mechanisms in achieving the primary drivers and the purpose of the Demonstration via the secondary drivers.

Evaluation Activities

As the independent evaluator of the 1115 Waiver, Northern Kentucky University is undertaking ongoing analyses of the program. Three reports will be delivered during the term of the waiver:

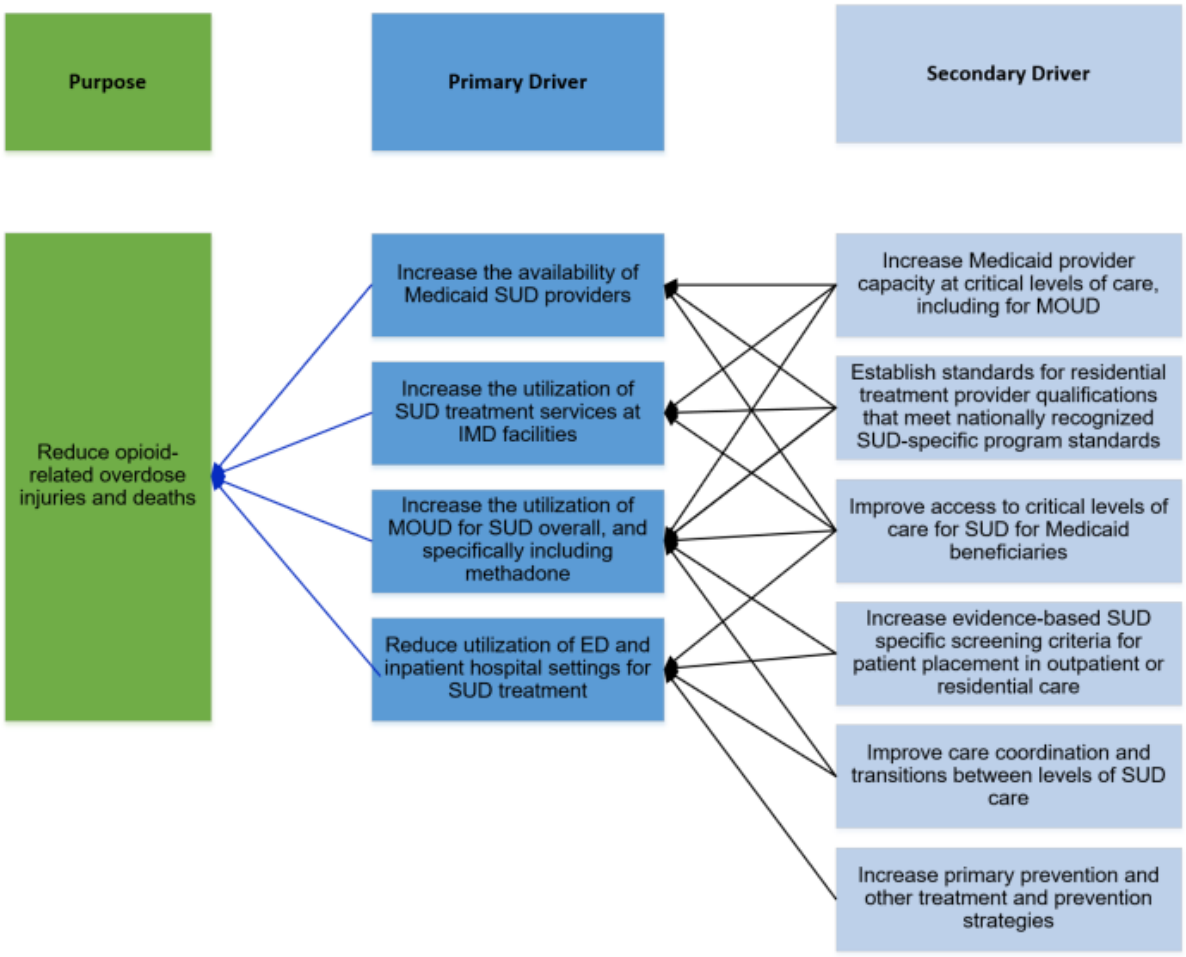
- Midpoint Evaluation (April 2021)
- Interim Assessment (January 2022)
- Final Assessment (July 2025)

In assessing the effectiveness of the 1115 waiver, the following hypotheses have been developed as part of the evaluation plan:

H1a: The Demonstration will increase the ratio of outpatient Medicaid SUD/OUD providers overall, and those specifically offering MAT and methadone as part of MAT, to beneficiaries in areas of greatest need.

H1b: The Demonstration will increase the ratio of SUD/OUD providers offering residential treatment, especially IMDs, to beneficiaries.

Figure 29. Driver Diagram



H1c: The Demonstration will increase the utilization of SUD/OUD services.

H1d: The Demonstration will decrease the rate of ED visits and inpatient admissions within the beneficiary population for SUD/OUD

H2a: Among beneficiaries receiving care for SUD/OUD, the Demonstration will decrease the rate of ED visits for SUD/OUD

H2b: Among beneficiaries receiving care for SUD/OUD, the Demonstration will reduce hospital readmissions for SUD/OUD care.

H3a: The Demonstration will decrease the rate of overdose deaths due to opioids.

In addition, based upon CMS recommendations, analyses will be conducted at three levels in evaluating the costs associated with the 1115 Waiver:

- Total expenditures
- SUD/OUD and non-SUD/OUD expenditures (with SUD/OUD expenditures disaggregated into IMD and non-IMD expenditures)
- Expenditures disaggregated by source of treatment—namely, inpatient expenditures, emergency department (ED) expenditures, non-ED outpatient expenditures, pharmacy expenditures, and long-term care expenditure.

Midpoint Evaluation

The Midpoint Evaluation must be submitted within 30 months of the award. The purpose of a midpoint evaluation is to provide an early assessment of the implementation of the Demonstration and a foundation for longer-term evaluation activities. It is a formative evaluation that examines both action steps and any short-term outcomes. The results of this evaluation should be used to adjust project operations, if needed.

This Midpoint Evaluation was conducted in collaboration with the stakeholders to ensure that the findings will influence the subsequent implementation activities and enhance the foundation for the longer-term evaluations. The hypothesis and cost questions are to be addressed in the Interim and Final Assessment Reports.

METHODOLOGY

As an evaluation of a particular program's operations, the Midpoint Evaluation will not produce generalizable research. No medical data were collected or analyzed as part of this evaluation. The stakeholders interviewed were professionals commenting on their understanding of system-level issues.

Methodological Limitations

This Midpoint Evaluation precedes the more formal Interim Assessment which is to be reported-out in eight months. The Interim Assessment will consist of formal hypothesis testing and cost analyses subject to statistical analyses and significance testing.

The methods employed in this Midpoint Evaluation are the application of two frameworks to develop an understanding of how the implementation of the Demonstration is proceeding, identification of modifications that could enhance or generally support the Demonstration, and identification of issues and data that could focus and refine the Interim and Final Assessments. The information gained from the stakeholder interviews and anecdotal observations are organized using the frameworks and subsequently reviewed to support outcomes of the evaluation. Thus, the Midpoint Evaluation methodology does not support empirical generalization at this point and should not be considered a rigorous assessment. Those are purposes of the Interim and Final Assessments.

Understanding the 1115 Demonstration in Context

Stakeholder groups within the Commonwealth had begun a variety of initiatives prior to the application for this 1115 Demonstration. It is therefore important to situate the midpoint evaluation within that statewide context to isolate the effects and understand interactions or synergies of the 1115 Waiver with other programs.

To do this, two analyses were developed:

- The first represents an overarching view of Kentucky's response to the opioid epidemic, and while 1115 Demonstration project mechanisms are mentioned, the scope is intended to be much broader than simply the 1115 Demonstration. This work is a product of a review of documents and interviews with stakeholders.

- The second focuses specifically on the 1115 Demonstration through an examination of narrow mechanisms that could be used for the first time or better exploited because of the 1115 Demonstration project, and how these mechanisms connect with other approaches being used or planned to fight the opioid epidemic in Kentucky. This analysis serves as a guide to how 1115 Demonstration mechanisms, in the context of other initiatives, might be expected to affect performance measures.

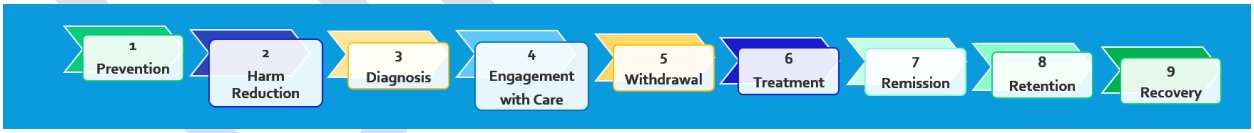
Two different methodological frameworks were used to develop the analyses. The Cascade of Care Model provides insight into Kentucky's global response to SUD/OUD and how the 1115 Demonstration project is embedded within the wide range of state, regional, and local initiatives. A SWOT Analysis (Strengths, Weaknesses, Opportunities, Threats) examines the relative impact of the 1115 Demonstration project with the context of Kentucky's particular Cascade of Care.

Cascade of Care Model Framework

A potential framework for understanding and measuring the efficacy of complex and multi-phasic care is via a Cascade of Care model, originally developed to measure HIV healthcare engagement and therapeutic follow-through. The HIV cascade framework established the primary components of care that ideal patients would follow. In sequential order, they are: (1) harm reduction, (2) diagnosis, (3) engagement with the healthcare system, (4) initiation of antiretroviral regimens, (5) viral suppression, (6) retention in care, and (7) sustained viral suppression. Important to this model is the notion that each component of the cascade must be activated in order to improve health. Only by moving through each component will individuals with HIV be successful in achieving a healthier outcome while reducing their risk to others.

A similar framework is available for evaluating care for persons with SUD/OUD. This organizational tool can assist in identifying gaps in the care continuum, provide a framework for data-driven resource allocations, and allow for benchmarking. The progressive stages of care we have identified for someone with SUD/OUD are (1) Prevention, (2) Harm Reduction, (3) Diagnosis, (4) Engagement with Care, (5) Withdrawal, (6) Treatment, (7) Remission, (8) Retention, (9) Recovery (see Figure 2).

Figure 30. Cascade of Care Model



Common across the HIV and the SUD/OUD Cascade of Care is that patients can often go undiagnosed for significant lengths of time, especially for those who are socially marginalized or with co-morbidities. In addition, both types of patients move can move back and forth or in and out of the care cascade – engaging in the healthcare system for a period of time and then disengaging or achieving viral suppression or remission and then stopping treatment regimes. And, in both cases, a failure to move from one component of the cascade to the next can signify a weakness or a barrier in the care cascade itself.

Identifying the potential challenges that individuals face at each stage of the cascade can pinpoint where efforts should be focused to maximize the impact of the care given. The Cascade of Care framework suggests that improving any single component in the care continuum will have only minimal impact on SUD/OUD remission or recovery, for navigating the entire continuum of care depends on overcoming multiple challenges, each of which can impact overall progression. Individuals who fail to overcome one barrier will not be able to engage in any of the subsequent components. Only by improving the entire

continuum of care by improving the transitions among all components will the proportion of persons with SUD/OUD who are in recovery be significantly impacted.

RESULTS: CASCADE OF CARE ANALYSIS

Table 1 below documents the goals for each stage in the SUD/OUD Cascade of Care, along with reported impediments to progressing through the stage for Kentucky citizens and the potential negative consequences for failure to progress through the stage. Successful interventions in the Care Cascade will minimize or eliminate the impediments to progression. The drivers of negative outcomes that the 1115 Demonstration project are projected to impact are bolded and italicized.

The Commonwealth of Kentucky, along with regional and local organizations, have initiated multiple intervention activities to disrupt the drivers for the negative outcomes. Three important initiatives at the state level include the 1115 Demonstration project, KORE programs, and the HEAL project. The 1115 Demonstration project is the focus of this review.

Kentucky's initiative associated with SAMHSA's State Targeted Response to the Opioid Crisis grant (or the Opioid STR grant) is the Kentucky Opioid Response Effort (KORE). Guided by the Recovery-Oriented Systems of Care Framework, the purpose of KORE is to implement a comprehensive targeted response to Kentucky's opioid crisis by sustaining and expanding access to a full continuum of high quality, evidence-based opioid prevention, treatment, recovery support services. Target populations include persons who have survived an opioid-related overdose, pregnant and parenting women, justice-involved individuals, children, transition-age youth, and families. KORE is aimed at addressing eight overarching goals:

(1) overdose prevention and naloxone distribution
(2) reducing opioid overprescribing and improving safe opioid use
(3) community-guided prevention
(4) harm reduction
(5) engagement and linkage to services
(6) access to FDA-approved medications for opioid use disorder
(6) reducing unmet treatment need
(7) recovery support
(8) provider education and training.

For the recent distribution cycles, KORE funding is allocated to major providers who will then manage distribution of funds and program implementation. The primary programming and initiatives funded through KORE are listed in Appendix B.

In 2019, the National Institutes of Health (NIH) launched the HEALing (Helping End Addiction Long Term) Communities Study. The University of Kentucky, in partnership with the Commonwealth, received one of the four HEAL grants and initiated a four-year, $87 million study aimed at reducing opioid overdose deaths by 40%. Kentucky HEAL seeks to address the opioid epidemic in a randomized study that includes 16 Kentucky counties acutely impacted by opioid abuse. The study leverages existing resources, initiatives, and community capacity to develop and implement SUD/OUD prevention, treatment, and recovery strategies and to develop evidence-based standards that can serve as a national model for reducing opioid mortality. As of 1 March 2021, selection of the particular strategies for each of the counties was not yet completed and full implementation of the strategies had not yet launched.

Table 45. SUD/OUD Cascade of Care in Kentucky

	STAGE	GOALS	POTENTIAL NEGATIVE OUTCOMES	DRIVERS OF NEGATIVE OUTCOMES
1	**Prevention**	Awareness of risk Increase in protective factors for substance misuse Abstinence except under medical supervision	Inappropriate opioid use Maladaptive coping skills resulting from misuse	***Inappropriate marketing by pharmaceutical companies*** ***Failure to follow best practices by prescribers*** Underlying Mental Illness/Severe Mental Illness Parental modeling/second generation environments Peer pressure among youth in middle and high school Schools lacking capacity/resources for education/prevention Genetic predisposition to addiction “Despair factors” Chronic pain Adverse childhood experiences

	STAGE	GOALS	POTENTIAL NEGATIVE OUTCOMES	DRIVERS OF NEGATIVE OUTCOMES
2	**Harm Reduction**	Reduced negative consequences for persons using opioids	Accidental poisonings Increased crime Family disruption Lack of self-sufficiency Hepatitis, HIV, endocarditis, especially for persons who inject drugs (PWID)	***Untrained or poorly trained providers (PCP's) or first responders*** Contaminated products Lack of screening Negative attitudes toward harm reduction practices Lack of access to harm reduction measures Barriers to acquiring naloxone
3	**Diagnosis**	Assessment of OUD Recommendation for treatment	Failure to diagnose Misdiagnosis	***Lack of diagnostic capability or expertise*** ***Failure to use evidence-based assessment tools*** Lack of access to assessment Lack of understanding around billing Stigma Lack of time in medical appointments Lack of administrative support

	STAGE	GOALS	POTENTIAL NEGATIVE OUTCOMES	DRIVERS OF NEGATIVE OUTCOMES
4	**Engagement with Care**	Connect individuals to appropriate level of care	Failure to recommend treatment Failure to connect user to a treatment provider Prioritizing penalties over treatment	***Lack of capacity*** Lack of transportation Negative attitudes toward OUD Lack of insurance/ability to pay Legal barriers for the justice-involved Lack of availability for those incarcerated or detained Fragmented care system Competing priorities for individuals with OUD
5	**Withdrawal**	Transition people off opioids with minimal personal disruption	Medically unsupervised withdrawal Failure to recommend Failure to complete	***Lack of education and training on the role of medically managed withdrawal*** Lack of transportation Lack of capability in criminal justice system Negative attitudes toward OUD Fragmented care system Poly-substance misuse

	STAGE	GOALS	POTENTIAL NEGATIVE OUTCOMES	DRIVERS OF NEGATIVE OUTCOMES
6	**Treatment**	Person with OUD initiates MOUD (medications for OUD) and behavioral therapy	Failure to recommend appropriate level of care Failure to connect user to treatment Return to use	***Lack of treatment capacity*** Lack of transportation Lack of insurance/ability to pay MOUD inconvenience Negative attitudes towards OUD Lack of availability Fragmented care system Dual diagnoses Homelessness/unstable housing Competing priorities for individuals with OUD
7	**Retention**	Person with OUD remains in treatment	Attrition from treatment Return to use	***Fragmented care system*** Lack of transportation Lack of insurance/ability to pay MOUD inconvenience Lack of availability Dual diagnoses Incarceration/detention Homelessness/unstable housing Interference with jobs/family responsibilities

	STAGE	GOALS	POTENTIAL NEGATIVE OUTCOMES	DRIVERS OF NEGATIVE OUTCOMES
8	**Remission**	Little or no opioid use	Return to use	***Inappropriate tapering of MOUD*** Negative attitudes toward OUD Lack of suitable housing Economic instability Community triggers Dual diagnoses Lack of recovery capital
9	**Recovery**	Self-sufficiency Social reintegration	Unemployment Unrepaired social networks Lack of stable housing Increased risk for returning to use	***Lack of recovery capital*** Negative attitudes toward OUD Lack of suitable housing Economic instability Community triggers Dual diagnoses

Table 2 crosswalks the stages in the SUD/OUD Cascade of Care with the 1115 Demonstration initiatives and additional KY DMS efforts to promote these initiatives, along with other major state-level programs supported primarily (though not exclusively) through KORE and HEAL. This table was developed by combining the conceptual framework for the 1115 Demonstration project as illustrated in Figure 1: Driver Diagram with stakeholder input on perceived goals. We note that these initiatives are also supplemented by multiple regional and local efforts which are unrecorded here. The additional state-level initiatives that directly support the 1115 Demonstration goals are bolded and italicized.

The 1115 Demonstration initiatives are the mechanisms by which the secondary drivers will be achieved. For clarity, Table 3 directly below Table 2 summarizes these initiatives or mechanisms as they pertain to the different stages of the SUD Cascade of Care.

It is important to note that any evaluation activity will be challenged in differentiating the impact of the 1115 Waiver mechanisms, DMS's efforts to support those mechanisms, and the italicized initiatives, as they are occurring concurrently and are directed toward identical goals. However, implementation mechanisms rarely occur without other supportive activities, so inability for finer-grained analysis is to be anticipated.

At the same time there are also additional initiatives (not listed) that promote progression across the SUD/OUD care stages that are extrinsic to the specific 1115 Demonstration goals for each stage. These initiatives address other negative drivers that impede progression (e.g., social determinants of health, dual diagnosis, stigma). A purely quantitative analysis of the beneficiary outcomes for each Cascade of Care stage will not be able to differentiate the impact of the1115 Demonstration initiatives and the additional initiatives, even as it does address the assessment hypotheses. (See Appendix C for the list of proposed quantitative assessment measures keyed to the Cascade of Care stages.) However, qualitative interviews with patients should provide some evidence regarding the causal connection between specific initiatives and outcomes.

This articulation of the interdigitation of the 1115 Demonstration mechanisms and efforts with the developed SUD/OUD Cascade of Care helps to both nuance and provide structure for the resultant SWOT analysis from stakeholder interviews. Stakeholder reactions and comments regarding the successes and challenges around the 1115 Demonstration activities must be filtered in light of the additional supporting initiatives as well as initiatives targeting other negative drivers the 1115 Demonstration project does not touch. That is, a purported success of an 1115 Demonstration support activity might well reflect the positive impact of an unrelated initiative. For example, waiving the IMD exclusion might only functionally increase access to residential care if helplines make appropriate referrals. Similarly, a purported weakness identified with a particular mechanism might actually reflect the interference of a negative driver for which an intervention unrelated to the 1115 Demonstration project has failed to blunt. For example, using evidence-based, SUD/OUD-specific placement criteria might not result in more patients receiving appropriate care due to mismanaged handoffs between referrer and care facility.

While we do not explicitly point out these secondary influencers that could be affecting stakeholder responses below, as we believe that we should report the actual stakeholder survey data as accurately as possible, in the interim and final assessments we shall be mindful of these potential impacts and tease out direct 1115 Demonstration effects from other potential contextual influences. Our final recommendations below assume that the additional initiatives that might impact SUD/OUD morbidity and mortality remains unchanged, and that the 1115 Demonstration project remains a significant initiative embedded with others.

Table 46. Crosswalk between SUD/OUD Cascade of Care and Kentucky Initiatives

STAGE	REQUIRED 1115 MECHANISMS	GOALS OF MECHANISMS	KY DMS 1115 SUPPORT EFFORTS	ADDITIONAL INITIATIVES
Prevention **and** **Harm Reduction**	Implement opioid prescribing guidelines	Increase primary prevention Disrupt inappropriate prescribing Impede "doctor shopping" Encourage responsible prescribing Reduce opioid intake Reduced adverse consequences of accidental poisonings Increase awareness of OUD	Encourage use of SAMHSA prescribing guidelines KASPER (Kentucky All Schedule Prescription Monitoring) user-interface enhancement Efforts to integrate interstate data	***Educational outreach to physicians, pharmacists, and community (KORE)*** ***Trainings to improve opioid prescribing safety and disposal (HEAL)*** Promote community engagement through coalitions (HEAL) Public health campaign to increase awareness of OUD (HEAL) Naloxone education and distribution (KORE, HEAL) Syringe exchange access programs (SAEP) (KY Health Departments [HD]) Education about harm (KY HD) Testing for complications for PWID (KY HD) State pharmacy map for naloxone (Ky Office of Drug Control Policy [ODCP]) Care coordination (KORE, HEAL) Annual Harm Reduction Summit
Diagnosis **and**	Use of evidence-based, SUD/OUD-	Improve access to critical levels of care	Added exception to Peer Support Specialist Service	***ASAM trainings (KORE)***

STAGE	REQUIRED 1115 MECHANISMS	GOALS OF MECHANISMS	KY DMS 1115 SUPPORT EFFORTS	ADDITIONAL INITIATIVES
Engagement with Care	specific placement criteria Protocol for placing patients at appropriate level of care	Improve patient placement Increase treatment retention Increase diversion from incarceration	requiring plan of care within 30 days of treatment in Bridge Clinics Screening and brief interventions (SBI) that do not meet criteria for referral to treatment may be covered Requirement for multi-dimensional assessment tool (ASAM) Requirement of *ASAM Criteria* across the treatment continuum (residential, partial hospitalization, IOP) ASAM certification requirement for BHSO and CMHC institutions enrolled in Medicaid DMS audits Requirement for MOUD on-site or facilitating off-site in residential treatment Waiver to provide Non-Emergency Medical Transportation for methadone treatment	***Train providers on Screening, Brief Intervention and Referral to Treatment (SBIRT) (KORE)*** ***Methadone clinics fund counselors*** ***Transportation reimbursement to methadone clinics (HEAL)*** Helplines DATA waiver trainings (HEAL) Gap coverage for individuals who cannot afford treatment (HEAL) Kentucky State Police Angel Initiative

STAGE	REQUIRED 1115 MECHANISMS	GOALS OF MECHANISMS	KY DMS 1115 SUPPORT EFFORTS	ADDITIONAL INITIATIVES
Withdrawal **and** **Treatment**	Use nationally recognized, SUD/OUD-specific program standards for provider qualifications Process of reviewing providers to ensure standards of care Access to critical levels of care for those with SUD/OUD Ensure sufficient provider capacity Waiver of IMD exclusion	Improve access to care Improve patient placement Increase safety of detoxification Increase utilization of MOUD Increase evidence-based services Increase provider capacity for SUD/OUD treatment	Authorized Medicaid coverage for appropriate treatment at multiple levels of care Expanded service planning to include SUD/OUD Added partial hospitalization in licensed organizations (BHSO) Management (WDM) to care Encouraged providers to become ASAM certified (will be required) Provided certification trainings DMS audits to ensure standards of care Eliminated prior authorization for MOUD	***Reimbursement education to providers (KORE)*** ***DATA waiver trainings (HEAL)*** ***Educate pharmacies on DEA regulations for carrying buprenorphine (HEAL)*** Helplines make referrals

STAGE	REQUIRED 1115 MECHANISMS	GOALS OF MECHANISMS	KY DMS 1115 SUPPORT EFFORTS	ADDITIONAL INITIATIVES
Retention **Remission** **and** **Recovery**	Implement policies to link inpatients to community-based services	Improve care coordination Increase support for treatment and recovery	Care coordination services for all patients in treatment centers Expand MOUD to include methadone	***Care coordination (KORE)*** ***Expand methadone clinic capacity (HEAL)*** ***Transportation reimbursement to methadone clinics (HEAL)*** Bridge primary care and SUD/OUD services (KORE) Advocate for recovery support groups to include those receiving MOUD (HEAL) Advocate for policy changes for access to Sublocade without prior authorization (HEAL) Gap coverage for individuals who cannot pay for treatment (HEAL)

Table 47. Demonstration Mechanisms and Cascade of Care Summary Chart

Mechanisms	Cascade of Care								
	Stage 1	Stage 2	Stage 3	Stage 4	Stage 5	Stage 6	Stage 7	Stage 8	Stage 9
	Prevention	Harm Reduction	Diagnosis	Engagement with Care	Withdrawal	Treatment	Remission	Retention	Recovery
Mechanism 1: Implement Opioid Prescribing Guidelines	X	X							
Mechanism 2: Use Evidence-Based, SUD/OUD-Specific Placement Criteria				X					
Mechanism 3: Protocol for Placing Patients at Appropriate Level of Care (LOC)				X					
Mechanism 4: Nationally Recognized SUD/OUD-Specific Program Standards for Provider Qualifications					X	X	X	X	
Mechanism 5: Use Process of Reviewing Providers to Ensure Standards of Care	X	X	X		X	X	X	X	
Mechanism 6: Provide Access to Critical Levels of Care for SUD/OUD					X	X			
Mechanism 7: Ensure Sufficient Provider Capacity					X	X	X	X	
Mechanism 8: Waiving the IMD Exclusion					X	X			
Mechanism 9: Implement Policies to Ensure Inpatients Are Linked to Community-Based Services							X	X	X

RESULTS: SWOT ANALYSIS

The SWOT analysis examines specific initiatives or mechanisms used to address key goals (the "secondary drivers" in Figure 1: Driver Diagram) of the 1115 Demonstration. These goals are:

1. Improve access to critical levels of care for OUD and other SUD/OUDs for Medicaid beneficiaries
2. Increase the use of evidence-based SUD/OUD screening criteria for patient placement in outpatient or residential care
3. Establish standards for residential treatment provider qualifications that meet nationally recognized SUD/OUD-specific program standards
4. Increase provider capacity at critical levels of care, including MOUD for OUD
5. Implement prescribing guidelines and other treatment and prevention strategies
6. Improve care coordination and transitions between levels of SUD/OUD care.

For clarity, Table 4 maps these goals, or secondary drivers, and the specific mechanisms utilized in the Demonstration from the Table 2 above.

Mechanism 1: Implement Opioid Prescribing Guidelines
Implementing opioid prescribing guidelines is a mechanism for impacting Prevention (Stage 1) and Harm Reduction (Stage 2)) in the SUD/OUD Cascade of Care Model.

The 1115 Demonstration activities for the implementation of opioid prescribing guidelines address one of the goals of the waiver:

- Implement prescribing guidelines and other treatment and prevention strategies.

As depicted in Table 5 below, at this midpoint of the Demonstration, clear actions have been taken for the Demonstration implementation. The establishment of clarifying prescribing guidelines and the supporting activities of state agencies and professional medical associations are both central to these activities. Managed Care Organizations (MCOs) have created Special Investigations Units help to monitor and report providers who may not be using best practices for prescribing opioids. However, clear guidelines are not fully backed by legislative authority and not all hospitals have signed on.

Education efforts are taking place to train more providers on these guidelines and to increase access to buprenorphine in hospitals and primary care facilities through the KY Statewide Opioid Stewardship program. These efforts include over 100 participating hospitals, with the potential to train up to 150 providers.

The creation of guidelines and the active use of KASPER, the Kentucky prescription drug monitoring program, has led to the dismantling of pill-mill operations that do not follow the guidelines. There is a risk that some of these entities may be repositioned as clinics specializing in Naloxone. Overall, there is a perception that there has been a disruption of "doctor shopping" through increased monitoring and clearer guidelines.

Access to care has increased as DMS covers all products within the class as required by the federal government. DMS has:

- Added a buprenorphine/naloxone tablet dosage form to the Preferred Drug List (PDL)
- Removed all Prior Authorizations (PAs) for buprenorphine/naloxone preferred products up to 24 mg.
- Removed PA for Vivitrol, making it a preferred drug.
- Removed PA for Sublocade, making it a preferred drug.

Table 48. Mechanisms and Secondary Driver Mapping

Mechanisms	Secondary Drivers/ Mechanism Goals					
	Increase primary prevention	Improve access to care	Improve patient placement	Increase provider capacity	Increase utilization of MOUD	Improve care coordination
Mechanism 1: Implement Opioid Prescribing Guidelines	X					
Mechanism 2: Use Evidence-Based, SUD/OUD-Specific Placement Criteria		X	X			
Mechanism 3: Protocol for Placing Patients at Appropriate Level of Care		X	X			
Mechanism 4: Nationally Recognized SUD/OUD-Specific Program Standards for Provider Qualifications			X	X	X	
Mechanism 5: Use Process of Reviewing Providers to Ensure Standards of Care	X		X		X	
Mechanism 6: Provide Access to Critical Levels of Care for SUD/OUD		X	X		X	
Mechanism 7: Ensure Sufficient Provider Capacity		X	X	X	X	
Mechanism 8: Waiving the IMD Exclusion		X	X	X	X	
Mechanism 9: Implement Policies to Ensure Inpatients Are Linked to Community-Based Services						X

A trade-off of the removal of prior authorization is a decrease in the ability to monitor high utilization. As well, their removal restricts DMS's ability to help steer patients/providers to the options that have the greatest clinical evidence, particularly while further evaluation of products within the same drug class is taking place (treating similar/same indication).

The relationship of these guidelines and activities to overdoses will be analyzed in the Interim and Final Assessments. However, recent data from non-Medicaid sources indicate a mixed picture. Test reports from Kentucky Injury Prevention Research Center (KIPRC) show data that may be skewed regarding overdose trends; statewide overdose-related deaths, ER visits related to overdoses, and overdose related hospitalizations declined 10-33% between 2017 and early 2020; however emergency medical services of suspected drug overdose-related encounters increased by 22% in the same period.
Similar to other regions, challenges continue within Kentucky with the use of other drugs such as methamphetamines and synthetic drugs such as fentanyl. Additionally, "pill-mills" continue to operate under the radar of state policies and monitoring capabilities.
Opportunities to be capitalized on during the Demonstration concerning prescribing guidelines focus on training, outreach, and legislative clarity. Interviews indicated that there is a need for increased education and training, particularly in rural counties. Initiatives by professional organizations and state agencies that encourage the use of the standards of practice by providers were also identified. On a policy front, opportunities include the consideration of the expansion of prescribing privileges to physician assistants and the assistance/encouragement to legislative authorities to clarify best practices based upon the evolving standards of care. A summary of the SWOT analysis for mechanism 1 is below in Table 5.

Table 49. SWOT Analysis on Implementing Opioid Prescribing Guidelines

Strength	Weakness
• Clear guidelines • Good partnership with MCOs • Strong support from KY DPH and Kentucky AMA • Increased provider training and associated patient access to buprenorphine • DMS covering all products within the federally defined class • Increased monitoring ability through KASPER (PDMP) • "Pill-mills" not following guidelines dismantled • Removal of prior authorization (PA) on Buprenorphine, Vivitrol, Sublocade	• Number of hospitals signed on clear guidelines • Lessened ability to monitor high utilization • Risk of over-prescribing by physicians • 22% increase in emergency medical services of suspected drug overdose-related encounters between 2017 and early 2020
Opportunity	**Threat**
• More education and training offerings to rural counties in Kentucky. • Evolving standards of practice to be more widely accepted by providers. • Help legislative authority to clearly outline details of best practices based on these evolving standards. • Expanding prescribing to physician assistants not currently covered under DMS regulations.	• Under the radar pill-mills • Increased use of other drugs, especially methamphetamines • Increased use of fentanyl • Removing PAs restricts ability to steer patients/providers to the options with the best clinical evidence

Mechanism 2: Use Evidence-Based, SUD/OUD-Specific Placement Criteria

The use of evidence-based, SUD/OUD-specific placement criteria is a mechanism for impacting Engagement with Care (Stage 4) in the SUD/OUD Cascade of Care Model.

The 1115 Demonstration activities for this mechanism address two goals of the waiver:

- Improve access to critical levels of care for OUD and other SUD/OUDs for Medicaid beneficiaries.
- Increase the use of evidence-based SUD/OUD screening criteria for patient placement in outpatient or residential care.

The research undertaken for this evaluation indicates performance improvement in evidence-based, SUD/OUD-specific placement during the early phase of the Demonstration. More treatment facilities have become certified by ASAM (American Society of Addiction Medicine), allowing facilities to place those with SUD/OUD at appropriate levels of care. There is not a standardized 6-dimensional assessment tool used by all providers; however, in a supporting policy initiative, the requirements to utilize ASAM criteria and 6-dimensional assessment tool have been added to the State Plan Amendment (SPA) across all the levels of care. Residential Crisis Stabilization Units (RCSU) regulations had to be refiled; ordinary regulations will not be effective until summer or fall 2021. The CMHC Manual has not been filed. BHSO and MSG ordinary regulations were effective January 2020. Due to the different regulatory filings, the requirement to utilize ASAM Criteria across all provider types varies among providers.

Pilot programs in larger healthcare networks throughout the state have integrated mental health/SUD/OUD screening into primary care practices. There appears to be increased participation in education/training regarding assessing patients and making referrals during initial phases of treatment. Respondents also indicated that there are increased referrals from the ED for patients identified as having SUD/OUD.
During the provisional certification desk audit associated with the waiver, providers' assessment tools and policies were reviewed. Provisional certification only included residential providers and is not a requirement. Therefore, not all providers are captured in the desk review process.
Stakeholders report that there are substantial economic challenges, and that there is no incentive for treatment centers to become certified. The MCOs' approach to incentivize programs and conduct outreach could be considered for enhancement. The approach is perceived as fiscally challenging for providers with large Medicaid populations due to reimbursement levels. Medicaid reimbursement may also be a barrier to sufficient inpatient treatment stays for some patients. However, we note that to incentivize providers to participate in the provisional process and early preparation for the ASAM Certification, DMS has allowed increased residential payment and waived IDM exclusion for reimbursement beyond 16 beds for these programs who participate in certification. Additional communication to providers on incentives could be considered.

Referring parties play a critical role in SUD/OUD-specific placements. For providers, the referral criteria are not fully accepted, and respondents indicated that there is a need for further provider training and technical support, including change management. Checklists and other handouts for referring parties were also recommended. Referrals for the justice system have special challenges. Drug courts are effective but overburdened, and it may not be possible to bring them to scale. Respondents suggested special training on SUD/OUD throughout the Kentucky Judicial College.

Finally, elimination of Prior Authorizations (PA) due to COVID has made monitoring evidence-based practices difficult. A summary of the SWOT Analysis for mechanism 2 is below in Table 6.

Table 50. SWOT Analysis on Evidence-Based SUD/OUD-Specific Placement Criteria

Strengths	Weaknesses
• More ASAM-certified treatment facilities • Pilot programs integrating mental health/SUD/OUD screening into primary care practices • Increased participation in the initial phases of treatment • Increased referrals from ED for patients diagnosed with SUD/OUD • ASAM criteria and 6- dimensional assessment tool added to SPA across all the levels of care • Providers' assessment tools and policies reviewed during the provisional certification desk audit	• No perceived incentive for treatment centers to become certified by providers • No standardized 6-dimensional assessment tool used by all providers • Not all providers captured in the desk review process • Coordination difficulties from referring party to provider • Reimbursement levels create financial challenges for provider • Variability in judges' responses • Few incentives in some communities for persons with SUD/OUD to seek treatment • Drug courts overburdened and hard to scale
Opportunities	**Threats**
• Incentivizing programs to create increased provider interest • Including follow-up post-ED as metric for those with SUD/OUD • Training providers regarding criteria, and how to utilize and support organizational change • Developing checklists for referring parties • Special training on persons with SUD/OUD for Kentucky Judicial College	• Degree of acceptance by referring providers • Limited provider capacity in rural areas • Medicaid reimbursement has become a barrier to sufficient inpatient treatment stays • Limitations imposed by policies and regulations on RCSU filing for ASAM criteria • Removal of PA during COVID

Mechanism 3: Protocol for Placing Patients at Appropriate Level of Care (LOC)
Implementing protocols for placing patients at appropriate levels of care is a mechanism that also impacts Engagement with Care (Stage 4) in the SUD/OUD Cascade of Care Model.

The 1115 Demonstration activities for this mechanism supports two of the goals of the 1115 Demonstration:

- Improve access to critical levels of care for SUD/OUD for Medicaid beneficiaries.
- Increase use of evidence-based SUD/OUD screening criteria for patient placement in outpatient or residential care.

Table 7 provides a summary for this Mechanism. The overall driving factor in placing patients at the appropriate level of care through the use of the protocols has been the increased acceptance of MOUD for the treatment of SUD/OUD. Challenges appear consistent with other mechanisms: economic/financial, regional differences, care coordination, and justice-involved individuals/corrections.

Respondents indicated that training offered by DMS in understanding level of care requirements and reimbursements as being important in addressing the financial challenges. Consistent with other mechanisms, Medicaid reimbursement was identified as the primary economic challenge, particularly for providers with large Medicaid populations. The MCO requirement of using ASAM criteria be applied to

utilization management when determining medical necessity and prior authorization (PA) for services is addressing the economic and associated capacity issues. However, inconsistencies in authorizations due to lack of standardized assessment tools and prior authorization requirements continues to be reported. In addition, the elimination of Prior Authorizations (PA) due to COVID has made monitoring protocols for placing patients at appropriate LOC difficult; depth of clinical updates is limited. Since elimination of PAs, MCOs have seen increase in inpatient stays that are 28 days or longer without clear evidence of clinical need.

Other identified actions that can support LOC appropriateness were:

- Additional ASAM trainings for both MCOs and providers
- Improves communication among MCOs, DMS, and providers to ensure providers are appropriately reimbursed
- Uniform usage of standardized assessment tool for utilization – which is being addressed by the SPA requirement of a uniform assessment tool

Transitions in care are an additional challenge to appropriate LOC. Capacity limitations (lack of access) may influence which LOC patient is placed for treatment, thereby creating a risk of mismatch between LOC and patient need. Retention in services for patients placed at appropriate LOC is an ongoing issue. Respondents indicated that appropriate dual diagnoses could assist with this challenge. Patient engagement during transitions may be overlooked during handoffs, as a consequence of the relative availability and convenience of initial assessments and fit with daily living.

Table 51. SWOT Analysis on Appropriate Level of Care (LOC)

Strengths	Weaknesses
• Reported increased retention in services for patients placed at appropriate LOC • Increased acceptance of MOUD • Training offered/provided through DMS • MCO on ASAM criteria • Training utilization management staff on ASAM criteria and placement • Required 6-dimensional assessment tool by State Plan Amendment and regulation	• Capacity limitations (lack of access) • Transitions between services or initial links to service • Patients' frustrations with handoffs • Sparse populations/payment structures/attitudes of providers • Reimbursement levels for providers with large Medicaid populations • Variances in approvals • No resources to provide MOUD in detention centers • No assessment offered in most jails
Opportunities	**Threats**
• Providing incentive to build provider capacity • Providers could travel to neighboring communities to initiate MOUD • Additional ASAM trainings for both MCOs and providers • Improving communication between MCOs and DMS • Standardized assessment tool • Exploring unintended consequences for providers	• Persisting notion that abstinence is best • Providers unwilling to live in high need communities • Difficult clients • Inconsistencies in authorizations • COVID-19 impacts on PAs

• Extending medical supervision of prisoners to short-term jails • Medicaid availability for persons in custody	

Justice-involved individuals and corrections were a focus of discussions concerning placing patients at the appropriate LOC. Kentucky's short-term detention centers – where most people sentenced to less than five years serve their sentences – have no resources or budget to provide or oversee MOUD. Most such jails reportedly do not even offer assessments. Justice-involved individuals who are in custody but who have not been convicted are not covered by Medicaid. Overall, there is a greater need for integration of this population with Medicaid services when possible.

Mechanism 4: Nationally Recognized SUD/OUD-Specific Program Standards for Provider Qualifications

Using nationally recognized SUD/OUD-specific program standards for provider qualifications is a mechanism for addressing Withdrawal (Stage 5),Treatment (Stage 6), Remission (Stage 7), and Retention (Stage 8) in the SUD/OUD Cascade of Care Model.

This mechanism addresses three of the goals of the 1115 Demonstration Waiver:

7. Increase use of evidence-based SUD/OUD screening criteria for patient placement in outpatient or residential care.
8. Establish standards for residential treatment provider qualifications that meet nationally recognized SUD/OUD-specific program standards.

Increase provider capacity at critical levels of care, including MOUD for OUD.
While ASAM provider qualifications pushed back to 2022, certification has improved in the past two years due to education and training. Effective communication and training provided by DMS has helped to educate MCOs and providers alike on specific ASAM criteria.

Table 8 provides a summary of the principal considerations around this mechanism dealt with the access to and burden of training, changes in workflow, and reimbursement for additional services.
Inconsistencies were reported in the application of the standards in a practice due to lack of specifics related to ASAM criteria. While reimbursement levels have increased, training remains a challenge, especially in the rural counties. More focus in the training is needed around how to utilize the criteria and how to support organizational change through collaborating agencies. Finally, the standards can be difficult to enforce due to capacity issues.

Table 52. SWOT Analysis on Using Nationally Recognized SUD/OUD-Specific Program Standards for Provider Qualifications

Strengths	Weaknesses
• Increased reimbursement of services • Requirement for ASAM criteria added to SPA • Good DMS communication with MCOs	• Lack of access to training in rural counties • Lack of clarity of practice • Need for more detailed materials on how to apply ASAM criteria

Opportunities	Threats
• Additional training for providers • Updating regulations to reference to ASAM criteria.	• Difficult to enforce • Diverse interpretation of the criteria • CEUs seen as a burden by providers

Mechanism 5: Use Process of Reviewing Providers to Ensure Standards of Care
Using the process of reviewing providers to ensure standards of care is a mechanism for addressing Prevention Stage 1), Harm Reduction, (Stage 2), Diagnosis (Stage 3), Withdrawal (Stage 5), Treatment (Stage 6), Remission (Stage 7), and Retention (Stage 8) in the Cascade of Care Model.

This mechanism addresses three of the goals of the 1115 Demonstration Waiver:

9. Increase use of evidence-based SUD/OUD screening criteria for patient placement in outpatient or residential care.
10. Increase provider capacity at critical levels of care, including MOUD for OUD.
11. Implement prescribing guidelines and other treatment and prevention strategies.

Kentucky is requiring ASAM LOC Certification through regulation changes, thereby directly supporting this mechanism. The regulation changes include a DMS process to provisionally certify programs to ASAM LOC to bridge the gap between the ASAM launch and providers successfully meeting the requirement. The process allows providers to perform a self-evaluation of the services they provide and whether they meet ASAM criteria, which allows for the opportunity to engage with providers regarding expectations and opportunities. However, self-evaluation also promotes a lack of rigor in the provisional certification process. Stakeholders suggested that enhanced rates for early adoption of ASAM certification could be provided, helping providers with the fees associated with preparing for the certification, or possibly making program/staffing changes to meet LOC. However, we note that residential reimbursement for provisionally certified or ASAM certified providers on April 1, 2020. Perhaps additional communication about this opportunity to providers could be considered.

MCOs have created special units to help monitor and report on providers who may not be using best practices for prescribing opioids. DMS has included MCOs in provider forums to allow for more effective communication.

There are two important challenges to this initiative. The first concerns measuring adherence and performance relative to standards of care. This is an inherent problem, and the collection of data has been particularly difficult due to COVID-19. There have been limited responses to provider surveys or other forms of feedback. Data on providers within integrated delivery networks have been a particular issue. Additionally, there is a lack of capacity to audit more programs by the DMS Behavioral Health (BH) team. There is a missed opportunity when BH team members are not being trained to certify programs.

Finally, there were some concerns raised about removing CARF from BHSOs, which could perhaps lead to a resurgence in “pill mill” operations. However, note that accreditation is still a requirement for BHSOs and has not been removed, so some misinformation exists within the provider community. These factors are included in the summary presented in Table 9.

Table 53. SWOT Analysis on Reviewing Providers to Ensure Standards of Care

Strengths	Weaknesses
• Provides accountability for quality of care • Requiring ASAM LOC Certification by DMS • Provisionally certifying programs to ASAM LOC	• Limited responses to surveys • Difficult to access data on provider networks • Lack of rigor in provisional process

• Self-evaluation by providers allowed • Effective partnership with MCOs	• Inherently difficult to know whether providers follow a standard of care
Opportunities	**Threats**
• Ongoing communication with providers • Enhanced rates for providers	• Outreach efforts difficult during pandemic • Lack of capacity to audit programs • BH Team members not trained to certify programs • Increase in pill-mill operations because of the removal of CARF from BHOs • Extending the date of self-attested provisional certifications due to Public Health Emergency • Removal of PA

Mechanism 6: Provide Access to Critical Levels of Care for SUD/OUD
Providing access to critical levels of care for SUD/OUD is a mechanism for addressing Withdrawal (Stage 5) and Treatment (Stage 6) in the SUD/OUD Cascade of Care Model.

This mechanism addresses three of the goals of the 1115 Demonstration Waiver:

12. Improve access to critical levels of care for OUD and other SUD/OUDs for Medicaid beneficiaries.
13. Increase the use of evidence-based SUD/OUD screening criteria for patient placement in outpatient or residential care.
14. Increase provider capacity at critical levels of care, including MOUD for OUD.

This mechanism is focused on access to evidenced-base care. Findings are summarized in Table 10. The 1115 Demonstration appears to expand access to care. Stakeholders report an expansion of services, including medically supervised withdrawal management and methadone treatment, as well as more MOUD referrals. In addition, residential treatment centers (RTCs) have expanded intensive levels of care for SUD/OUD patients, especially in the rural areas. As previously discussed, the Commonwealth is facilitating the coverage of all levels of care through SPA and regulation changes and public health and education activities.
This environment provides for the opportunity to enhance coordination across stakeholders including better integration between larger systems and smaller and lower-level providers, as well as increased opportunities for engagement across most transitions across the Care Cascade. Access to capital for system expansion is a potential area of risk for care expansion.

Barriers to care are well documented, including housing insecurity, transportation, stigma, and reimbursement complexity. These remain as unaddressed challenges. Stakeholders raised some concerns regarding Corrections ability to implement evidence-based practices with fidelity.

Table 54. SWOT Analysis on Access to Critical Levels of Care for SUD/OUDs

Strengths	**Weaknesses**

• Expansion of services • More RTCs in rural areas • Utilization of centralized operations by some healthcare networks • Public health campaigns/education efforts • Increased opportunity for engagement • All levels of care covered by DMS through SPA and regulations changes	• Long-term stays covered for maximum of 90 days • Difficult to access to capital for expansion • Varying licensure and DMS regulations requirements
Opportunities	**Threats**
• KORE funding for inpatient stays not covered by Medicaid • Strengthening recovery support systems • Increase public service announcements and web-based outreach • Increase partnerships among high-level and lower-level treatment providers • Improve communication among MCOs, DMS, and providers • Potential partnerships with healthcare networks and investment firms	• Complexity in reimbursement across MCOs • Pandemic impacting referrals • Provider misconceptions about DEA regulations • Transportation/access to treatment • Corrections failing to implement evidence-based practices • Gap in coverage due to licensure and DMS regulation inconsistencies

Mechanism 7: Ensure Sufficient Provider Capacity
Ensuring sufficient provider capacity is a mechanism for addressing Withdrawal (Stage 5), Treatment (Stage 6), Remission (Stage 7), and Retention (Stage 8) in the SUD/OUD Cascade of Care Model.

This mechanism addresses four of the goals of the 1115 Demonstration Waiver:

15. Improve access to critical levels of care for OUD and other SUD/OUDs for Medicaid beneficiaries.
16. Increase the use of evidence-based SUD/OUD screening criteria for patient placement in outpatient or residential care.
17. Establish standards for residential treatment provider qualifications that meet nationally recognized SUD/OUD-specific program standards.
18. Increase provider capacity at critical levels of care, including MOUD for OUD.

Note: the measurement of provider capacity does itself not address a goal of the 1115 Demonstration. However, indirectly, it is a measurement of easing constraints to access and provides an understanding of the baseline or capacity for care and treatment alternatives. Thus, it is addressed in hypothesis H1a as a foundational and control measure for assessing the increase in the number of individuals treated..

As described in Table 11, this mechanism is being addressed on several fronts. The first is through a better understanding of service characteristics. CHFS is locating and understanding geographic and treatment level gaps in service, despite there being low provider responses to surveys and other data gathering initiatives. Through a combination of policy initiatives and programs, there has been a statewide push for MOUD, an increase in licensed behavioral health providers, and continued RTC growth in rural counties. Waiving the Institutes for Mental Disease (IMD) exclusion has led to an increase in residential treatment. Covering methadone resulted in the successful enrollment in all Narcotic Treatment Programs (NTPs) by 2019. MCO's have seen significant increase in inpatient admissions in the last two years.

Challenges continue to be a shortage of qualified licensed providers to meet demand as well as insufficient reimbursement levels. Potential responses to these challenges include incentives to achieve ASAM certification and expanding prescribing privileges to physician assistants.

Table 55. SWOT Analysis on Ensuring Sufficient Provider Capacity

Strengths	Weaknesses
• Analysis of service gaps • Support for buprenorphine education/implementation • Increase in licensed behavioral health providers. • Increase in RTC services in rural counties • Increase in residential treatment • Enrollment of all NTPs • Added coverage for medically monitored inpatient services to SPA and regulations	• Low response rates to data gathering activities by providers • Too few qualified providers to meet demand
Opportunities	**Threats**
• Incentivizing programs for increased provider enrollment by KY MCOs • Including transitional living or recovery housing in LOC • Expanding prescribing to physician assistants	• Lack of counselors and licensed clinicians • Enrollment deterred by stigma or previous experience treating SUD/OUD patients • Lack of Medicaid reimbursement if providers fail to receive ASAM certification

Mechanism 8: Waiving the IMD Exclusion
Waiving the IMD exclusion is a mechanism for addressing Withdrawal (Stage 5), and Treatment (Stage 6) in the SUD/OUD Cascade of Care Model.

This mechanism addresses three of the goals of the 1115 Demonstration Waiver:

19. Improve access to critical levels of care for OUD and other SUD/OUDs for Medicaid beneficiaries.
20. Increase the use of evidence-based SUD/OUD screening criteria for patient placement in outpatient or residential care.
21. Increase provider capacity at critical levels of care, including MOUD.

Waiving the IMD exclusion allows for reimbursement for crisis stabilization, withdrawal management, and SUD/OUD treatment during short-term residential stays at certified IMD facilities with more than 16 beds. Concomitant with this change, language was added to SPA and regulation to require residential providers to provide MOUD or to facilitate MOUD off-site, if they do not provide it on-site; and prior authorization for extended-release buprenorphine was removed. These ancillary supports helped to increase expansion. At the same time, in some regions there continues to be and a shortage of doctors for the initial in-person in-take evaluation as well as limited capacity for treatment. To assist with the latter, KORE and HEAL have allocated funds to hire additional counselors.

Stakeholders report that some persons have not been able to continue with their MOUD as they moved into an IMD facility. They have had difficulties ascertaining whether faith-based programs are in compliance with requirements and whether off-site access is supported by all IMD facilities.

There were also concerns raised about potential abuses or misuses of this mechanism as it is difficult to monitor practices occurring in inpatient facilities. Perhaps unscrupulous providers might both bill Medicaid and charge patients' exorbitant monthly fees, while prescribing the highest possible doses of MOUD, or a focus on abstinence might lead to early termination of programs.

Justice remains a consistent theme, both negatively and positively. Stakeholders expressed concern about the amount of misinformation courts have, especially regarding MOUD, which can lead to sub-optimal treatment recommendations. But they also saw opportunities to connect inmates with resources and treatment more effectively and at a lower cost.

Summary findings for this mechanism are presented in Table 12.

Table 56. SWOT Analysis Waiving the IMD Exclusion

Strengths	Weaknesses
• Removal for prior authorization for extended-release buprenorphine • Catalyst for ancillary supports to help with expansion efforts • Language in SPA and regulation to require MOUD • Provisional certification desk audits include questions about providers' ability to provide MOUD and relationship with a prescriber	• Limited capacity for treatment in some areas • Lack of doctors for required in-person initial evaluations • Persons are not always able to continue receiving methadone • Confirming faith-based programs are compliant with requirements • Confirming facilities are providing the off-site MOUD
Opportunity	**Threat**
• Additional funding for methadone clinics to increase capacity • Treat detainees before release • Encourage relationships among residential and NTP providers to expand patient choice • Improve payment mechanisms for justice-involved persons • Pre-release connection of inmates with services • Provider "scorecards"	• Unscrupulous providers • High turn-over among providers • Misinformation within court systems leading to detrimental outcomes • Focus on abstinence may lead to early termination of treatment services. • Difficult to ensure that individual can remain on their treatment medication choice • Limited ability to monitor facilitation within inpatient facilities

Mechanism 9: Implement Policies to Ensure Inpatients Are Linked to Community-Based Services
Implementing policies to ensure inpatients are linked to community-based services is a mechanism for addressing Remission (Stage 7), Retention (Stage 8), and Recovery (Stage 9) in the SUD/OUD Cascade of Care Model.

This mechanism addresses the following goal of the 1115 Demonstration Waiver:

- Improve care coordination and transitions between levels of SUD/OUD care

A focus on care coordination across levels/types of care, as opposed to targeted case management, has helped to bridge referral gaps. Findings for this mechanism are listed in Table 13. It seems to have helped to strengthen ancillary efforts in the Commonwealth, whether by filling other service gaps or acting in tandem with 1115 mechanisms. However, because some ancillary support programs are not evaluated, it is difficult to measure the value-add.

While the pandemic has made follow-through more challenging, it has also demonstrated that technology can provide virtual assistance in connecting individuals to services, whereas before an on-site presence was required. This shift in modality offers possibilities for easier expansion of care coordination activities. However, increase in care coordination has also revealed a lack of adequate recovery support systems in some communities and vulnerabilities in grant-funded (and therefore, time-limited) support systems.

Again, the justice system presented as a theme. Probation officers and other correctional reform employees appear to be unfamiliar with available resources and how to connect newly released inmates to Medicaid, as that is suspended during incarceration. Incarceration/recidivism cycles lead to compassion fatigue and burnout among helping professionals, including care coordinators.

Table 57. SWOT Analysis on Implementing Policies to Ensure Inpatients Are Linked to Community-Based Services

Strengths	Weaknesses
• Bridges referral and service gaps • Improved patient-provider communication • Added care coordination language to SPA and regulations requiring care coordination • Follow-up appointments required post-discharge in MCO contracts • Transportation and other treatment support for justice-involved persons	• Some ancillary support programs lack evaluation • Difficult to measure a successful recovery • Mismatch between billing codes and services provided
Opportunities	**Threats**
• Advocating for SUD/OUD treatment and support in correctional institutions • Educating providers on care coordination requirements • Improving technologies to connect people to services • Improve communication among MCOs, DMS, and providers around billing	• Lack of adequate recovery support systems • Time-limited supports • Transient population • Compassion fatigue/burnout • Correctional employees unfamiliar with resources • Suspension of Medicaid during incarceration • Pandemic made follow-through more difficult • Duplication of services • No monitoring mechanism; claims data do not include discharge data.

CONCLUSIONS

The goal of the midpoint evaluation is to inform decision-making about how to improve Kentucky's response to the opioid epidemic by more effectively exploiting available 1115 Demonstration mechanisms in support of that goal.

Below we discuss several themes identified through this evaluation process that could be useful for sharpening Kentucky's on-going response to substance misuse, along with some possible alterations in practice or policy that could help alleviate some perceived challenges and barriers.

Policies and Regulation

The comprehensive response by the Commonwealth in addressing evidence-based treatment through public policies and evolving regulation was a consistent theme throughout the evaluation. This includes changes to prior authorization requirements, changes to regulations, policies supporting engagement and education, and standardization and coordination of actions across departments and cabinets. Recommendations resulting from subsequent assessments of the 1115 Demonstration are likely to require continued proactive policy responses. Nonetheless, Kentucky should be applauded for thoroughness in which it has implemented complementary supports for the 1115 Demonstration.

At the same time, resource constraints for the implementation of these supporting activities were the principal concern identified by stakeholders. However, it appears that at least some of these concerns have been addressed through additional DMS actions and additional communication to providers around reimbursement and related changes might be advised.

Justice-Involved Persons with SUD/OUD

Key informants from multiple systems believe there is a gap for persons involved in the criminal justice system between the SUD/OUD services they need and those they are able to receive. Since the inception of the ACA, about 15 states have applied for the addition of a Justice-Involved 1115 Waiver Initiative and 13 states are currently implementing them. Kentucky has applied for a similar waiver but has yet to hear whether its application has been approved. However, its supportive actions, including reimbursement, intervention and treatment for pre-trial detainees, and increased services connecting to inmate's pre-release, go beyond what other states are implementing.

The following programs were raised by stakeholders for consideration for implementation:

- Reimbursement for case management services helping to link offenders to social support and health services.
- Early intervention and treatment for pre-trial detainees by utilizing collaborative efforts between healthcare systems and law enforcement with an incentivized payment model that increases reimbursement to those who serve greater numbers of Medicaid/ uninsured individuals and to those who achieve milestones/appropriate outcomes.
- Education and outreach around the nature of SUD/OUD, the promise of MOUD, and innovative models for connecting inmates to services pre-release.

However, no recommendations for change with the justice-involved population are possible until the status of the Demonstration amendment is resolved.

Education and Training

A third consistent response from multiple key informants was the need for both increased and targeted education for providers. Incenting the training programs remains a challenge, as does reaching those in rural regions – who are most in need of technical assistance.

The following topics were raised by stakeholders as knowledge areas that need further development in providers:

- Buprenorphine use and management
- Referral criteria
- Change management
- ASAM
- Care coordination requirements

Reducing Complexity

A fourth theme that emerged was the increased complexity that comes with adopting ASAM and other standards. A central issue is how these new criteria will be folded into current accreditations.

Here are a few suggestions for possibilities of reducing overhead on providers:

- Coordinate DMS accreditations with those of CARF and COA to reduce demands on providers.
- Subsidize a standardized ASAM-consistent six-dimensional assessment tool, perhaps a computer-guided version (e.g., ASAM Co-Triage®) to promote provider adoption.

Reimbursement

A final theme that emerged was the issue of reimbursement for providers who serve large numbers of Medicaid clients. We appreciate that this is an on-going issue and not specific to this 1115 Demonstration project. However, several stakeholders did raise the possibility that reimbursement and payment challenges disincentivized providers from participating more fully. It might be worth investigating whether some small changes in reimbursement schedules might make wider adoption of these measures more palatable.

MIDPOINT EVALUATION METHODOLOGY

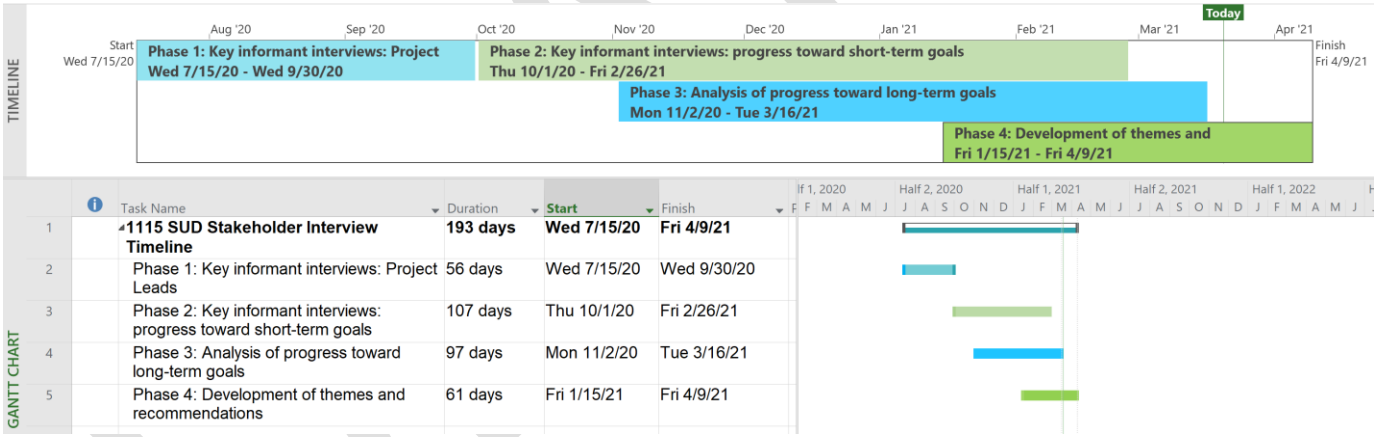
The purpose of this evaluation is to provide an early assessment of the implementation of the Demonstration and a foundation for longer-term evaluation activities. It is a formative evaluation that examines both action steps and any short-term outcomes. The results of this evaluation should be used to adjust project operations, if needed.

This Midpoint Evaluation was conducted in collaboration with the stakeholders to ensure that the findings will influence the subsequent implementation activities and enhance the foundation for the longer-term evaluations. As an evaluation of a particular program's operations, it will not produce generalizable research.

The stakeholders interviewed were professionals commenting on their understanding of system-level issues. Stakeholder interviews accorded in two overlapping waves. The focus of the first set of interviews establishment the Cascade of Care Model components and the second specifically focused on the SWOT analysis. The accrual methodology consisted of a snowball sampling technique built from an initial purposive sample group.

The four essential elements of the evaluation procedure and the timeline of their implementation are captured below in Figure 3, with a detailed description of each element following.

Figure 31. Project Timeline



Phase 1: Key informant interviews: Project Leads (July 15, 2020 – September 30, 2020)

Beginning with the state team leaders, the Midpoint Evaluation team conducted key informant interviews with members of the state team and people they recommended we consult. The purpose of these interviews was to:

- Identify, for each planned action (listed below in Table 14), the initiative owner and a small number of other key stakeholders who can be expected to have insight into the impact the planned action has had on the system of care.
- Identify other initiatives across the Commonwealth that are directed to or supportive of the same goals as the 1115 Waiver.
- Identify stakeholders who should be involved in reviewing our MPE report later in the process.

Table 14: Implementation Actions

Implementation Actions	
1	Amend state plan to include coverage of SUD/OUD treatment planning
2	Amend state plan to include coverage of methadone
3	Amend service definitions to include withdrawal management
4	Amend state plan to require SUD/OUD providers to use ASAM's 6-dimensional assessment
5	Amend state plan to include care coordination definition of residential SUD/OUD treatment
6	Amend regulations to include partial hospitalization as allowable for BHSOs
7	Certify residential treatment providers at recognized standards for SUD/OUD treatment
8	Expand coverage of MOUD to include methadone
9	Establish standards for residential treatment provider qualifications
10	Implement prescribing guidelines and other treatment and prevention strategies
11	Waive Medicaid Institutions for Mental Disease (IMD) exclusion

Phase 2: Key informant interviews: Progress toward short-term goals (October 1, 2020 and February 26, 2021)

The MPE team built a database with each planned action, its target date, the short-term goal(s) it was intended to bring about, the current state of the system, obstacles encountered, adjustments made to implementations plans, and what has been learned to date using data collected via interviews (or email exchanges) in October of 2020 and again in February 2021.

A total of 24 stakeholders were interviewed, with interviews lasting an average of 60 minutes. Job titles included:

- Care Coordinator
- Chief of Police
- Chief of Services at NorthKey Community Health
- Director of KORE
- Director of the Institute for Pharmaceutical Outcomes and Policy at the University of Kentucky
- DMS Behavioral Health Specialist
- DMS Chief Analytics Officer
- DMS Senior Behavioral Health Policy Advisor
- Executive Director for the Kentucky Office of Drug Control Policy
- MD practicing Addiction Medicine and Behavioral Health
- Medical Director for Department for Behavioral Health, Developmental, and Intellectual Disabilities
- Senior personnel at Addiction Recovery Care
- Senior personnel at WellCare
- Principal Investigator of NIH Kentucky HEALing Communities Study
- Probation/Parole Officer
- Senior Director of Behavioral Health at WellCare

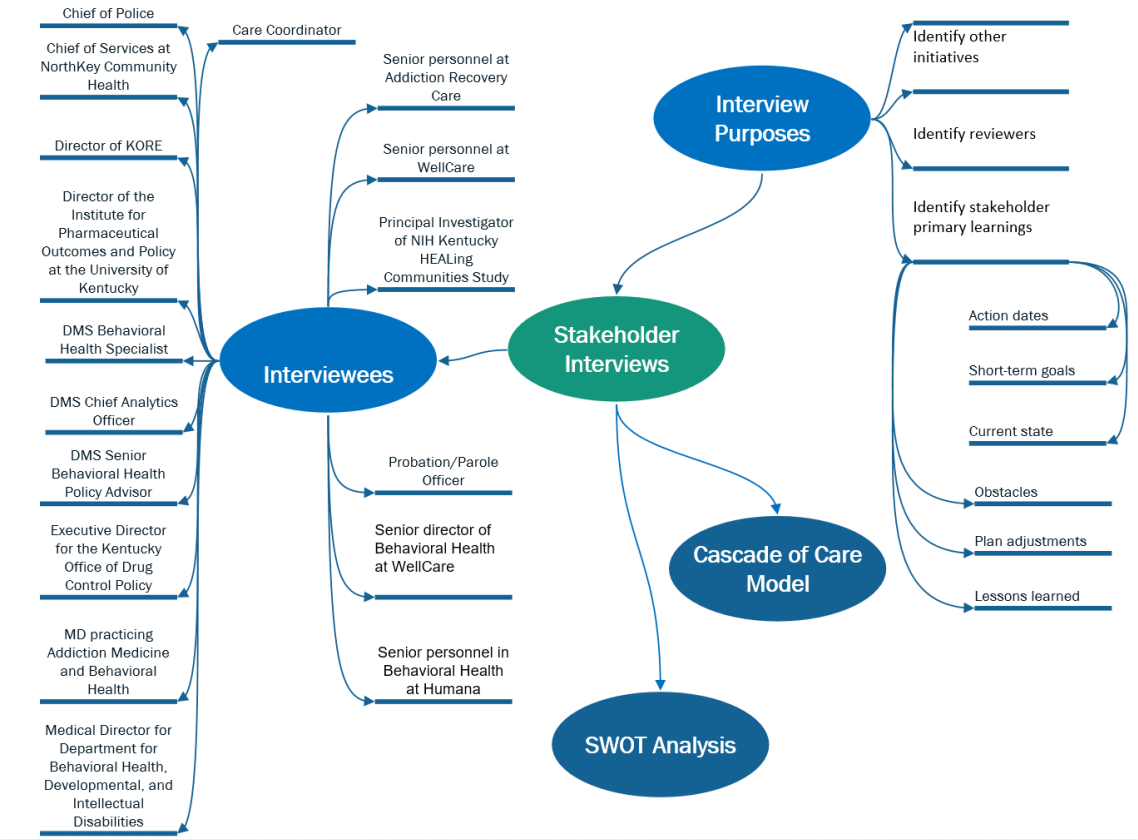
- Senior Personnel in Behavioral Health at Humana.

While queries and conversations varied depending on the respondent's relationship to the 1115 Demonstration, core questions included:

- What is your role/s within your agency?
- In the last 2 years, how has the 1115 Demonstration impacted your services in terms of:
    - Opioid prescribing guidelines?
    - Use of evidence-based placement criteria like SBIRT Assessments and ASAM Criteria?
    - Utilizing Appropriate Levels of Care?
    - Use of SUD/OUD-Specific Standards (ASAM, CARF)?
    - Reviewing providers to ensure standards of care?
    - Access to critical levels of care for OUD/SUD/OUDs?
    - Provider capacity?
    - Offering Medications for Opioid Use Disorder (MOUD) with therapy on-site or off-site?
    - Policies to ensure inpatients are linked to community based services?
- Of these changes, what has been working well?
- Of these changes, what barriers are you facing to implementation?
- Of these changes, what opportunities for improvement do you see?
- How is communication among organizations/entities working toward similar goals?
- Are there any other comments you would like to make regarding SUD/OUD in Kentucky that may be useful knowledge for policy makers?

A summary of the interview structure and the conceptual development of the frameworks used in our analysis in provided in Figure 4.

Figure 32. Interview Overview

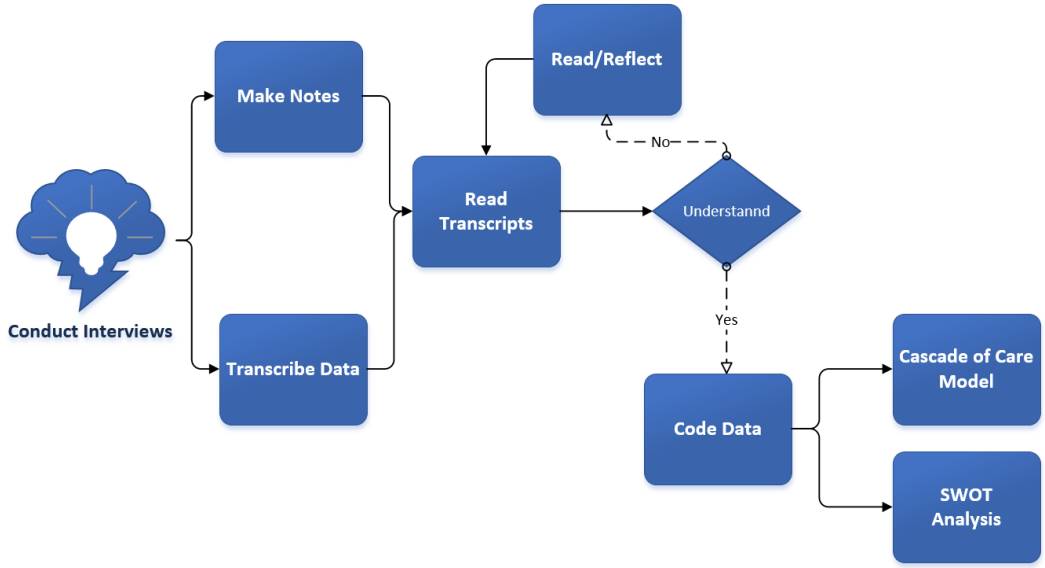


Phase 3: Analysis of progress toward long-term goals (November 2, 2020 to March 16, 2021)

Because system change takes time, and because there is a several-month lag in Medicaid reporting, the Midpoint Evaluation has only limited ability to examine results pertaining to long-term outcomes (e.g., reduced overdose deaths) and quantitative analyses are not part of this evaluation. We do note that COVID-19 has shifted the goalposts for metrics, which will be more fully explored and documented in our Interim Assessment.

However, the qualitative data were synthesized and harmonized across the individual stakeholder responses to allow for preliminary evaluation of progress towards goals. Figure 5 below captures the details of the analytic process for the qualitative analysis.

Figure 33. Qualitative Analysis Diagram



Phase 4: Development of themes and recommendations (January 15, 2021 to April 9, 2021)

The Midpoint Evaluation (MPE) team organized its preliminary findings and its recommendations in a form that could be easily understood by stakeholders. The report focuses on key factors that affected implementation, identified concerns that might affect short-term or long-term outcomes, and recommendations for consideration.

In early March 2021, we shared a preliminary report with staff in the Kentucky Department for Medicaid Services (DMS). A revised draft was then shared with select stakeholders who had contributed to the development of this report in mid-March 2021. In both cases, their feedback was considered and incorporated into the analysis as appropriate. Finally, the evaluation was circulated more broadly within the Kentucky Cabinet for Health and Family Services. This process provided the final set of contributions to the material presented in this report.

KENTUCKY OPIOID RESPONSE EFFORT (KORE) PRIMARY FUNDING PRIORITIES

Prevention
Naloxone distribution in emergency departments, mobile and community pharmacies, residential treatment programs, community events
KASPER enhancements to integrate toxicology screens, nonfatal overdose, and controlled substance convictions within KASPER
Opioid Overdose Toolkit training delivered to prescribers, first responders, and the general community
Primary prevention in and after school to empower youth with social-emotional learning and substance use prevention skills
Technical assistance to schools to enhance OUD education, prevention policies, and procedures
Community youth empowerment to promote student resilience
Community coalition building to align efforts and change community norms around substance misuse
Opioid Stewardship training to decrease inappropriate opioid prescribing
SBIRT training and promotion to increase early detection and treatment of substance misuse
Harm reduction program support to increase access to harm reduction services and treatment
Early childhood services to promote healthy child-parent relationships
Treatment
Treatment & Methadone Stipend Programs to increase access to MOUD
Bridge Clinics to treat opioid withdrawal and increase access to harm reduction, treatment, and recovery support in the emergency department and other hospital services
Federally Qualified Health Centers medication assisted treatment to increase the capacity of primary care to treat OUD.
Coordinated system of care for pregnant and parenting women with OUD
Vivitrol administration through community pharmacies to develop the community-pharmacy care delivery model
Services Sobriety Treatment and Recovery Team (START) and Targeted Assessment Program (TAP) expansion to expand and enhance services for women and families with child welfare involvement who are affected by OUD
Quick Response Team start up or expansion to increase access to harm reduction, treatment, and recovery support for persons affected by OUD.
Kenton County Detention Center medication assisted treatment within the Jail Substance Abuse Program
Recovery Support
Access to Recovery voucher program to reduce barriers to maintaining recovery through basic needs, transportation, and recovery housing support
Employment support to increase job placement and retention
Community reentry coordination to facilitate access to treatment and recovery supports following release from incarceration
Double Trouble in Recovery and SMART Recovery groups expansion to increase access to evidence-based, medication assisted treatment recovery support
Recovery Community Centers to provide locatable resources for community-based recovery support

Recovery reentry and retention support to assist persons in recovery who come to the Kentucky Career Center seeking (re)reemployment and training.
Oxford House staff to support the expansion or high-quality recovery residencies statewide
Peer Support Specialist training and support to increase the capacity of Peer Support Specialists to provide support in the addiction recovery field
Recovery support to support young people in or seeking recovery by empowering them to obtain stable employment, secure suitable housing, and explore continuing education
Transition Age Youth Launching Realized Dreams (TAYLRD) Drop-In Centers expansion to increase capacity to serve youth with OUD
Infrastructure
Evidence-based curriculum training including Comprehensive Opioid Response with the Twelve Steps, Community Reinforcement Approach, ASAM Multidimensional Assessment
OUD education, policy review, and Casey's Law training to increase knowledge of evidence-based prevention, treatment, and recovery support as well as awareness of the resources within the state to support access to treatment and recovery
Buprenorphine waiver trainings and prescriber/provider education to increase the number of physicians and nurse practitioners delivering high quality medication assisted treatment
Regional Prevention Center expansion to increase primary, secondary, and tertiary prevention in the highest risk regions of the state
Evaluation and fidelity of KORE projects
Capacity initiatives to increase substance use prevention providers
Statewide OUD needs assessment to identify gaps in care as well as community strengths

1115 DEMONSTRATION METRICS BY STAGE OF SUD/OUD CASCADE OF CARE

Stage	1115 Outcome Metrics
Prevention	• % beneficiaries with prescriptions for opioids > 90 morphine mg equivalents in 90 days • % beneficiaries with prescriptions for opioids from multiple sources ≤ 180 days • % beneficiaries with concurrent prescriptions for opioids and benzodiazepines
Harm Reduction	• % ED visits for beneficiaries with AOD receiving follow-up within 30 days • % ED visits for beneficiaries with mental illness receiving follow-up within 30 days • Number ED visits for SUD/OUD per 1,000 beneficiaries • % beneficiaries with SUD/OUD with ambulatory or preventive care visit.
Engage-ment with Care	• Beneficiaries screened for SUD/OUD treatment needs • Beneficiaries with a SUD/OUD diagnosis • Beneficiaries with a SUD/OUD-related service • % beneficiaries with a new episode of abuse or dependence who began treatment • Beneficiaries receiving residential or inpatient treatment for SUD/OUD • Beneficiaries using early intervention services • Beneficiaries using outpatient services for SUD/OUD • Beneficiaries using intensive outpatient or partial hospitalization services for SUD/OUD • Beneficiaries using residential or inpatient services for SUD/OUD • Beneficiaries using withdrawal management services • Beneficiaries using MOUD for SUD/OUD • Inpatient stays for SUD/OUD per 1,000 beneficiaries • Hospital readmission rate for beneficiaries with SUD/OUD • Medicaid SUD/OUD spending • Medicaid SUD/OUD spending on residential or inpatient treatment • Per capita SUD/OUD spending during the measurement period • Number beneficiaries with OD deaths

Stage	1115 Outcome Metrics
Withdrawal and Treatment	• Providers enrolled in Medicaid and qualified to deliver SUD/OUD services • Providers enrolled in Medicaid and qualified to deliver SUD/OUD services and who met standards to provide MOUD • Length of stay for beneficiaries discharged from IMD inpatient or residential treatment for SUD/OUD • Beneficiaries using MOUD for SUD/OUD • Inpatient stays for SUD/OUD per 1,000 beneficiaries • Hospital readmission rate for beneficiaries with SUD/OUD • Medicaid SUD/OUD spending • Medicaid SUD/OUD spending on residential or inpatient treatment • Per capita SUD/OUD spending during the measurement period • Grievances filed related to SUD/OUD treatment services • Appeals filed related to SUD/OUD treatment services • Critical incidents filed related to SUD/OUD treatment services
Retention Remission and Recovery	• Beneficiaries using MOUD for SUD/OUD • % beneficiaries with pharmacotherapy for OUD with 180+ days of continuous treatment • Medicaid SUD/OUD spending • Per capita SUD/OUD spending during the measurement period • Grievances filed related to SUD/OUD treatment services • Appeals filed related to SUD/OUD treatment services • Critical incidents filed related to SUD/OUD treatment services

STATEMENT OF EVALUATOR INDEPENDENCE

Northern Kentucky University (NKU) is highly qualified to undertake the evaluation of the Medicaid 1115 Waiver Demonstration Program for SUD. NKU is a neutral and respected leader in health innovation, research, education, and service. NKU has served in similar capacities as a neutral evaluator of large federally funded programs undertaken by the Kentucky Cabinet for Health & Family Services, including an assessment of the Medicaid Transformation Grant (2009 – 2012) and assessments of the Office of National Coordinator Cooperative Agreement Grants (2012 – 2016). These included similar qualitative and quantitative research activities as required in this evaluation, including patient and provider surveys and interviews and data-mining and analysis of administrative and Medicaid claims data.

NKU's Institute for Health Innovation (IHI) in particular has active SUD research programs and is engaged across the Commonwealth. It currently has over $2.6 MM in federal and private funding specifically dedicated to SUD innovation, including implementing new methods of reaching persons with SUD in rural areas and ushering them into treatment, evaluating the effectiveness of contingency management in outpatient SUD treatment, enhancing reentry services for the justice-involved, developing certified on-line training programs for paraprofessionals engaged with SUD clients, and creating new curricular and co-curricular prevention activities for youth. IHI personnel also serve on the Northern Kentucky Agency for Substance Abuse Policy and the Data Committee for the Northern Kentucky Office of Drug Control Policy.

The Northern Kentucky University research team is committed to performing a fully independent evaluation of the Commonwealth of Kentucky's 1115 Waiver Demonstration for Substance Use Disorder. We attest to our independence and will present the results to the Centers for Medicare and Medicaid Services and the public through a variety of channels without being influenced by external partners, including the Commonwealth of Kentucky.