TEAM KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES

1115 Demonstration
EXTENSION REQUEST

2022

PRESENTED TO

U.S. Department of Health and Human Services

PREPARED BY

Kentucky Department for Medicaid Services

KENTUCKY MEDICAID

SECTION 1115 WAIVER DEMONSTRATION:

TEAMKY

Formally Known As: Kentucky Helping to Engage and Achieve Long Term Health (Kentucky HEALTH)

August 12, 2022

TEAM KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES

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Introduction

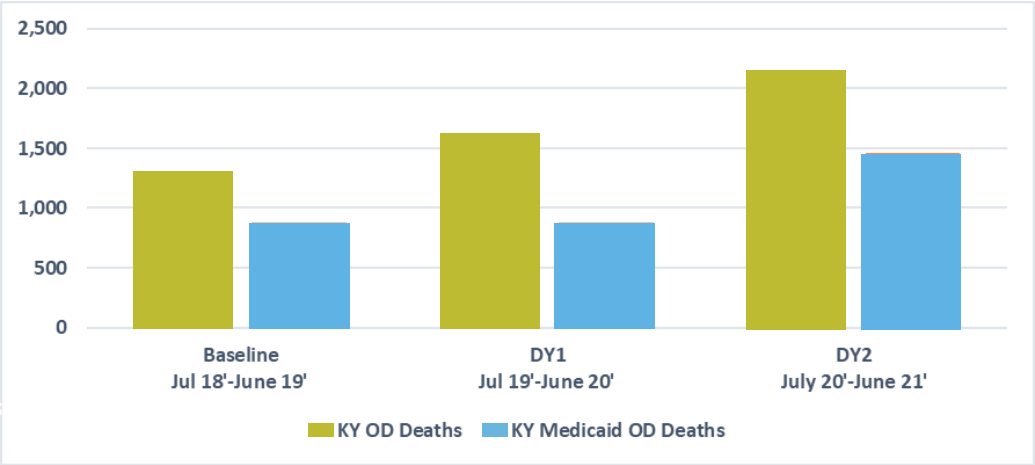
The Commonwealth of Kentucky, Department for Medicaid Services (DMS) is requesting a five-year extension of the state's current Section 1115(a) Demonstration, entitled "Kentucky Helping to Engage and Achieve Long Term Health (KY HEALTH)," (Project Nos. 11-W-00306/4 and 21-W-00067/4). DMS requests to amend the Section 1115 Demonstration to be titled as, "TEAMKY", effective with the approval of the extension.

Kentucky's 1115 Demonstration currently contains the following components: Substance Use Disorder (SUD) Section 1115, waive of Non-Emergency Medical Transportation (NEMT) for methadone treatment, eligibility for out of state former foster care youth and alignment of Employer Sponsored Insurance (ESI) open enrollment dates.

The SUD Demonstration recently completed Demonstration Year (DY) 3 of implementation and has provided an opportunity to enhance the Commonwealths' SUD service array, while increasing access to services across a full continuum of care further combatting the Opioid Epidemic, especially during the state public health emergency (PHE).

Outcomes of the SUD 1115 Demonstration thus far indicate overall, more beneficiaries are receiving SUD diagnosis and treatment. However, with the changing combinations and purity of substances, our state faces an even greater challenge in combatting the Opioid Epidemic. KY Medicaid beneficiaries account for nearly two-thirds of the states overdose fatalities. Figure 1 illustrates the number of overdose deaths statewide and number of overdose deaths within DMS**[1].**

Figure 1: Kentucky Overdose (OD) Deaths, July 2018 – June 2021



[1] KIPRC Kentucky Injury Prevention and Research Center. Mirzaian, M., Steel, M . "Drug Overdose Deaths In Kentucky, July 2018 – June 2021". March 10, 2022.

≈ 2/3 OF KENTUCKY OVERDOSE DEATHS ARE MEDICAID BENEFICIARIES

While the Commonwealth had seen a slight decrease in number of fatal overdoses prior to COVID-19, Kentucky like many other states, experienced a significant increase in overdose deaths during the PHE. Such factors include**[2]**:

- Social isolation and lack of community engagement.
- Changes to treatment interventions due to social distancing requirements.
- Increased levels of stress due to isolation, loss of employment and supports.
- Changes in types of substances, purity, patterns, and combinations of use.

*[2] NIH National Library of Medicine. "Impact of the COVID-19 Pandemic on Opioid Overdose Deaths: a Spatiotemporal Analysis". February 18, 2022. Available **here**.*

The PHE exacerbated the need for behavioral health services, while placing additional barriers on individuals with existing disorders. Preliminary research suggests, approximately 4 in 10 adults in the U.S. suffered from mental illness and SUD symptoms during the pandemic, whereas prior to COVID-19, 1 in 10 adults reported symptoms. Additionally, it is estimated nearly 13% of adults reported new or increased SUD due to COVID-19 related stress**[3]**. A comprehensive analysis of the full impacts of the PHE have yet to be determined; however, as history has shown, behavioral health impacts due to disasters may outlast the physical impacts.

The Commonwealth anticipates constraints of the PHE to impact Kentuckians for years to come. KY's Section 1115 extension is valuable to the Commonwealth's ongoing efforts to enhance services and improve health outcomes for its beneficiaries.

Demonstration History

The KY HEALTH Section 1115 Demonstration approved **January 12, 2018,** aimed to transform the Medicaid program to empower beneficiaries and improve their overall health. The initial Demonstration sought to continue health coverage for the existing Medicaid population while evaluating new policies designed to engage members in their healthcare and communities. DMS requested to extend eligibility under the "Kentucky HEALTH" program for adults who would not qualify for Medicaid based on disability as a condition of participating in community engagement requirements, while providing incentives for healthy behavior. Several exemption categories that would prevent an individual from complying with the established requirements were included. Such categories included: pregnant women, former foster youth up to age 26, individuals eligible for 1915(c) waivers, individuals on Medicaid due to a disability, individuals over 65 years of age, individuals residing in an institution and individuals deemed medically frail**[4]**.

The KY Section 1115 Demonstration includes a Substance Use Disorder (SUD) Section 1115 Demonstration available to all Medicaid beneficiaries, to ensure a broad continuum of care is available across the Commonwealth for individuals with SUD. The SUD 1115 Demonstration Protocol was approved **October 2018** and implemented **July 1, 2019[5]**. Under the SUD Section 1115, KY Medicaid expanded access to critical levels of care and adopted the *American Society for Addiction Medicine (ASAM) Criteria* as the standard evidence-based treatment for SUD**[6]**.

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[3] KFF. "The Implications of COVID-19 for Mental Health and Substance Use". February 10, 2021. Available here.

[4] DMS. "Demonstration Application August 2016". August 24, 2016. Available here.

[5] DMS. "KY HEALTH SUD Implementation Plan Approved October 2018". Available here.

[6] Mee-Lee D, Shulman GD, Fishman MJ, Gastfriend DR, Miller, eds. The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions. 3rd ed. Carson City, NV: The Change Companies; 2013. Copyright 2013 by the American Society of Addiction Medicine.

The Demonstration defines SUD residential treatment as a statewide average length of stay (ALOS) of thirty (30) days and includes a waive of the institution for mental disease (IMD) exclusion, to allow reimbursement for up to 96 beds per location (amended November 2019 from 192 beds to 96**[7]**) for programs meeting DMS established provider qualifications. Such requirements include appropriate state license, utilizing a six-dimensional biopsychosocial assessment tool to determine level of care, ensuring access to Medication Assisted Treatment (MAT) and obtaining the newly established residential *ASAM Level of Care Certification***[8]**.

DMS received approval **July 1, 2019** to add coverage of methadone for SUD treatment to the KY State Plan. As a contingency of adding methadone to the State Plan, under the Demonstration, DMS received approval to waive non-emergency medical transportation (NEMT) for individuals receiving methadone in an opioid treatment facility with exemptions to pregnant women and former foster care youth up to age 26.

The KY HEALTH Section 1115 Demonstration also includes aligning Medicaid beneficiary's annual redetermination with their ESI open enrollment period and extends eligibility for Medicaid to former foster care youth who are under 26 years of age and were in foster care under the responsibility of another state.

In **December 2019**, the Commonwealth rescinded the Kentucky HEALTH program, keeping the following components of the KY HEALTH demonstration: SUD 1115, waive of NEMT for methadone treatment, eligibility for out of state former foster care youth and alignment of ESI open enrollment dates.

Waive of Transportation for Methadone Treatment

Care for Former Foster Care Youth

Employer Open Enrollment Alignment

[7] DMS. "KY HEALTH SUD Implementation Plan Amended November 2019'. Available here.

[8] ASAM. "The ASAM Criteria, Level of Care Certification Program". Last updated 2022. Available here.

Pending Amendment

DEPARTMENT FOR MEDICAID SERVICES

DEPARTMENT OF CORRECTIONS

CARE FOR THE INCARCERATED

DMS in partnership with the KY Department of Corrections (DOC) filed an amendment to the KY Section 1115 Demonstration (Project Nos. 11-W-00306/4 and 21-W-00067/4) on **November 25, 2020**, to the Kentucky HEALTH Section 1115 Demonstration, titled, "Continuity of Care for Incarcerated Individuals", requesting approval to allow the Commonwealth to reimburse for SUD treatment provided to eligible individuals while incarcerated.

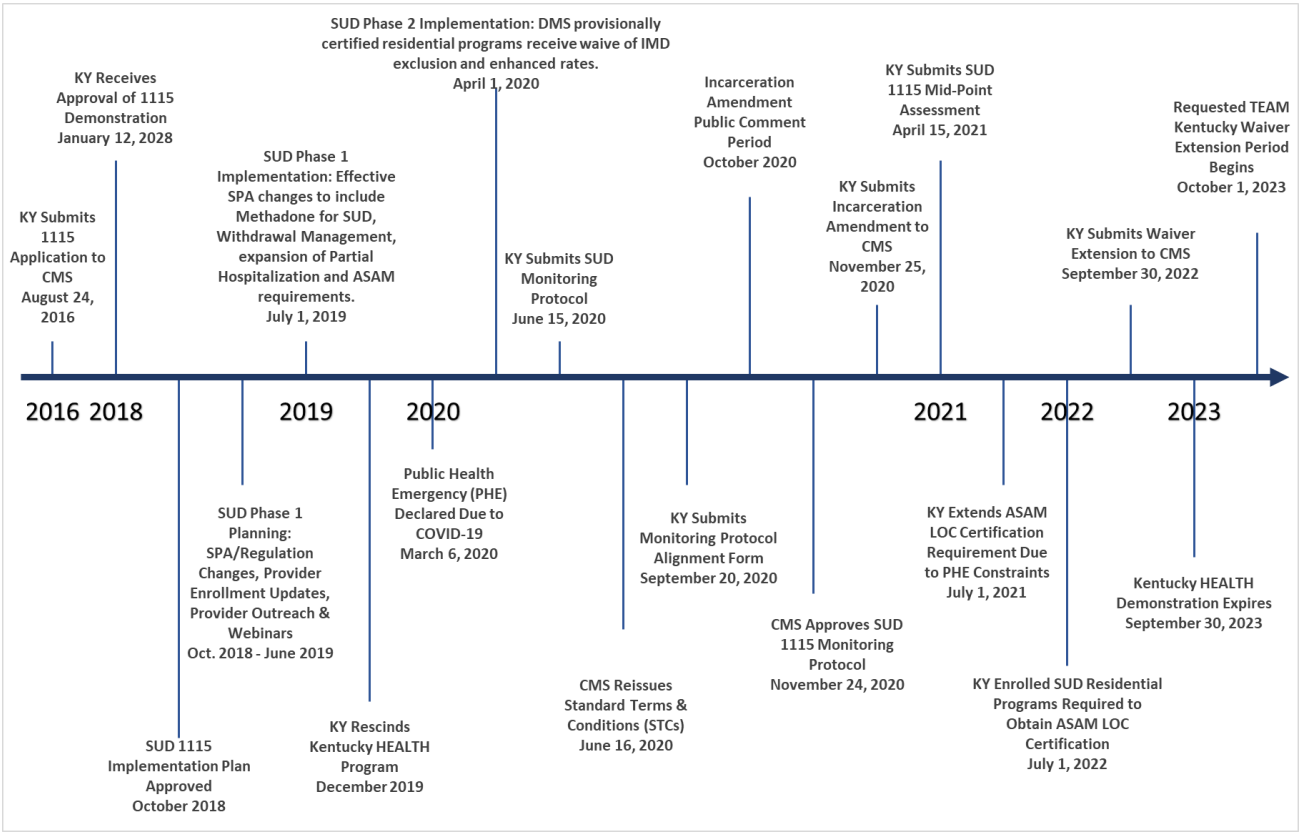
The application included a request to provide similar SUD services approved under the KY State Plan, to individuals participating in the established DOC SUD treatment programs and ensure these individuals receive needed treatment and coordination of care thirty (30) days prior to release**[9]**. KY requests to include the pending incarceration amendment application in the states 1115 Demonstration extension.

Expanding Access to Individuals Who Are Justice-Involved

*[9] DMS. "KY Health Amendment Application Incarceration November 2020". November 25, 2020. Available **here**.*

Figure 2 provides a timeline of Kentucky's Section 1115 Demonstration initiatives.

Figure 2 : Kentucky HEALTH 1115 Demonstration Timeline, 2016-2023



Program Goals, Objectives & Outcomes

Kentucky HEALTH Program Objectives

The goals of the Kentucky HEALTH Program included [4]:

- Improve members' health and help them be responsible for their health
- Encourage individuals to become active participants & consumers of healthcare who are prepared to use commercial health insurance
- Empower people to seek employment and transition to commercial health insurance coverage
- Implement delivery system reforms to improve quality and outcomes
- Ensure long-term fiscal sustainability

The Kentucky HEALTH Program was rescinded in December 2019; this component of the Demonstration was not implemented.

SUD Program Goals

Through KY Medicaid's expansion, DMS began providing coverage for behavioral health, including SUD services in **2014**. Under the SUD Section 1115 Demonstration, DMS was able to further expand and enhance these services. The overall goal of the Demonstration is to improve quality, care and health outcomes for individuals experiencing SUD.

[4] DMS. "Demonstration Application August 2016". August 24, 2016. Available here.

SUD Program Goals

Kentucky has historically ranked as one of the states with the highest rates of overdose deaths. Increasing access to critical levels of care and ensuring provider capacity across the state is vital to Medicaid recipients who account for nearly two-third of the states overdose deaths.

Improving quality of services utilizing evidence-based practices is essential for Medicaid beneficiaries experiencing SUD to successfully obtain and sustain recovery.

Improving care coordination ensures the healthcare system works collaboratively to provide the best care possible for high-risk individuals experiencing SUD.

Utilizing a standard six-dimensional biopsychosocial assessment tool further streamlines SUD treatment for beneficiaries across the state, while providing a holistic treatment approach aimed at addressing the dimensional needs of the individual at the most appropriate level of care.

PROVIDER CAPACITY

EVIDENCE-BASED PRACTICE

CARE COORDINATION

SUD Program Objectives

Figure 3 : SUD 1115 Demonstration Objectives [10]

Improve quality, care, and health outcomes for individuals experiencing SUD

- Improve access to critical levels of care for Opioid Use Disorder (OUD) and other SUDs.
- Use evidence-based SUD-specific patient placement criteria.
- Apply nationally-recognized SUD-specific program standards for the certification of residential treatment facilities establishing standards of care.
- Assess sufficient provider capacity at critical levels of care, including medication-assisted treatment for OUD.
- Implement a comprehensive treatment and prevention strategy to address opioid abuse and OUD.
- Develop a SUD Health IT Plan.
- Improve care coordination and transitions between levels of SUD care.

[10] CMS, Medicaid.gov. "KY HEALTH Demonstration Reissuance". Reissued June 16, 2020. Available here.

SUD Program Outcomes

Objective 1 Outcomes: Improve access to critical levels of care for Opioid Use Disorder (OUD) and other SUDs

To improve access to SUD treatment services for Medicaid beneficiaries and ensure access to a full continuum of care, DMS applied a phased approach to implementing the SUD Demonstration. Phase 1 Implementation, included State Plan changes effective **July 1, 2019** to**[11]**:

- **Extend service planning for SUD treatment.**
- **Require a 6-dimensional psychosocial assessment tool for SUD treatment.**
- **Expand partial hospitalization services to Behavioral Health Service Organizations (BHSO).**
- **Add coverage of Withdrawal Management (WDM) to be incorporated into a recipient's care at the appropriate level according to the most current version of the *ASAM Criteria*.**
- **Add definition of Medication Assisted Treatment (MAT) to include medication with behavioral health therapies.**
- **Add methadone coverage for SUD treatment provided by a Narcotic Treatment Program (NTP).**

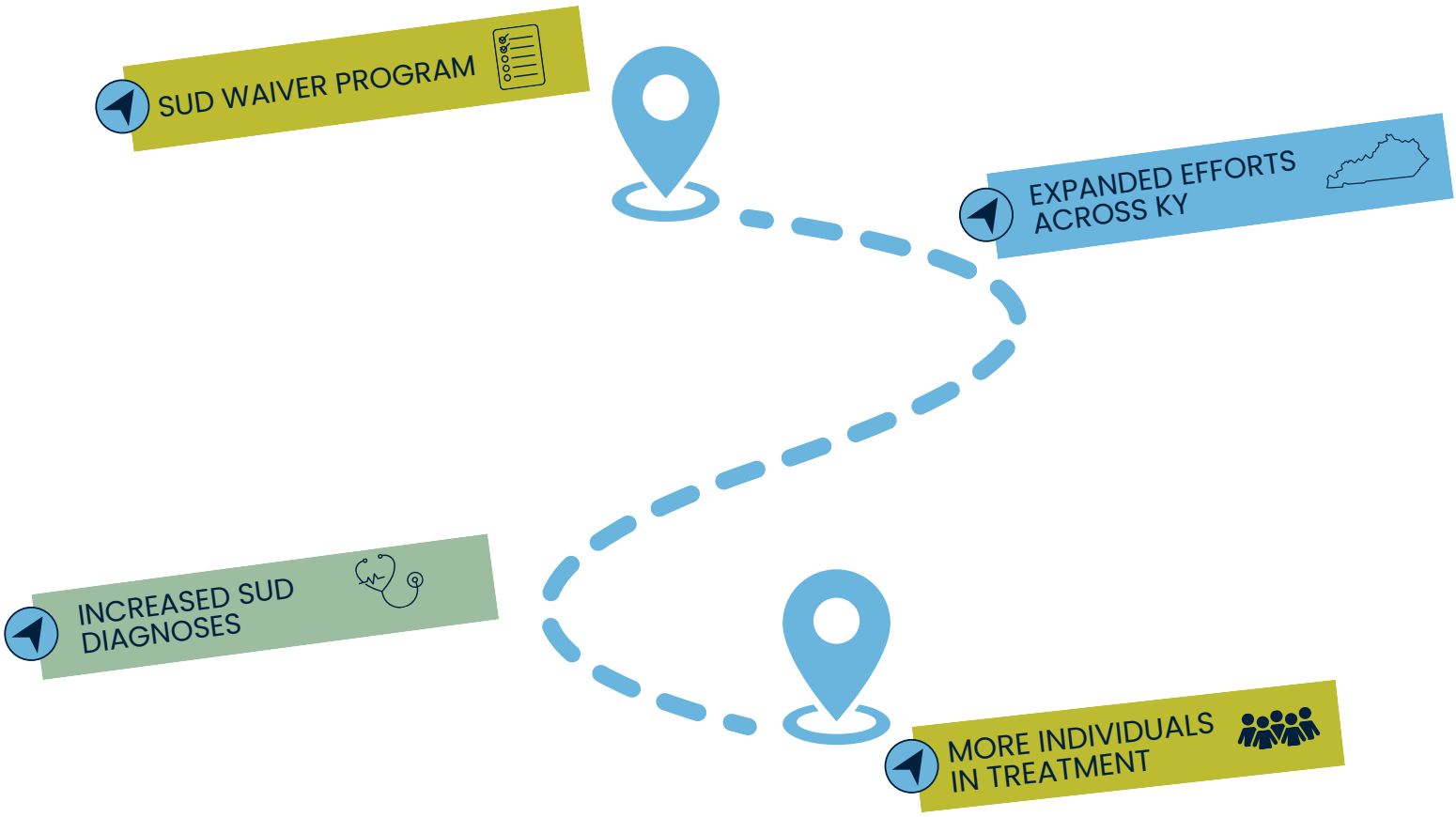
State Plan changes effective **January 1, 2020** included**[12]**:

Adding inpatient coverage to Chemical Dependency Treatment Centers (CDTC) to allow reimbursement for programs meeting Medically Monitored Intensive Inpatient criteria according to the most current version of the *ASAM Criteria*, and

Expanding coverage in Residential Crisis Stabilization Units (RCSU) treatment SUD allow reimbursement for programs meeting Medically Monitored Intensive Inpatient criteria according to the most current version of the ASAM Criteria.

[11] DMS. "Substance Use/Mental Health Changes". July 1, 2019. Available here.

[12] DMS. "MH/SUD Revision". June 17, 2020. Available here.



By expanding services and increasing provider capacity, DMS, along with other statewide efforts, have successfully increased **access to** and **utilization of** SUD services across the Commonwealth. From baseline through DY3, DMS has seen **overall a trend in increasing number of Medicaid beneficiaries** receiving SUD diagnosis, and beneficiaries receiving treatment.

According to the approved monitoring protocol, KY deviates from the SUD Monitoring Technical Specification Manual and does report metrics to CMS with a six-month claim lag[13]**. Due to the claim lag, KY's most recent SUD quarterly metrics are reported through DY3Q3 and annual metrics are reported through DY2.*

*[13] DMS. "KY HEALTH SUD Monitoring Protocol Part B". November 2020. Available **here**.*

Figure 4 shows the quarterly average of Medicaid beneficiaries who received MAT or a SUD-related treatment service with an associated SUD diagnosis**[14]**. From baseline through DY3Q2 of the Demonstration, beneficiaries with an SUD diagnosis receiving treatment increased overall by 25%.

Figure 4 : Beneficiaries with SUD Diagnosis Receiving Treatment (Quarterly), Baseline – DY3Q2

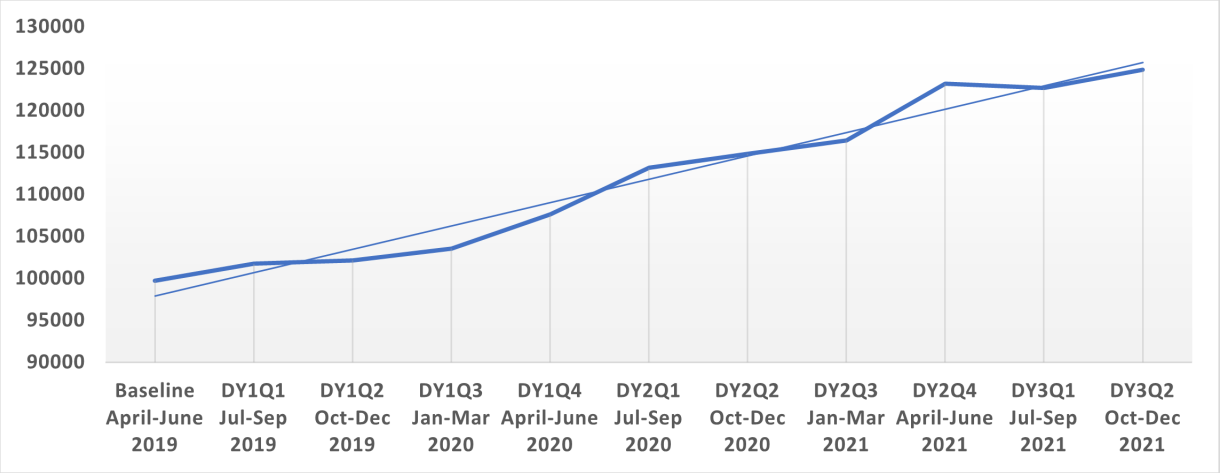
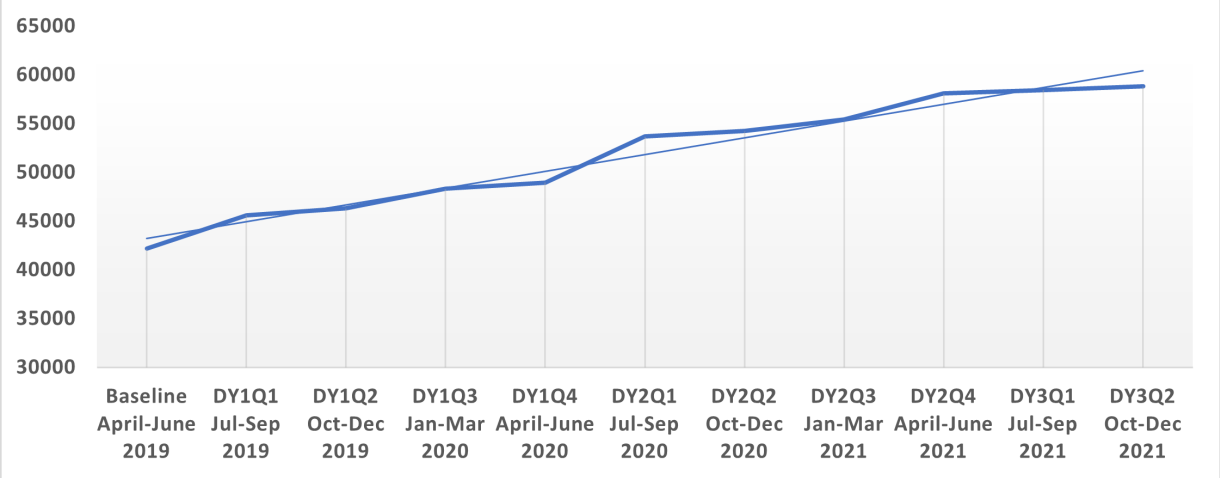


Figure 5 illustrates beneficiaries enrolled and receiving any SUD treatment service, facility claim, or pharmacy claim during the measurement period**[14]**. From baseline through DY3Q2 of the Demonstration, beneficiaries' diagnosis receiving treatment has increased overall by 40%.

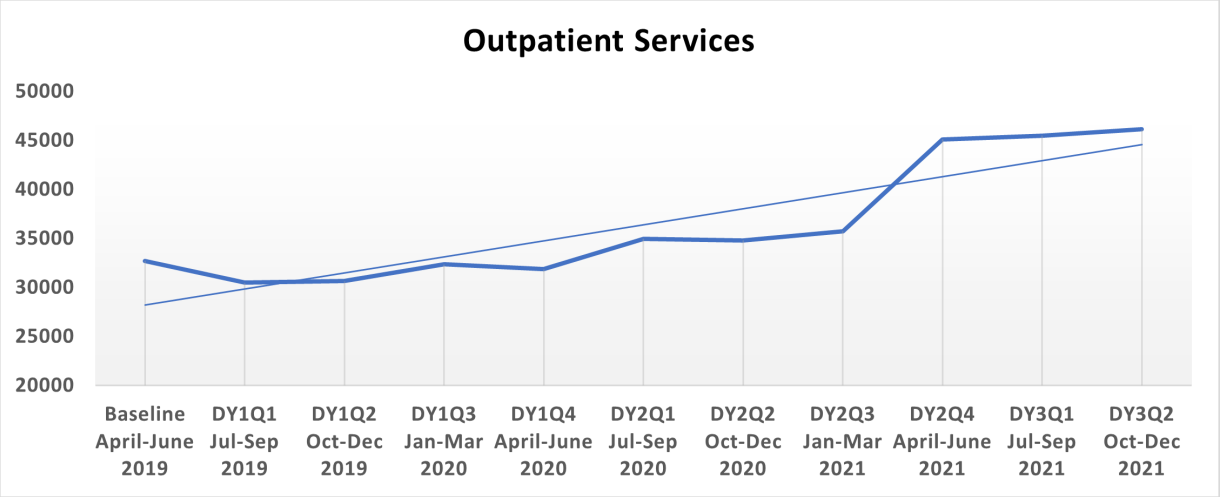
Figure 5 : Any SUD Treatment (Quarterly), Baseline through DY3Q2

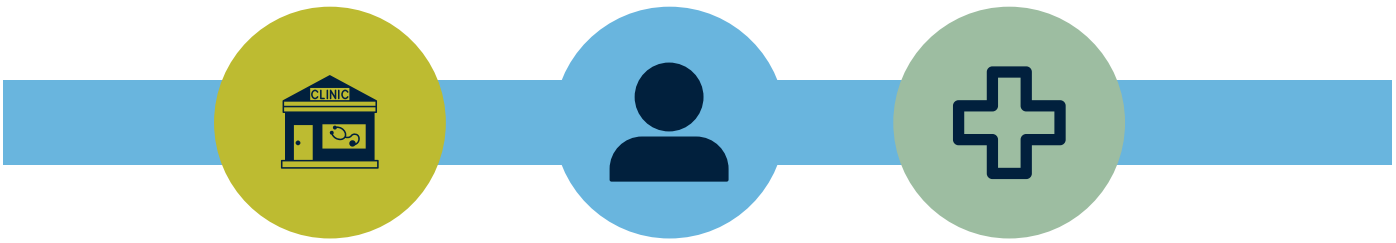


{14] DMS. "Kentucky Medicaid Section 1115 SUD Part A Monitoring Metrics Rolling – Baseline through DY3Q2". July 2022.

Figure 6 illustrates the quarterly average number of Medicaid beneficiaries who received outpatient services for SUD**[14]**. From baseline through DY3Q2 of the Demonstration, outpatient utilization increased overall by 41%.

Figure 6 : Outpatient Services (Quarterly), Baseline through DY3Q2



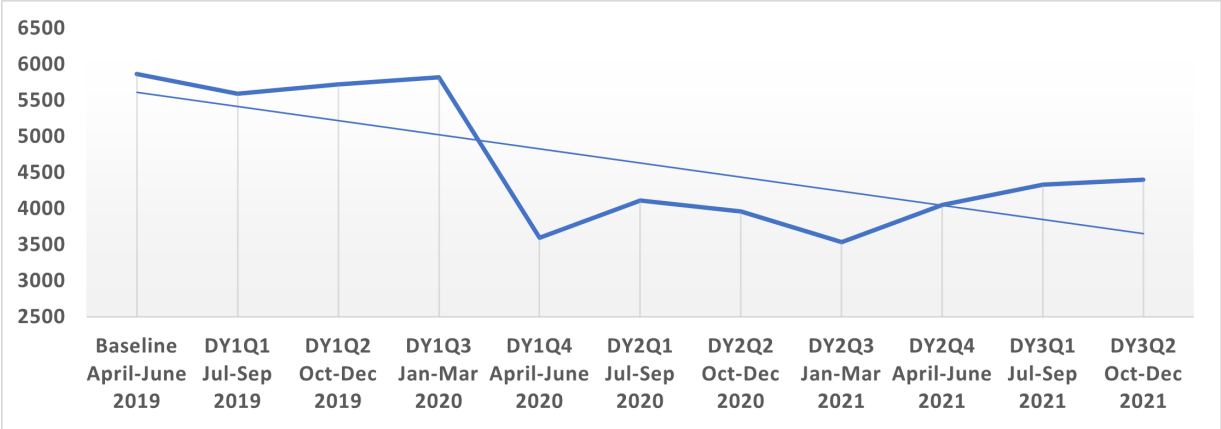


[14] DMS. "Kentucky Medicaid Section 1115 SUD Part A Monitoring Metrics Rolling – Baseline through DY3Q2". July 2022.

The PHE greatly impacted delivery of intensive outpatient and partial hospitalization programs. Prior to the PHE, these programs by nature provided face-to-face, in person intensive treatment, typically several hours a day. At times during the PHE, intensive outpatient and partial hospital programs were incapable of providing face-to-face services, and due to the intensity of services, providing these programs via telehealth shown to be challenging.

Figure 7 illustrates the quarterly average Medicaid beneficiaries who received intensive outpatient and/or partial hospitalization services for SUD**[14]**. From baseline through DY3Q2 of the Demonstration, utilization decreased overall by 25%. However, the figure also shows an increase in utilization at implementation through the start of the PHE, and another trending increase in utilization as the state moves out of the PHE peak, and in-person delivery of services begin to resume.

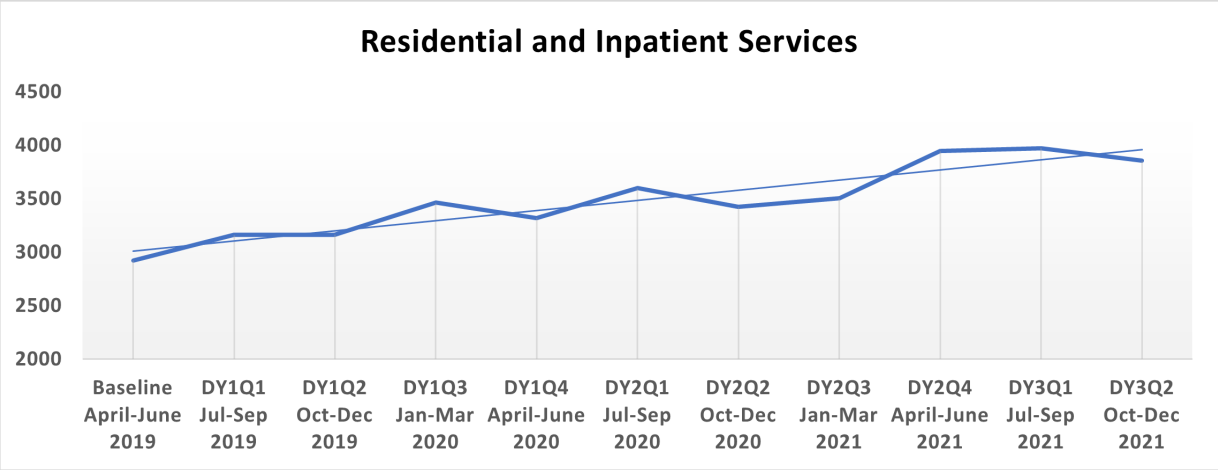
Figure 7 : Intensive Outpatient and Partial Hospitalization Services (Quarterly), Baseline – DY3Q2



[14] DMS. "Kentucky Medicaid Section 1115 SUD Part A Monitoring Metrics Rolling – Baseline through DY3Q2". July 2022.

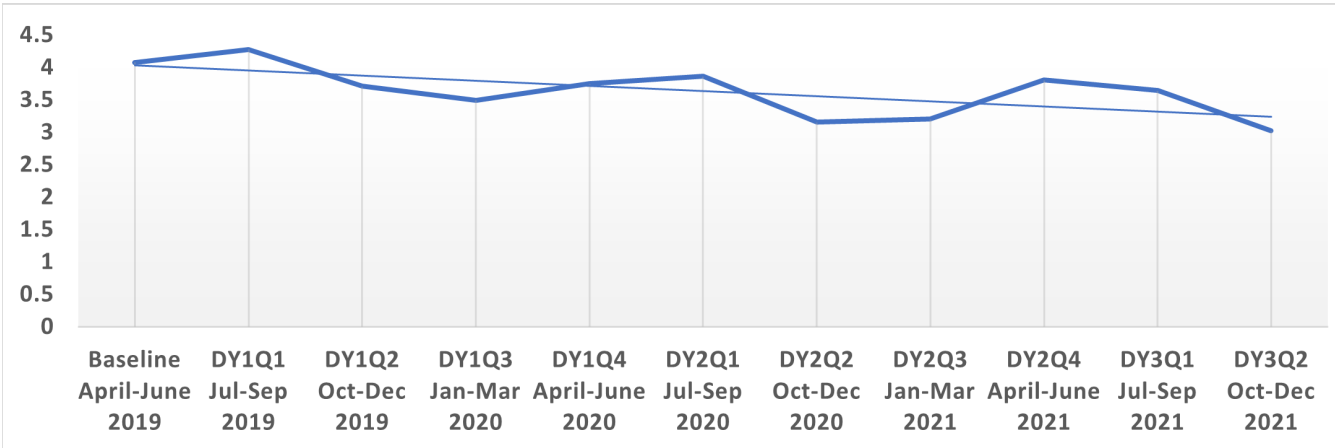
Figure 8 illustrates the quarterly average Medicaid beneficiaries who received residential and/or inpatient services for SUD**[14]**. From baseline through DY3Q2 of the Demonstration, residential and/or inpatient utilization increased overall by 32%.

Figure 8: Residential and Inpatient Services (Quarterly), Baseline – DY3Q2



It is estimated 13-27% of ED visits can be managed in outpatient offices and clinics where individuals with mental health and SUD may receive effective treatment and management**[15].** With the increased access to services, DMS has seen a growth in utilization at outpatient and residential levels, while seeing a slight downward trend in ED visits for SUD by 1.05 visits per 1,000 beneficiaries. Figure 9 illustrates the quarterly total number of ED visits for SUD per 1,000 beneficiaries**[14].**

Figure 9: ED Utilization for SUD per 1,000 Beneficiaries (Quarterly), Baseline – DY3Q2



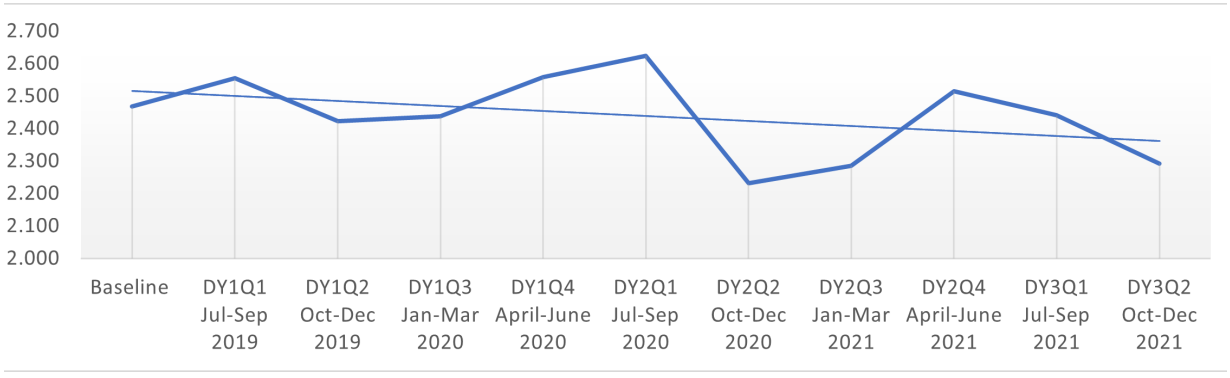
[14] DMS. "Kentucky Medicaid Section 1115 SUD Part A Monitoring Metrics Rolling – Baseline through DY3Q2". July 2022.

[15] Agency for Healthcare Research and Quality. "Preventable Emergency Department Visits". June 2018. Available at here.

Furthermore, approximately 15% of ED visits result in inpatient admissions; by decreasing preventable ED visits, healthcare providers can provide treatment at the least restrictive, appropriate level of care**[16]**.

While the number of inpatient stays has not significantly decreased through DY3Q2, the state has seen a slight overall downward trend, and thought the full impacts of the PHE are yet to be determined, DMS notes the PHE is one key factor for inpatient stays for SUD. Preliminary studies indicate there are certain periods throughout the PHE, such as positive COVID-19 case peaks, where behavioral health inpatient stays spiked**[17]**. Figure 10 illustrates the quarterly total number of inpatient stays for SUD per 1,000 beneficiaries and correlates with these findings relative to KY COVID peaks**[14]**.

Figure 10: Inpatient Stays for SUD per 1,000 Beneficiaries (Quarterly), Baseline – DY2Q2



[14] DMS. "Kentucky Medicaid Section 1115 SUD Part A Monitoring Metrics Rolling – Baseline through DY3Q2". July 2022.

[16] NIH National Library of Medicine. Meng-Han Tsai, Sudha Xirasagar, Scott Carroll, Charles S. Bryan, Pamela J. Gallagher, Kim Davis, Edward C. Jauch. "Reducing High-Users' Visits to the Emergency Department by a Primary Care Intervention for the Uninsured: A Retrospective Study". March 28, 2018. Available at here.

[17] NIH National Library of Medicine. Ghose R, Forati AM, Mantsch JR. "Impact of the COVID-19 Pandemic on Opioid Overdose Deaths: a Spatiotemporal Analysis". February 18, 2022. Available at here.

Objective 2 Outcomes: Use evidence-based SUD-specific patient placement criteria

Through Phase 1 State Plan and regulatory changes implemented under the Demonstration, DMS requires all enrolled SUD treatment providers to utilize a holistic six-dimensional biopsychosocial assessment tool according the *ASAM Criteria* to determine the appropriate LOC.

Additionally, KY requires Managed Care Organization (MCO) utilization management (UM) approaches to utilize *ASAM Criteria* to determine medical necessity and the appropriate LOC for SUD treatment in order to ensure interventions are appropriate for the diagnosis and LOC provided**[18]**.

While requiring a evidence-based tool and standardized criteria for utilization management approaches further ensures consistency in the assessment and treatment planning process, DMS is aware variations still exist in assessment tools utilized and UM processes. These variations may result in differences in interpretation and implementation of the ASAM Criteria and level of care placement among treatment providers and payors.

Throughout the Demonstration, the Department for Behavioral Health, Developmental and Intellectual Disabilities (BHDID) and Kentucky Opioid Response Effort (KORE) sponsored various ASAM Trainings and ASAM E-Learning modules free to participants. DMS encouraged participation in these trainings as opportunities to further develop provider awareness, knowledge and implementation of the *ASAM Criteria*.

DMS has been engaged with other states, national organizations and sister agencies regarding opportunities to further enhance and streamline the SUD assessment process; during the Demonstration extension period, DMS will continue collaboration with state partners to explore possibilities of a uniform assessment tool for providers and UM processes. DMS will also continue partnerships to collect stakeholder feedback regarding best practices, barriers and/or challenges to utilizing the *ASAM Criteria* and six-dimensional assessment, as well as resources needed to support utilization and implementation of these policies.

[18] DMS. "Attachment C – Medicaid Managed Care Contract and Appendices". May 21, 2021.

Objective 3 Outcomes: Apply nationally-recognized SUD-specific program standards for the certification of residential treatment facilities establishing standards of care.

During implementation of the Demonstration, DMS established additional standards and provider qualifications for SUD treatment. Under KY legislation, DMS collaborated with sister agencies to enhance licensure and quality standards for SUD treatment providers across the Commonwealth based on nationally recognized and evidence-based treatment. All enrolled SUD treatment providers are required to obtain state licensure, as well as meet the service criteria at the appropriate level of care setting; including the components for support systems, staffing, assessment/treatment planning, and therapies outlined in the most current edition of the *ASAM Criteria*. Licensed organizations are also required to obtain national accreditation to ensure quality of services provided to Medicaid beneficiaries.

To ensure residential providers have the capacity to deliver services at specific levels of care, DMS is requiring all enrolled SUD residential treatment facilities to obtain the *ASAM LOC Certification.* To assist in meeting this goal, as part of Phase 2 Implementation, DMS established the SUD Residential Provisional Certification effective **April 1, 2020[19]** . SUD residential providers who obtained DMS Provisional Certification received the following benefits:

Awareness of and greater preparation for the ASAM LOC Certification.

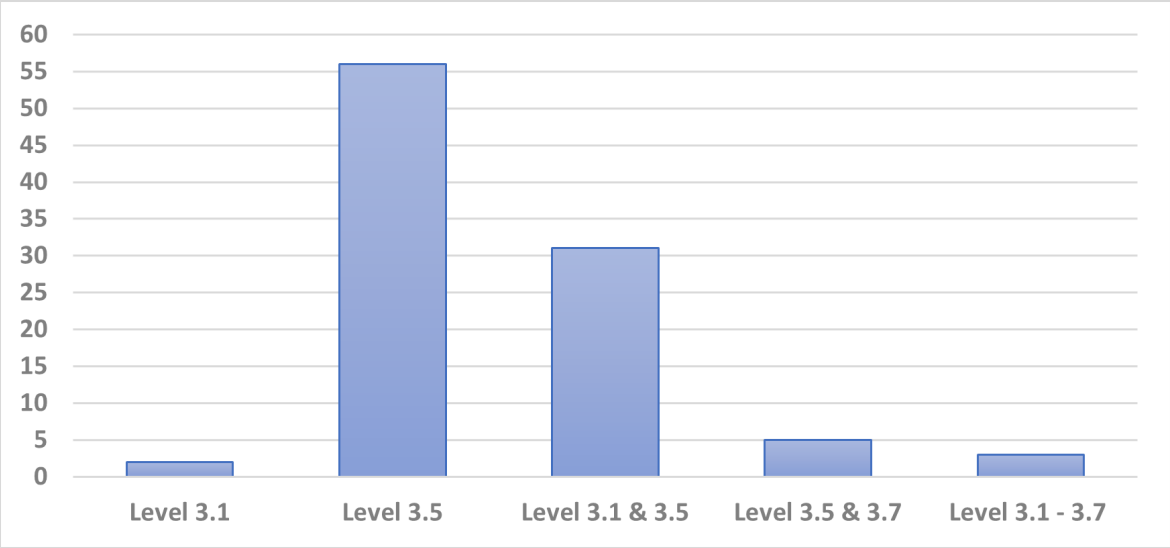
A waive of the IMD Exclusion to receive reimbursement up to 96 beds per location.

Enhanced residential reimbursement.

DMS established a time-limited residential provisional certification intended to ensure providers are aware of *ASAM LOC Certification* requirements and allow the provider an opportunity to prepare for and successfully obtain certification. Figure 11 represents the total number of KY enrolled SUD residential programs who received *ASAM LOC Certification* as of July 1, 2022 by LOC.

[19] DMS. "SUD Phase II Implementation". November 6, 2019. Available here.

Figure 11: KY SUD Residential Programs By ASAM Residential LOC, July 1, 2022



Additional standards outlined in State Plan and regulatory requirements effective **July 1, 2019** require SUD residential treatment facilities to offer MAT on-site, or facilitate access off site. As research indicates that medication and therapy combinations can effectively treat SUD and sustain recovery, DMS defined MAT as the use of medications, in combination with counseling and behavioral therapies**[20].** Adherence to these requirements are monitored through the DMS Provisional Certification self-attestation process. Through DY3, 130 residential programs received DMS Provisional Certification.

In addition to the DMS established standards, *ASAM LOC Certified* programs noted in Figure 11 also have established procedures and access to at least two medications approved by the FDA for the treatment of OUD.

[20] Substance Abuse and Mental Health Services Administration (SAMHSA). "Medication-Assisted Treatment (MAT)". Last updated July 1, 2022. Available at here.

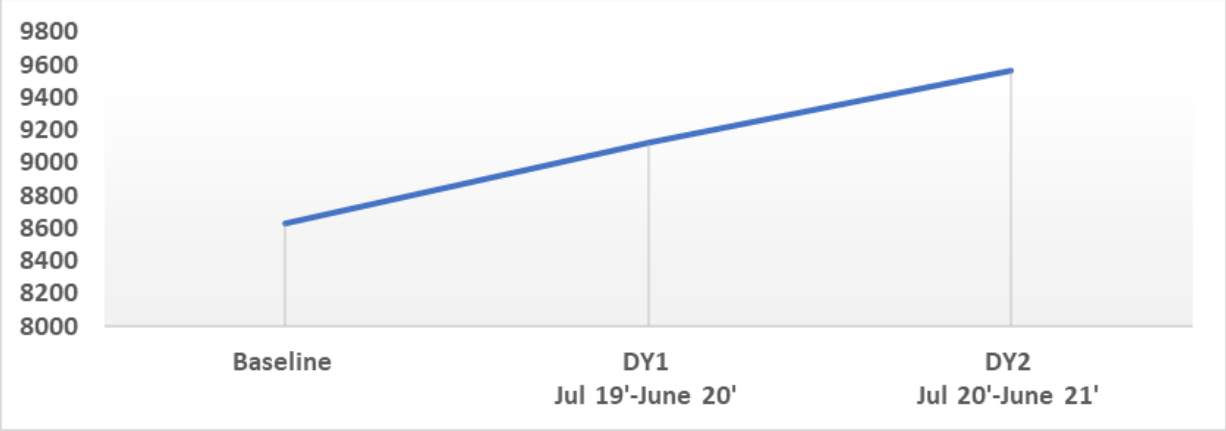
Objective 4 Outcomes: Assess provider capacity at critical levels of care, including for medication-assisted treatment for OUD.

Prior to Phase 1 Implementation in April 2019, DMS conducted a survey for Medicaid and Non-Medicaid providers to determine what SUD services are provided at what level of care, as well as potential for Medicaid enrollment. The survey also included capability to provide medication assisted treatment (MAT) services. While MAT was not verified through onsite visits, as mentioned previously, is monitored through the provider attestation process. Due to low survey participation, DMS was not able to draw a comprehensive conclusion of available services from the results.

Following the initial survey, through Phase 1 and 2 Implementation, enhancements were made to the KY Medicaid Partner Portal Application (KY MPPA), DMS's provider enrollment portal to capture additional provider information. Through the Demonstration, provider enrollment and Medicaid claims data has been utilized to determine provider capacity.

Figure 12 illustrates annually the number of providers who were enrolled in Medicaid and qualified to deliver SUD services from Baseline through DY2, indicating an overall 11% increase in enrolled SUD provider capacity increased by 11%**[14]**.

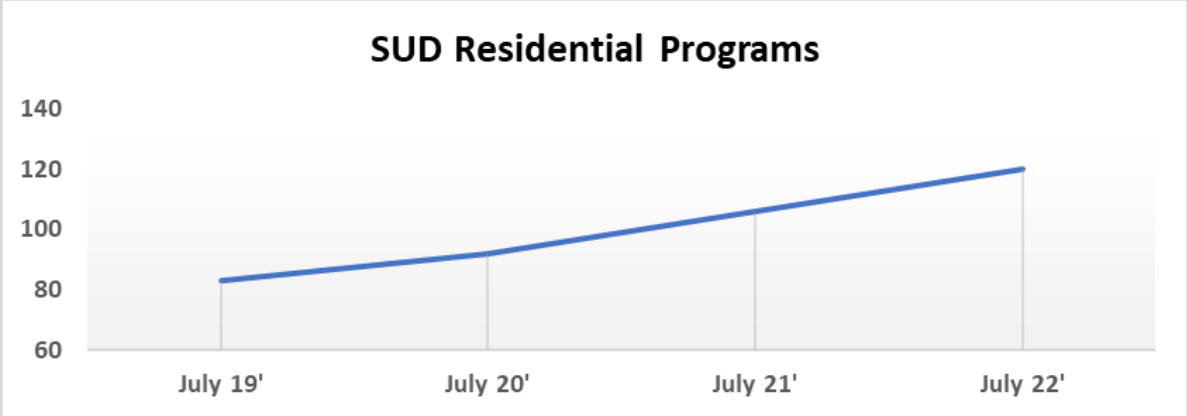
Figure 12 : SUD Provider Availability (Annual), Baseline – DY2



[14] DMS. "Kentucky Medicaid Section 1115 SUD Part A Monitoring Metrics Rolling – Baseline through DY2Q2". July 2022.

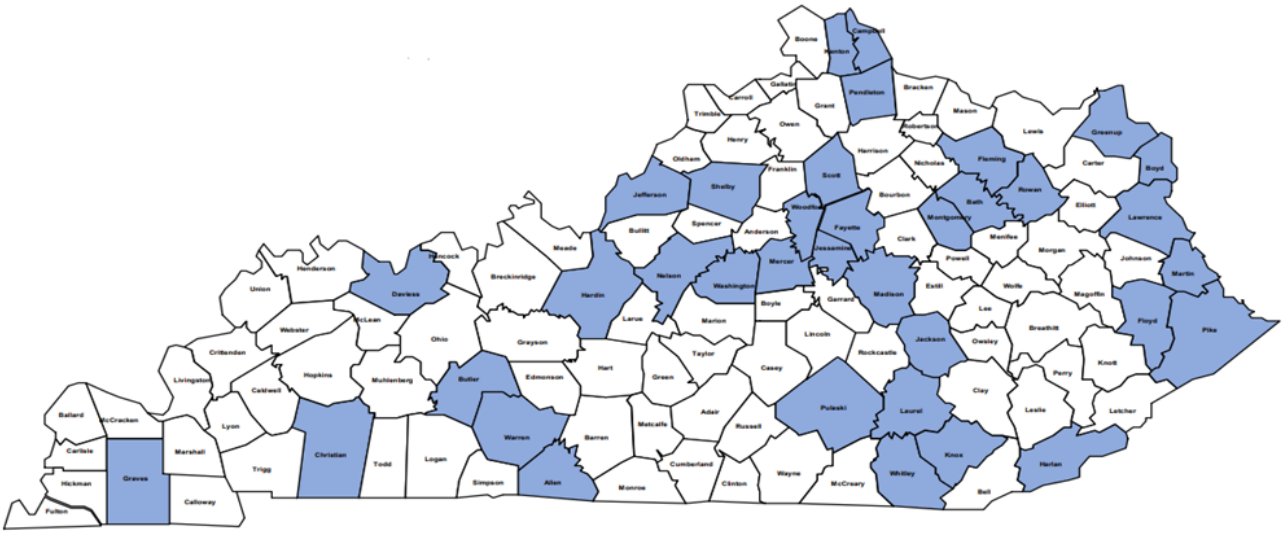
Following the established DMS Provisional Certification process, the number of enrolled SUD residential programs increased by 26% through DY3. Figure 13 illustrates number of enrolled SUD residential programs meeting provider requirements annually, from baseline through DY3.

Figure 13: SUD Residential Programs (Annual), Baseline – DY3



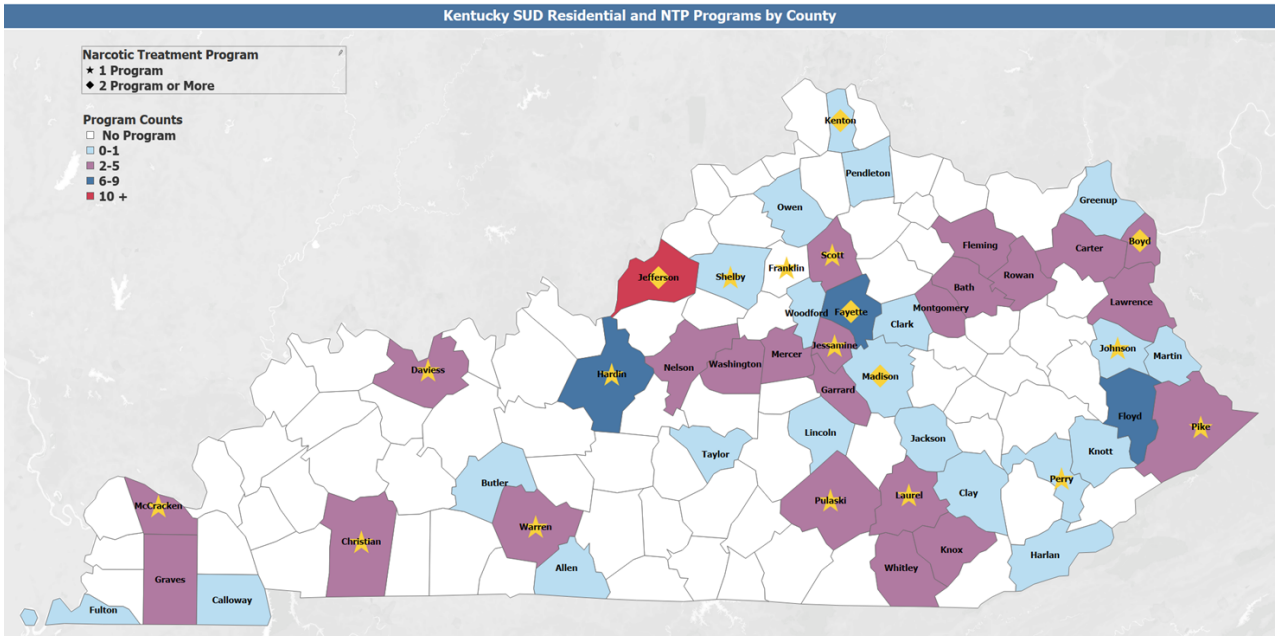
Map 1 illustrates enrolled Kentucky SUD residential treatment programs by county at the time of implementation of the Demonstration in 2019.

Map 1: SUD Residential Treatment Programs, July 2019



Two key initiatives under the Demonstration included expansion of residential treatment services and adding coverage of methadone for SUD treatment. Map 2 illustrates enrolled Kentucky SUD Residential Programs and NTPs by county, as of July 2022 meeting provider qualifications.

Map 2: KY SUD Residential and Narcotic Treatment Programs by County, July 2022



[14] DMS. "Kentucky Medicaid Section 1115 SUD Part A Monitoring Metrics Rolling – Baseline through DY2Q2". July 2022.

Objective 5 Outcomes: Implement a comprehensive treatment and prevention strategy to address opioid abuse and OUD.

Throughout implementation of the Demonstration, DMS developed opioid prescribing guidelines to prevent prescription drug abuse and expand access to Naloxone and OUD medications.

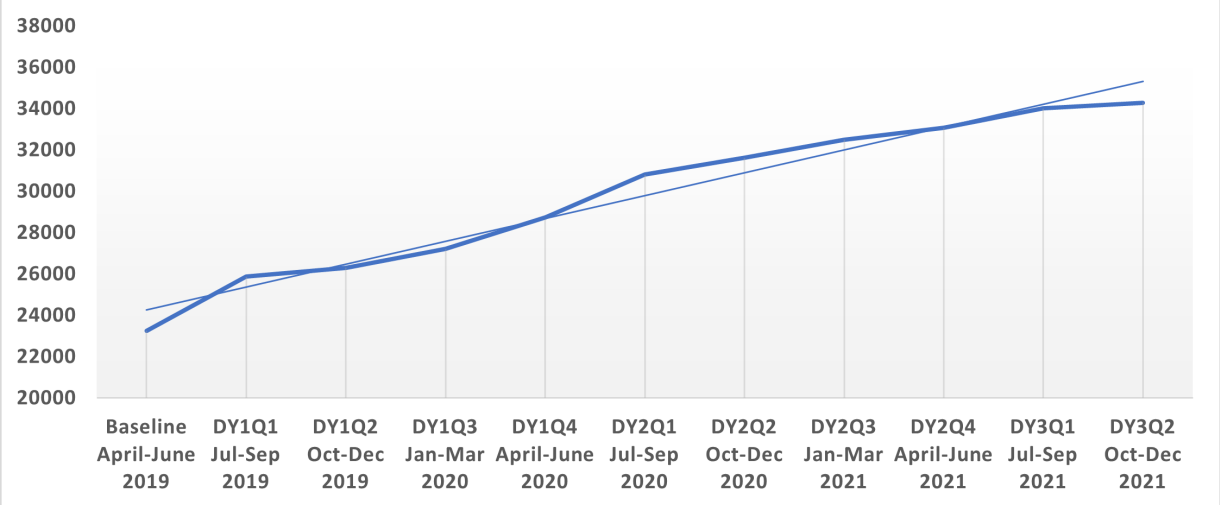
One provision to expand access to naloxone across the Commonwealth was the development of the state's protocol for a standing order by pharmacists. With a “standing order,” pharmacists are allowed to dispense naloxone to an at-risk-person or individual who may assist an at-risk-person and does not have a patient-specific prescription. DMS has partnered with our sister agency, the Department for Public Health (DPH), to ensure these pharmacies are enrolled with KY Medicaid.

To further ensure access to Naloxone and OUD medications, during the PHE, DMS removed prior authorization requirements (PAs) for all Food and Drug Administration (FDA) approved OUD medications, including Naloxone; prior to the PHE prior authorizations were only required for mono buprenorphine and for medications greater than 24 milligrams.

Following removal of prior authorization for OUD medications, KY no longer had a need to align requirements and process for these authorizations; therefore the Implementation Protocol was amended to not include these steps at that time.

As access to medications expanded, and during the PHE when the need for behavioral health services increased, KY did experience an growth in utilization of opioids therapies. Figure 14 illustrates the quarterly average Medicaid beneficiaries who received MAT for OUD**[14]**. From baseline through DY3Q2 of the Demonstration, MAT utilization increased overall by 47%.

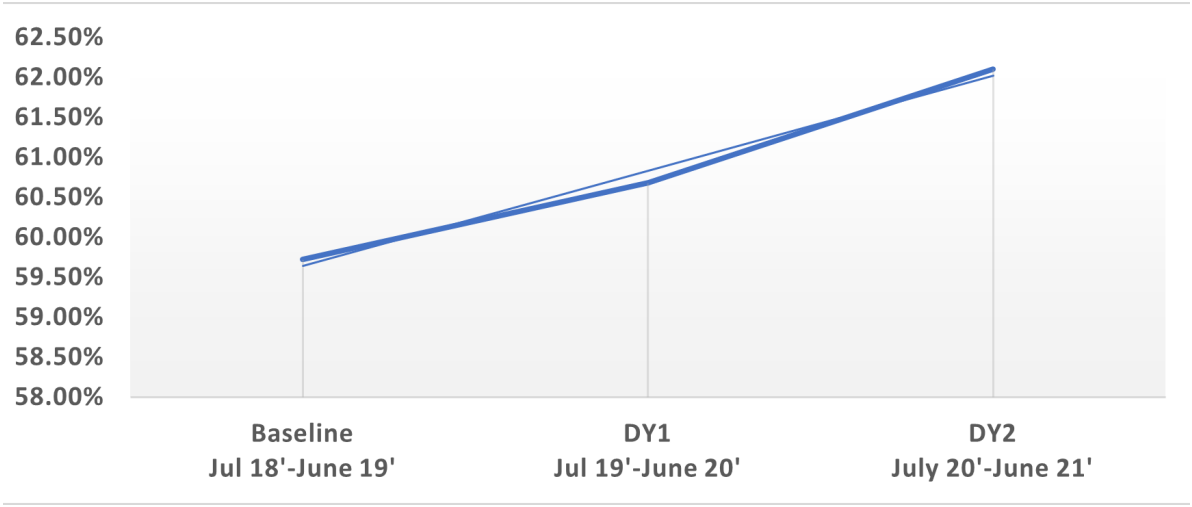
Figure 14: Medication Assisted Treatment (Quarterly), Baseline – DY3Q2



[14] DMS. “Kentucky Medicaid Section 1115 SUD Part A Monitoring Metrics Rolling – Baseline through DY3Q2”. July 2022.

Figure 15 illustrates annual the percent of adults, 18 years of age and older, with pharmacotherapy for OUD who have at least 180 days of continuous treatment**[14]**. From baseline through DY3Q2, DMS continues to show an upward trend.

Figure 15: Continuity of Pharmacotherapy for OUD, Baseline through DY2Q2



To further simplify pharmacy coverage for beneficiaries and prescribers, and align coverage of drug products, effective **January 1, 2021**, DMS moved to a unified preferred drug list (PDL) across all Managed Care Organizations (MCOs) and Fee-for-Service (FFS). Opiate dependent treatments, including generic Narcan was added to the preferred drug list at this time.

[14] DMS. "Kentucky Medicaid Section 1115 SUD Part A Monitoring Metrics Rolling – Baseline through DY3Q2". July 2022.

Objective 6 Outcomes: Develop a SUD Health IT Plan.

To increase utilization and improve functionality of prescription drug monitoring program (PDMP), the Office of Inspector General (OIG) developed a Health IT plan aimed at enhancing the health IT functionality to support PDMP interoperability and enhancing and/or supporting clinicians in their usage of the state's PDMP.

OIG manages the **Kentucky All Schedule Prescription Electronic Reporting (KASPER)** as the Commonwealth's controlled substance prescription monitoring system designed to be a source of information to **assist practitioners and pharmacists** with providing medical and pharmaceutical patient care using **controlled substance medications**. Currently, 18 states participate in interstate data sharing through KASPER. Throughout the Demonstration period, **enhancements** to KASPER improved the PDMP functionalities and expanded capabilities to better support clinicians' office workflows and assist prescribers with informed decision-making and improve coordination of care.

KASPER System Enhancements included:

- Implementing additional interstate data sharing agreements.
- Mandate electronic prescribing of controlled substances (EPCS) with a wavier.
- Software to support additional KASPER learning modules for users regarding KASPER topics of interest.
- Developed data analytic functions to allow prescriber/pharmacist users to make a more informed decision. Such functions include patient dashboards to identify overlapping prescriptions, early refills, multiple provider episodes, potential drug interactions, and other indicators that may indicate overdose risk, or controlled substance abuse or diversion.
- Implemented a link to the KY Administrative Office of the Courts (AOC) CourtNet system to allow PDMP users to obtain information on a patient's drug convictions on the PDMP patient profile report.
- Enhancements to the KASPER Prescriber Report Card to include patient-level data allowing prescribers easier identification of at-risk patients. Prescriber Report Cards are also available in Kentucky prescriber licensure boards to assist with reviewing for inappropriate or illegal controlled substance prescribing.

PDMP User Workflow Enhancements:

- Integration with Kentucky Health Information Exchange (KHIE) and data request capabilities to:

Allow authorized KHIE users to view the PDMP data in KHIE without leaving their clinical workflow to access the PDMP. Integration provides real time, fast, reliable and simplified access to KASPER report information within the user's workflow to provide on the spot information needed to treat and serve those with SUD.

Allow the PDMP user to automatically request information regarding whether a patient experienced a non-fatal drug overdose in an emergency department.

- Implemented "overlap" flag to notify PDMP users of an overlap in prescribing of opioids in real time.

As prescribing of controlled substance medications increases in the Commonwealth, with additional monitoring capabilities and enhancements, KASPER continues to expand it user capacity reporting **38,996 users** through DY2 and a **68% growth** in PDMP requests**[14]**. Since implementing the overlap indicator to the patient KASPER report, there has been an overall **40% reduction** in overlap prescribing when prescribers are alerted of these practices.

[14] DMS. "Kentucky Medicaid Section 1115 SUD Part A Monitoring Metrics Rolling – Baseline through DY2Q2". July 2022.

Objective 7 Outcomes: Improve care coordination and transitions between levels of SUD care.

Providers contracting with MCOs are encouraged to participate in Kentucky Health Information Exchange (KHIE); the state's designated health information exchange platform, to facilitate care coordination resulting in higher quality care and better outcomes for the beneficiaries**[21]**. KHIE provides a holistic view of a patient's health history to facilitate access to clinical data needed to provide safe, timely, efficient, effective, equitable, and patient-centered care. Currently there are 460 behavioral health, including SUD provider locations participating in KHIE.

Each participating Kentucky MCO has established policies and procedures regarding clinical coordination between Behavioral Health Service Providers, including SUD providers, and Primary Care Physicians (PCPs)**[18]**.

To further improve continuity of care, providers contracting with KY Medicaid MCOs are required to ensure all Medicaid beneficiaries receiving inpatient behavioral health services, including SUD services, are scheduled for the appropriate follow-ups and/or continuous of treatment prior to discharge**[18]**.

In addition, SUD residential treatment includes care coordination to ensure beneficiaries receive appropriate community service referrals, facilitation of medical and behavioral health follow ups, and linkage to the appropriate level of SUD within the continuum to ensure ongoing recovery supports. Provider care coordination and discharge planning policies are monitored through the provisional attestation review.

[18] DMS. "Attachment C – Medicaid Managed Care Contract and Appendices". May 21, 2021.

[20] KHIE, Ky.gov. "KHIE Mission and Vision". Last updated 2022. Available here.

NEMT for Methadone

Objective

Initially, the waiver of NEMT was included in the Kentucky HEALTH program with the goal of offering a commercial market experience, to the newly eligible adult group under the Kentucky HEALTH demonstration. Effective **July 1, 2019**, DMS with a State Plan Amendment expanded coverage for methadone for SUD treatment. A waive of NEMT assurance was granted to allow the state not to provide NEMT for methadone services to Medicaid beneficiaries, except for children under age 21 who are subject to EPSDT, former foster care youth, and for pregnant women.

Outcome

Between DY1 and DY3, individuals receiving methadone for SUD treatment increased overall by 64%. Kentucky estimates with the waive of NEMT for methadone treatment services, $14,992, 891.80 through DY3 was not applied capitation payment calculations for NEMT, which includes Medicaid beneficiaries in each transportation brokerage region across the state.

Table 1: NEMT Summary, DY1 – DY3

Metric Description	DY1	DY2	DY3
Unique number of beneficiaries who received methadone for SUD treatment	5,489	8,553	8,988
Number of beneficiaries receiving methadone treatment eligible for NEMT	312	275	278
Statewide estimated total cost per region for eligible enrollees if NEMT was provided for Methadone treatment	$4,877,492.88	$5,252,941.30	$4,862,457.60

**Due to claims lag, DY3 metrics are subject to increase.*

Adult Former Foster Care Out-of-State (ADFF)

Objectives

Following the Demonstration approval in 2018, DMS began providing Medicaid coverage to former foster care youth under age 26 who were in foster care under the responsibility of another state. DMS defines this group as the "Adult Former Foster Care Out-of-State" (ADFF) population. ADFF beneficiaries receive the same Medicaid State Plan benefits and subject to the same cost-sharing requirements effectuated by the state for the mandatory title IV-E foster care youth eligibility category enacted by the Adoption Assistance and Child Welfare Act of 1980 (Pub. L. 96-272).

Outcomes

ADFF enrollment has varied throughout the Demonstration, with the highest enrollment of 129 beneficiaries and lowest enrollment of 2 beneficiaries during an enrollment period. DMS monitors utilization of an array of services in the ADFF population, such as: beneficiaries with any claim, with a primary care visit, emergency department visits, inpatient visits, and behavioral health services.

DMS requests to extend coverage of ADFF under the Demonstration to ensure access to services for individuals who are more vulnerable and at risk than the general Medicaid population. DMS anticipates the PHE to have a great impact on the needs of the Medicaid population; ADFF being no exception. The extension of this benefit allows the Commonwealth to continue severing the ADFF population and maintain health coverage for those who are eligible.

Employee Sponsored Insurance (ESI):

Objectives

Renewal Alignment was included in the Demonstration to streamline the renewal process for beneficiaries with employer-sponsored insurance (ESI) while lessening the burden of the beneficiary to renew benefits for both Medicaid and their ESI. The functionality to align a beneficiary's Medicaid annual redetermination with their ESI open enrollment period was included in Kentucky Integrated Health Insurance Premium Payment (KI-HIPP) enhancement initiative. In Phase 3 of the project, the realignment of dates was implemented on **February 26, 2021**.

The alignment was achieved based on the KI-HIPP renewal dates and the beneficiary's first encounter during one of the following: KI-HIPP Approval or Medicaid Approval, Medicaid Recertification or Medicaid Report A Change, and KI-HIPP Renewal. DMS has established an ongoing process for renewals and new cases approved for KI-HIPP.

Outcomes

Renewal alignment is conducted on an ongoing basis for individuals approved for KI-HIPP. Since implementation, **386 beneficiaries'** Medicaid recertification dates have been aligned with their KI-HIPP renewal date. For a case to be eligible for renewal alignment, the Policy Holder must first meet a defined set of conditions, including:

- KI-HIPP Policy Holder must be a Medicaid Individual.
- Policy Holder must be the Head of the Household of the case.
- Policy Holder must be assigned with a Medicaid Rectification due date, meaning the policyholder should not be receiving benefits such as SSIR, ASMA or FCMA, or SSPM.
- Policy Holder is not receiving temporary benefits, due to which their case recertification date would not be aligned with the household's case recertification date.

In addition to the Policy Holder meeting these requirements, policies will only be eligible for renewal alignment if there is a maximum of six months difference between their KI-HIPP renewal date and Medicaid recertification date. During any avenues where Renewal Alignment is completed, a Medicaid Notice of Eligibility is triggered to communicate the updated Medicaid Recertification date to the household and a notification is sent to the member. The ongoing count of individuals and policies that have renewal alignment completed is communicated in the daily KI-HIPP KPI report.

Phase-Out Plan

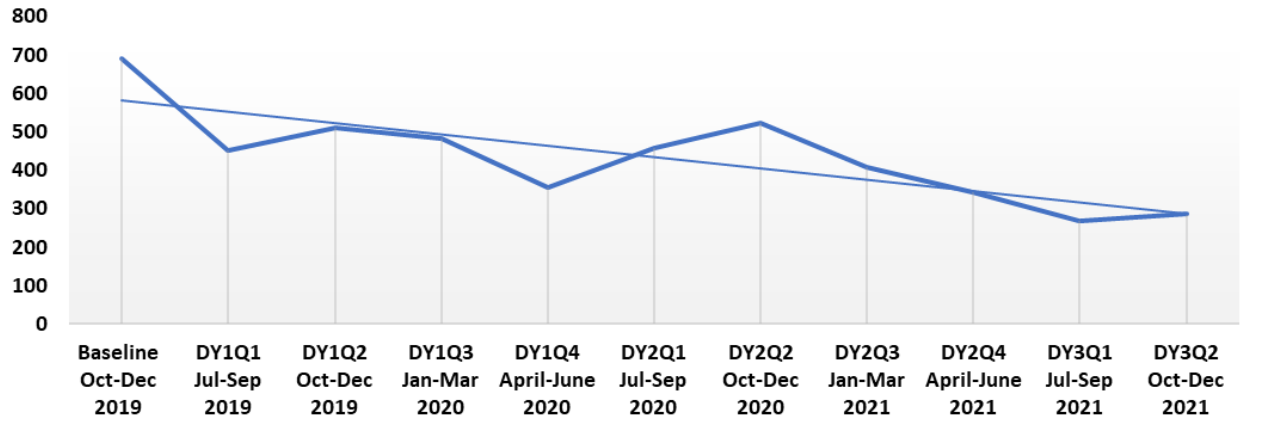
Kentucky successfully completed the realignment of eligible beneficiaries' annual redetermination with ESI open enrollment date according to the STCs. As such, the state has completed this phase of the project and established an ongoing process for currently enrolled and newly enrolling eligible beneficiaries and request not to include this component in the extension of the Demonstration.

Proposed Demonstration Changes

Implementation

At present time, KY is not proposing changes to the Demonstration implementation, however, DMS will continue to monitor and evaluate opportunities DMS may expand the Commonwealth's service array, to provide additional supports and engage individuals into services. Following monitoring protocols and stakeholder feedback, DMS identified areas for growth, including early intervention phases of treatment illustrated in Figure 16; the quarterly average number of beneficiaries who received early intervention services from baseline through DY3Q2**[14]**.

Figure 16: Early Intervention Services (Quarterly), Baseline - DY3Q2



14] DMS. "Kentucky Medicaid Section 1115 SUD Part A Monitoring Metrics Rolling – Baseline through DY3Q2". July 2022.

DMS partners with sister agencies and various Departments across the state, advocacy organizations and stakeholders to explore innovative opportunities to enhance and expand services for Kentuckians. Since 2017, the Kentucky Opioid Response Effort (KORE), housed in the Department for Behavioral Health, Developmental and Intellectual Disabilities (BHDID), has led the KY's opioid response to reduce opioid-related overdose deaths, by expanding and sustaining a recovery-oriented system of care and increasing access to evidence-based prevention, harm reduction, treatment, and recovery support services**[22]**. During the Demonstration extension period, DMS remains committed to maintaining valuable collaborative partnerships with these agencies to address opportunities for DMS to support expanding and sustaining the recovery-oriented system of care, and further succeed in achieving better health outcomes and improving the lives of Kentuckians.

Monitoring

Historically race and ethnic populations experience worse health outcomes. Research suggests collecting data, measuring outcomes and reporting is needed to better identify the nature of health disparities which is critical to improving care for all**[23]**.

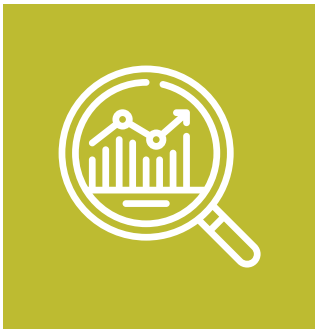
The Commonwealth strives to ensure equitable access to quality care for all Kentuckians and proposes to include race and ethnicity categories as state-specific subpopulations incorporated into the SUD 1115 and pending incarceration amendment monitoring plan. Throughout the extension of the Demonstration, the state will monitor established SUD metrics to identify whether there are disparities among certain race and ethnic populations with SUD. As the state begins to navigate “post COVID”, the extension of the Demonstration will play a vital role in serving Kentuckians and addressing impacts of the PHE. The U.S. Government Accountability Office (GAO) found that certain populations, including race and ethnic populations, are at higher risk of new or exacerbated behavioral health conditions, including SUD, related to the pandemic, and has since worsened health, social, and economic outcomes among racial and ethnic communities**[24]**.

[22] CHFS, BHDID. “About KORE”. August 2021. Available here .

[23] NIH National Library of Medicine. Fremont, A. and Lurie, N., “Appendix D: The Role of Racial and Ethnic Data Collection in Eliminating Disparities in Health Care”. 2004. Available here.

[24] GAO, U.S. Government Accountability Office Gao.gov. “Behavioral Health and COVID-19: Higher-Risk Populations and Related Federal Relief Funding”. December 10, 2021. Available here.

Additionally, the University of Kentucky's (UK) HEALing Communities Study (HCS) found the rate of deadly drug overdoses among Black Kentuckians more than doubled from 2016 to 2020, and that "this reflects national data, which show that disparities in opioid overdose deaths continue to worsen for Black people"**[25]**. In addition, the Centers for Disease Control (CDC) and Prevention found fatal overdoses continue to increase among racial and ethnic minority groups, and of these groups individuals who experience fatal overdoses are least likely to have obtained treatment**[26]**. Over the course of the Demonstration, Medicaid recipients accounted for nearly two-thirds of KY's overdose deaths. While the state acknowledged there are limitations with collecting race and ethnicity data; this data will further help DMS determine causes of such disparities, and how to better address them to ensure improved health outcomes for all Medicaid beneficiaries.

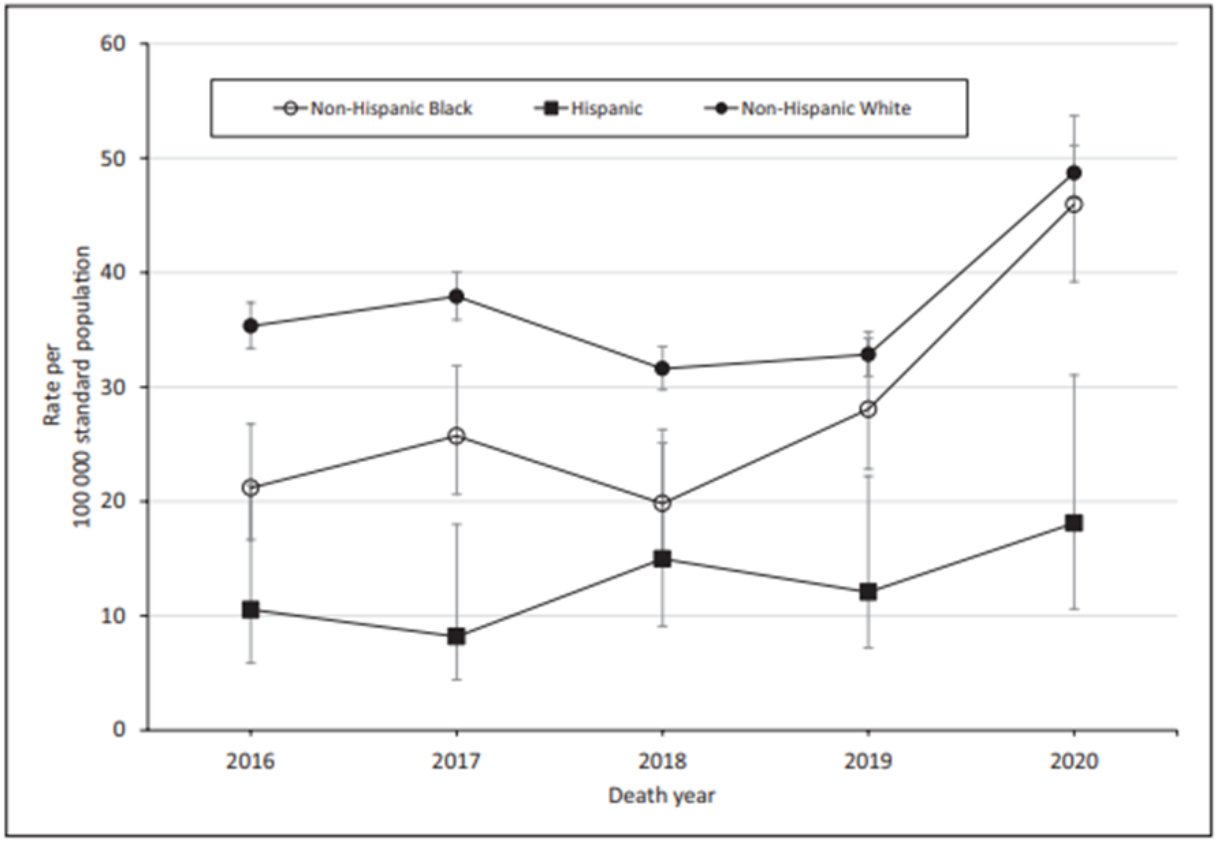


[25] Research.uky.edu. "UK Study: Black Overdose Death Rate Doubles in Kentucky | University of Kentucky Research". June 1, 2022. Available here.

[26] CDC. Kariisa M, Davis NL, Kumar S. "Vital Signs: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics — 25 States and the District of Columbia". July 19, 2022. Available here.

Figure 17 illustrates the age-adjusted drug overdose death rate per 100,000 standard population among Kentucky residents, by race and ethnicity, from 2016 through 2020. “Error bars indicate 95% CIs. Data source: Kentucky Office of Vital Statistics death certificate records as part of the Kentucky Drug Overdose Fatality Surveillance System. The reported numbers are provisional (as of April 13, 2021) and subject to change. The 2020 rates are based on 2019 bridgedrace population estimates because at the time this analysis was performed, the 2020 bridged-race population estimates produced by the National Center for Health Statistics (NCHS) were not available. Data source for population estimates: NCHS. Bridged race resident population estimates, 1990-2019"**[27]**.

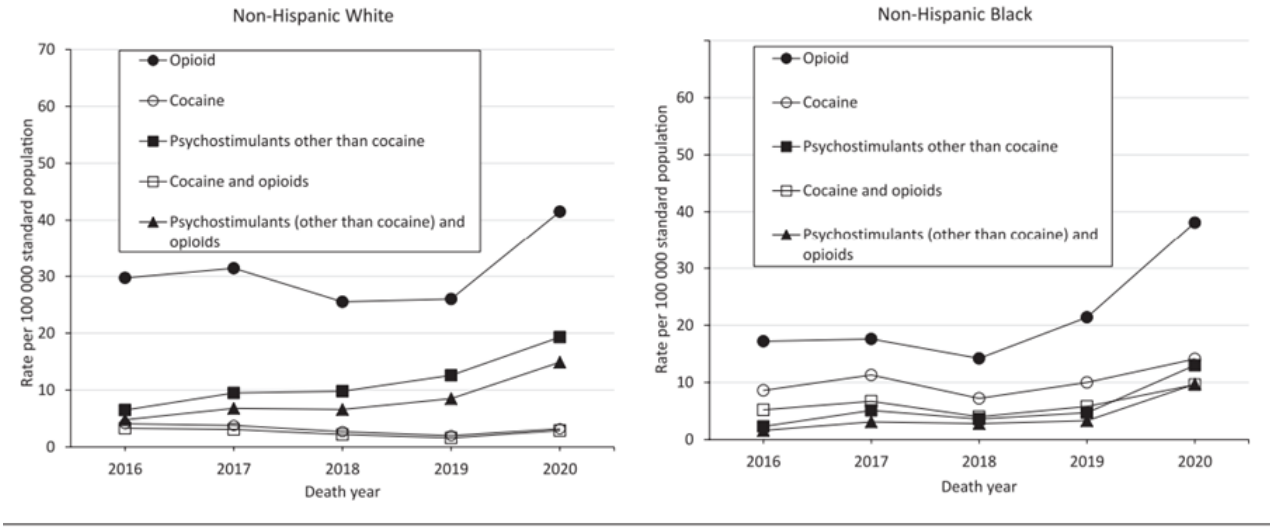
Figure 17: KY Overdose Death Rate per 100,000 by Race and Ethnicity, 2016-2020



[27] Research.uky.edu. “UK Study: Black Overdose Death Rate Doubles in Kentucky | University of Kentucky Research”. June 1, 2022. Available at here.

Figure 18 illustrates the age-adjusted drug overdose death rate per 100,000 standard population among non-Hispanic White and non-Hispanic Black Kentucky residents, by drug involvement from 2016 through 2020. Data source: "Kentucky Office of Vital Statistics death certificate records as part of the Kentucky Drug Overdose Fatality Surveillance System. The reported data are provisional (as of April 13, 2021) and subject to change. The 2020 rates are based on 2019 bridged-race population estimates because at the time this analysis was performed, the 2020 bridged-race population estimates produced by the National Center for Health Statistics (NCHS) were not available. Data source for population estimates: NCHS. Bridged-race resident population estimates, 1990-2019"**[27].**

Figure 18: KY Overdose Death Rate per 100,000 Among Non-Hispanic White and Non-Hispanic Black Residents, 2016-2020



During Phase 2 of the SUD 1115 Implementation, DMS implemented residential level specific procedure codes for ASAM Levels 3.1 – 3.7. KY plans to incorporate state specific metrics into the Monitoring Plan during the extension of the Demonstration to report ALOS by ASAM residential levels for beneficiaries discharged from residential treatment for SUD.

Monitoring ALOS by LOC will:

- **P**rovide the state with better analysis of beneficiary's treatment needs.
- Ensure individuals are receiving patient centered care at the appropriate levels and least intensity as possible.
- Ensure residential stays do not exceed a statewide average length of stay of thirty (30) days.

[27]Sage Journals. Slavova, S., Freeman, P. R., Rock, P., Brancato, C., Hargrove, S., Liford, M., ... & Walsh, S. L. (2022). "Changing Trends in Drug Overdose Mortality in Kentucky: An Examination of Race and Ethnicity, Age, and Contributing Drugs," 2016-2020. Public Health Reports, 00333549221074390. Available here .

Waivers and Expenditure Authorities

DMS requests to extend the following waiver authorities through September 30, 2028 under Kentucky's Section 1115 (a)(1) of the Social Security Act, contained in section 1902 of the Act.

Table 2: Waiver Authority Request

Waiver Authority	**Use of Waiver Authority**
Methods of Administration: Section 1902(a)(4) insofar as it incorporates 42 CFR 431.53	To the extent necessary to relieve Kentucky of the requirement to assure non-emergency medical transportation to and from providers for all Medicaid beneficiaries to the extent the non-emergency medical transportation is for methadone treatment services. The waiver does not apply with respect to pregnant women or former foster care youth, and also does not apply if the service is provided subject to early and periodic screening, diagnostic, and treatment (EPSDT).
Provision of Medical Assistance: Section 1902(a)(8) and 1902(a)(10)	To the extent necessary to permit Kentucky to limit the provision of medical assistance (and treatment as eligible) for individuals described in the eligibility group under section 1902(a)(10)(A)(ii)(XX) of the Act and the state plan to only former foster care youth who are under 26 years of age, were in foster care under the responsibility of another state or tribe on the date of attaining 18 years of age (or such higher age as the state has elected), and who were enrolled in Medicaid on that date.

Kentucky successfully completed the realignment of eligible beneficiaries' annual redetermination with ESI open enrollment date according to the states issued STCs. DMS is not requesting to extend the following expenditure authority beyond October 1, 2023 under the authority of section 1115(a)(1) of the Social Security Act:

Waiver Authority	Use of Waiver Authority
Continuous Eligibility: Section 2107(e)(1)(R)	To the extent necessary to enable Kentucky to align a beneficiary's annual redetermination with their employer sponsored insurance (ESI) open enrollment period, including any children enrolled in CHIP and covered by a parent or caretaker's ESI, in a manner inconsistent with requirements under section 1943 of the Act as implemented in 42 CFR 457.343 and 42 CFR 435.916(a).

To promote objectives of title XIX of the Social Security Act, under the authority of Kentucky's Section 1115(a)(2) of the Act, DMS requests to extended expenditures authorities through September 30, 2028 made by the Commonwealth to be regarded as matchable expenditures under the state's Title XIX plan.

Table 3: Expenditure Authority Request

Expenditure Authority	Use of Expenditure Authority
Expenditures related to IMDs for SUD Treatment	Expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental disease (IMD).

Kentucky successfully completed the realignment of eligible beneficiaries' annual redetermination with ESI open enrollment date according to the states issued STCs. DMS is not requesting to extend the following expenditure authority beyond October 1, 2023 under the authority of section 1115(a)(2) of the Social Security Act:

Expenditure Authority	Use of Expenditure Authority
Expenditures related to aligning a beneficiary's annual redetermination date	Expenditures to the extent necessary to enable Kentucky to align a beneficiary's annual redetermination with their employer sponsored insurance (ESI) open enrollment period, including any children enrolled in Medicaid and covered by a parent or caretaker's ESI, in a manner inconsistent with requirements under section 1943 of the Act as implemented in 42 CFR 435.916(a).

External Quality Review Organization (EQRO), Quality Assurance Strategy and MCO Reports

External Quality Review Organization (EQRO) Report

DMS contracted with IPRO, an EQRO, to conduct the states EQR activities for Kentucky's six (6) MCOs contracted to furnish Medicaid services in the state, which include: Aetna Better Health of Kentucky (Aetna), Anthem Blue Cross Blue Shield (Anthem), Humana Healthy Horizons in Kentucky (Humana), Passport Health Plan (Passport), UnitedHealthcare Community Plan (UHC) and WellCare of Kentucky (WellCare).The Executive Summary and full **SFY 2021 EQRO Report** can be reviewed on the DMS website**[28]**.

EQRO activity findings to assess the performance of Kentucky Medicaid MCOs in providing quality, timely, and accessible healthcare services to Medicaid members. The individual MCOs were evaluated against state and national benchmarks for measures related to the quality, access, and timeliness domains, and results were compared to previous years for trending when possible.

Quality of Care is measured on:

- ☑ Compliance Review
- ☑ HEDIS Performance Measures of Quality
- ☑ Consumer Satisfaction
- ☑ PIP Validation
- ☑ MCO Quality Ratings
- ☑ NCQA Accreditation

[28] DMS. "External Quality Review Annual Technical Report State Fiscal Year 2021". April 2022. Available here.

Access/Timeliness of Care is measured on:

- ☑ Compliance Review
- ☑ Network Adequacy
- ☑ HEDIS Performance Measures of Access/Timeliness
- ☑ Focus Studies

Managed Care Quality Strategy (MCQS)

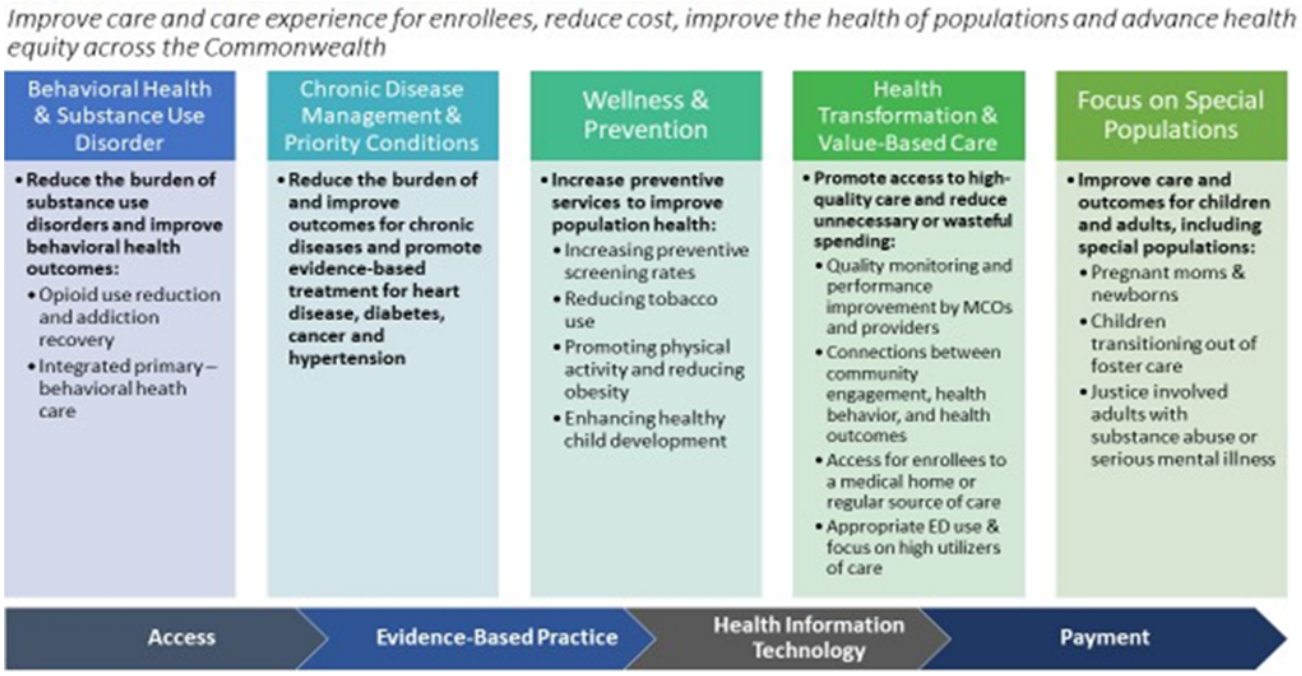
In accordance with 42 CFR§438.340, the DMS 2019-2022 Managed Care Quality Strategy (MCQS) is built on the foundation of improving not only the health of Kentuckians covered by Medicaid and the Kentucky Children's Health Insurance Program (KCHIP), but also the communities in which they live**[29]**.

The vision for the MCQS is not only for Medicaid enrollees to experience more patient-centered, outcomes-oriented care, but for DMS efforts to serve as a catalyst for further transformation of health and health care in Kentucky. The MCQS outlines DMS's overall vision for achieving this vision:

Goal 1	Reduce the burden of substance use disorder (SUD) and engage enrollees to improve behavioral health outcomes.
Goal 2	Reduce the burden of and outcomes for chronic diseases.
Goal 3	Increase preventive service use.
Goal 4	Promote access to high quality care and reduce unnecessary spending.
Goal 5	Improve care and outcomes for children and adults, including special populations

[29] DMS. "Fiscal Year 2021 Comprehensive Evaluation Summary Commonwealth of Kentucky Strategy for Assessing and Improving the Quality of Managed Care Services". Available here.

Figure 19 : Kentucky Medicaid Quality Aims, 2019–2022



Each year, the DMS Managed Care Oversight - Quality Branch completes a comprehensive evaluation summary of the Commonwealths strategy for assessing and improving the quality of managed care services. Effective **January 1, 2021**, DMS entered into new contracts with six risk-based MCOs serving Kentucky Medicaid enrollees statewide. Between April 2019 and April 2021, statewide program enrollment increased by 23.1%.

Table 4 : List of Kentucky Medicaid MCOs by Enrollment

MCO	Enrollment 4/2019	Enrollment 4/2020	Enrollment 4/2021	Percent Change 2019–2021
Aetna	213,996	211,220	244,373	14.2%
Anthem	127,620	136,633	159,978	25.4%
Humana	143,051	147,788	167,293	16.9%
Passport by Molina	305, 051	303,197	324,486	6.4%
UnitedHealthcare	N/A	N/A	140, 251	N/A
WellCare of Kentucky	435,981	441,271	472,939	8.5%
Total	1,225,699	1,240,109	1,509,320	23.1%

According to the SFY21 Comprehensive Evaluation Summary, regarding Goal 1: To reduce burden of SUD and engage enrollees to improve behavioral health outcomes, the report indicates:

There are five HEDIS measures in **Goal 1,** but only four could be compared to previous years' rates. The two IET measures, Initiation and Engagement of Abuse and Dependence Treatment (AOD), increased steadily over the last three years, while the two rates for Antidepressant Medication Management (AMM) decreased. Since the previous year, 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 resulted in a rate that met or exceeded the national 75th percentile but was below the 90th percentile. Both of the AMM measures were at or above the national 25th percentile but below the 50th percentile.

Table 5: Overview of Comprehensive KY Medicaid Quality Strategy, Goal 1, 2019-2022

Goals & Aims	Interventions	Core Measures	Monitoring, Feedback &Transparency
Goal 1. Reduce burden of SUD and engage enrollees to improve behavioral health outcomes **Aim 1.1** Reduce Opioid Use through access to addiction recovery services **Aim 1.2** Enhance BH care through integrated primary care-BH care **Aim 1.3** Increase the number of screenings for OUD	Waiver of IMD Exclusion (Pilot) to enhance access (1.1); Pilot or care coordination programs to integrate primary care and BH care (1.2) Core measures for MCOs include: BH and SUD treatment Pharmacy and provider 'lock in' program	**HEDIS Measures:** • Antidepressant Medication Management (AMM) (2 measures) • Initiation and Engagement of Alcohol and other Drug (IET) **Clinical Measures:** • Use of Opioids at High Dosage (NCQA proposed); • Screening for Clinical Depression and Follow Up Plan (NQF 418)	Quarterly reports from MCOs; reviewed internally to evaluate progress and possible changes to interventions publicly shared after an evaluation period of no less than 3 years

Fiscal Summary

States must demonstrate budget neutrality to receive approval of the project under Section 1115(a) of the Act, and to receive federal financial participation (FFP) for state expenditures that would not qualify for FPP under section 1093 of the Act. The state is subject to a limit on the amount of federal Title XIX funding that the state may receive on selected Medicaid expenditures during the period of approval of the demonstration; the upper limit represents what the state could have received in the absence of the 1115 Demonstration. The budget neutrality expenditure limits are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration**[10]**.

Appendix A, SUD Budget Neutrality Summary, illustrates KY's SUD Section 1115 Demonstration current without-waiver (WOW) total expenditures and with-waiver (WW) total expenditures reported using the quarterly Budget Neutrality Workbook. The Section 1115 Demonstration Budget Neutrality Workbook is used to determine financial performance for the demonstration in terms of budget neutrality.

Figure 20 illustrates KY's rebased budget neutrality expenditure limit through the requested extension period, according to procedures outlined in the SMD#18-009 RE: Budget Neutrality Policies for Section 1115(a) Medicaid Demonstration Projects**[30]**.

Figure 20: Kentucky's Rebased Budget Neutrality Expenditure, DY6 - DY10

Budget Netrality Summary

Without-Waiver (WOW) Total Expenditures

	DEMONSTRATION YEARS (DY)					
	DY06	DY7	DY8	DY9	DY10	TOTAL
SUD TOTAL	$34,778,208	$ 39,892,287	$45,758,431	$ 52,486,958	$ 60,204,853	$ 233,120,737

With-Waiver (WW) Total Expenditures

	DEMONSTRATION YEARS (DY)					
	DY6	DY7	DY8	DY9	DY10	TOTAL
SUD TOTAL	$34,778,208	$ 39,892,287	$45,758,431	$ 52,486,958	$ 60,204,853	$ 233,120,737

[10] CMS, Medicaid.gov. "KY HEALTH Demonstration Reissuance". Reissued June 16, 2020. Available here.

[30] CMS, Medicaid.gov. "Budget Neutrality Policies for Section 1115(a) Medicaid Demonstration Projects." August 22, 2018. Available here.

Budget Statement Regarding Former Foster Youth

According to STC 75, CMS determined provision of benefits and services for the former foster care youth demonstration population was budget neutral based on CMS' assessment that the waiver authorities granted for this population were unlikely to result in any increase in federal Medicaid expenditures. As a result, a budget neutrality test was not required for this demonstration population, therefore no budget neutrality expenditure limits were established and rebasing budget neutrality limits for this demonstration population is not applicable for the extension period.

Evaluation Summary

University of Pennsylvania (UPenn) began implementation of the proposed evaluation plan in **October 2019**. DMS closed the evaluation contract with UPenn **April 2020**, at which time Northern Kentucky University (NKU) assumed responsibility for the SUD 1115 Evaluation on **July 1, 2020**.

The final SUD Evaluation Design was approved by CMS on **June 16, 2020** and was adopted by NKU when onboarding to the Demonstration. The full approved evaluation design can be viewed**[31]**: https://chfs.ky.gov/agencies/dms/BHI/SUDEvaluationApprovalLetter.pdf.

The SUD Demonstration evaluation hypotheses includes:

- **H1a:**The demonstration will increase the ratio of outpatient Medicaid SUD/OUD 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/OUD providers offering residential treatment, especially IMDs, to beneficiaries.
- **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.

Evaluation Activities to Date

Utilizing two frameworks, NKU completed and submitted the **SUD Mid-Point Assessment** April 15, 2021**[32]**. 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, as well as to identify common themes and issues across the mechanisms being used to implement the demonstration.

[31]DMS. "SUD Evaluation Approval Letter". June 16, 2020. Available at here.

[32] DMS. Northern Kentucky University. "Mid-Point Evaluation: Section 1115 Substance Use Disorder Demonstration, Department for Medicaid Services." April 12, 2021. Available here.

Second, SWOT (Strength, Weakness, Opportunity, Threats) analyses was applied to mechanisms used to implement the 1115 Demonstration. This analyses was used to evaluate the positioning of the 1115 Demonstration relative to the program goals, encompassing performance, competition, risk, and potential.

Data sources included:

- 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

Evaluation Findings To Date

Appendix D contains the full Interim Evaluation Report. The report contains both quantitative and qualitative analyses with two principal analytic methods used to conduct the report: Longitudinal analysis of descriptive statistics and thematic analysis of provider and beneficiary interviews.

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. 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 crosssectional design.

Data sources include:

- Medicaid Claims data
- Kentucky Medicaid Provider Enrollment Portal
- Kentucky Treatment Outcome Survey (KTOS)
- Kentucky Opiate Replacement Treatment Outcome Survey (KORTOS)
- Beneficiary and Patient Interviews

Based on the findings, preliminary conclusions include:

- **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 though 2020.
- **H1b:** The number of Medicaid providers billing for residential SUD treatment increased from 2017 though 2020, as did the number of licensed IMD facilities.

- **H1c:** Definitive answers regarding utilization of services are unavailable at this time. While the number of beneficiaries newly diagnosed with SUD and those receiving treatment for the first time both increased from 2017 through 2020, the rate as a percentage of beneficiaries ultimately did not show an increase, due largely, we believe, to the impact of COVID-19. Similarly, while there was an increase in the number of beneficiaries receiving residential treatment for SUD from 2017-2020, the rate as a percentage of beneficiaries ultimately did not show an increase either. However, there was an increase in the number of beneficiaries receiving outpatient treatment for SUD from 2017-2020, and, while the rate as a percentage of beneficiaries declined with the advent of COVID-19, it did not completely erase the gains seen after the waiver started. Similarly, there was both an increase in the total numbers and the rate of beneficiaries with OUD who received MOUD as well as those receiving methadone as their MOUD (though the rates did taper slightly during the pandemic). More data will need to be collected before we will be able to accurately assess these metrics.
- **H1d/H2a**: The number of ED visits for SUD-related diagnoses among beneficiaries did not decrease, but it increased from 2017 to 2020. However, the rate of visits followed roughly the same cyclical pattern from 2017 to 2020. These outcomes appear to be impacted by the dramatic increase in the number of beneficiaries with SUD seen across the same study period. For, the number of beneficiaries with a primary SUD diagnosis who then accessed SUD services within 30 days after visiting the ED increased from 2017 through July 2020. As well, the number of beneficiaries with a primary SUD diagnosis who then had accessed SUD services within 30 days prior to visiting the ED decreased steadily from 2017 through 2020.
- **H2b:** The rate of hospital admissions for SUD-related diagnoses remains ambiguous. 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 October of 2020. More data will need to be collected before we can accurately assess this metric.
- **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 76 continued illicit drug usage. No changes were noted in self-reported outcomes from pre-waiver to post-waiver.

Planned Evaluation Activities During the Extension

Ensuring Continuity and Communication

NKU does not plan to make changes to the evaluation design at this time and will continue to conduct the evaluation activities through the extension of the Demonstration. NKU will discuss with CMS any and all evaluation deliverables required through the extension of the Demonstration. DMS will keep NKU apprised of future changes or amendments to the Demonstration during the extension period that may impact the evaluation.

Public Notice

Prior to submission of Kentucky's Section 1115 Demonstration extension application to CMS, the Commonwealth conducted the state public notice process according to § 431.408. See Appendix C for Summary of Public Hearings and Comment Procedures.

KENTUCKY MEDICAID PROGRAM

PUBLIC NOTICE

Kentucky Medicaid Section 1115 Demonstration:
Kentucky Helping to Engage and Achieve Long Term Health (KY HEALTH)

In accordance with 42 CFR 431.408, the Cabinet for Health and Family Services (CHFS), Department for Medicaid Services (DMS) announces its intention to submit a request to the Center for Medicare and Medicaid Services (CMS) to extend the Kentucky Medicaid Section 1115(a) Demonstration, entitled "Kentucky Helping to Engage and Achieve Long Term Health (KY HEALTH)" to September 30, 2028. KY requests to amend the title of the Demonstration as "TEAMKY".

Kentucky is requesting to extend the following waiver and expenditure authorities: Expenditures related to IMDs for SUD treatment, methods of administration for waiving non-emergency medical transportation (NEMT) for methadone treatment, and provision or medical assistance to provide Medicaid coverage to former foster care youth under age 26 who were in foster care under the responsibility of another state.

Kentucky successfully completed the realignment of eligible beneficiaries' annual redetermination with employer sponsored insurance (ESI) open enrollment date according to the states issued standard terms and conditions (STCs). DMS is not requesting to extend this waiver and expenditure authority beyond October 1, 2023 under the authority of section 1115(a)(1) of the Social Security Act.

No additional changes to implementation of the Demonstration will be requested at this time. KY's goal for the extension request will be to continue monitoring and evaluating opportunities DMS may expand the SUD service array by providing additional supports and engaging individuals into treatment, to achieve better health outcomes and improve the lives of Kentucky Medicaid beneficiaries.

Public Forums

DATES & TIMES:

August 25, 2022 from 11:00AM-12:00PM EST

August 30, 2022 from 3:00PM-4:00PM EST

PLACE:

Join via ZOOM at https://zoom.us/join

Meeting ID: 2269634060
Password: 606335

Phone: 888-822-7517
Conference Code: 186903

Public Comments

A draft of the Demonstration extension application and copies of this notice are available on the DMS website: https://chfs.ky.gov/agencies/dms/Pages/default.aspx. Notices are available in the following news publications: Louisville Courier-Journal, Lexington Herald-Leader and the Cincinnati Enquirer. Comments or inquiries should be submitted via email received on or before September 13, 2022 to: DMS.ISSUES@ky.gov. Written comments must be postmarked by September 13, 2022 and mailed to:

Kentucky Medicaid Section 1115 Comment
c/o DMS Commissioner's Office
275 E. Main St. 6W-A
Frankfort, KY 40621

Post -Award Public Forum

DMS conducted post-award public forums to summarize the Kentucky HEALTH Section 1115 Demonstration and solicit feedback in accordance with § 431.420(c). The initial public form was held: (1) **June 28, 2016** in Bowling Green, Kentucky; (2) **June 29, 2016** at the Advisory Council for Medical Assistance (MAC) Special Meeting in Frankfort, Kentucky; and (3) **July 6, 2016** in Hazard, Kentucky.

Though the Kentucky HEALTH program was not implemented, following the approval of the Demonstration, three monthly Stakeholder forums were held in **January, February and March 2019** across the state to provide an opportunity for outreach and education.

Shortly following SUD Phase 1 Implementation, Kentucky hosted it's initial SUD post-award community forum on **July 11, 2019**, at the Gateway Community and Technical College in Covington, Kentucky. The forum was open to the public, as well as viewable on Kentucky HEALTH's Facebook Live and audio listening with a "dial-in" option. A panel with Q&A session was conducted at the forum during which time attendees' questions and concerns were addressed.

Additionally, DMS hosted 8 MCO Public Forums across the state from **September 30 through October 16, 2019**. Prior to forms being conducted, the forum schedule and agenda were posted on the DMS website. During each forum, DMS provided an SUD 1115 update, including an outline of the overall demonstration goals and overview of Phase 1 & 2 Implementation. Questions and concerns were addressed during each forum; following the conclusion of the forums, KY amended pending filed regulations based on comments received during that time.

DMS held a series of webinars prior to Phase 1 and 2 Implementation designed to share relative information about the Demonstration including, State Plan and regulation changes, policies and procedures, enrollment updates and provider requirements. Webinar recordings, presentations, guides, and FAQs may be viewed on the **Training and Webinar** page of the DMS Website.

In addition to webinars, prior to and following SUD Phase 2 Implementation, DMS conducted monthly SUD Residential Provider Check-In Calls via ZOOM to provide updates, review expectations, and address questions regarding the DMS Provisional Certification process and ASAM LOC Certification expectations. Participants included providers, representatives, advocates and MCOs. In addition to the provider check-in calls, DMS also distributed SUD Residential Provider Newsletters with informative updates relative to the SUD Demonstration.

Prior to submitting the amendment to the KY Health Section 1115 Demonstration, DMS conducted two virtual Town Hall meetings on **October 12, 2020** and **October 26, 2020**, during which time DMS provided updates on the 1115 Demonstration and overview of the proposed incarceration amendment. Prior to the meetings, notifications were posted on the **Public Notice** webpage of the DMS Website, as well as notifications sent to stakeholder groups across the state.

DMS also provided SUD Demonstration, including pending incarceration amendment updates to the Behavioral Health (BH) Technical Advisory Committee (TAC) on **March 3, 2021**, **May 11, 2021** and **November 3, 2021**. The BH TAC meeting information including agendas, locations, materials, and minutes can be viewed on the **BH TAC** webpage on the DMS Website

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Appendix

Appendix A: SUD Section 1115 Budget Neutrality Summary

Actuals + Projected

Without-Waiver (WOW) Total Expenditures

	DEMONSTRATION YEARS (DY) 1	2	3	4	5	6	TOTAL
SUD TOTAL	$ 1,430	$ 111,125	$ 23,014,535	$ 52,964,620	$ 60,179,585	$ 71,333,770	$ 224,058,446

With-Waiver (WW) Total Expenditures

	DEMONSTRATION YEARS (DY) 1	2	3	4	5	6	TOTAL
SUD TOTAL	$ 174	$ 42,174	$ 12,027,526	$ 26,653,935	$ 26,433,993	$ 34,778,208	$ 99,935,020

Demonstration Year 5- 6 calculations are currently based on projected expenditures according to and reported in the Section 1115 Demonstration Budget Neutrality Workbook.

Appendix B: Additional Quality Reports

A copy of the Fiscal Year 2021 Comprehensive Evaluation Summary Commonwealth of Kentucky Strategy for Assessing and Improving the Quality of Managed Care Services can be viewed here.

Additional reports such as MCO Annual Compliance Reviews, Quality of Care Focus Studies, and Reports Cards completed by the DMS Managed Care Oversight - Quality Branch can be viewed at here.

Appendix C: Summary of Public Hearings & Comments

Prior to submitting KY's Section 1115 Demonstration extension request to CMS DMS will follow all guidelines and procedures according to 42 CFR § 431.408 regarding collection, review of and response to public comments.

Appendix D: Interim Evaluation Report

INTERIM EVALUATION

Section 1115 Substance Use Disorder Demonstration

Kentucky Cabinet for Health & Family Services

Department for Medicaid Services

August 9, 2022

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

EVALUATION TEAM

Valerie Hardcastle
Gary Ozanich
Xiaoni Zhang
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Clay Driscoll
Joveria Baloch

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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
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
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
SUD	Substance Use Disorder

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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/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. This 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 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;

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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).

A1a: The demonstration will decrease the total SUD/OUD expenditures;

A1b: The demonstration will decrease SUD/OUD and non-SUD/OUD expenditures, with SUD/OUD expenditures disaggregated into IMD and non-IMD expenditures;

A1c: 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.

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. As a result, the study period for the Interim

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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.

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.

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

1. 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 though 2020.
2. The number of Medicaid providers billing for residential SUD treatment increased from 2017 though 2020, as did the number of licensed IMD facilities.
3. Definitive answers regarding utilization of services are currently unavailable. While the number of beneficiaries newly diagnosed with SUD and those receiving treatment for the first time both increased, the rate as a percentage of beneficiaries ultimately did not show an increase, due largely, we believe, to the impact of COVID-19. Similarly, while there was an increase in the number of beneficiaries receiving residential treatment for SUD, the rate as a percentage of beneficiaries ultimately did not show an increase either. However, there was an increase in both the number and the rate of beneficiaries receiving outpatient treatment for SUD, as well as both an increase in the total numbers and the rate of beneficiaries with OUD who received MOUD.
4. The number of ED visits for SUD-related diagnoses among beneficiaries increased. These outcomes appear to be impacted by the dramatic increase in the number of beneficiaries with SUD seem across the same study period. However, the number of beneficiaries with a primary SUD diagnosis who then accessed SUD services within 30 days after visiting the ED also increased as well.
5. The rate of hospital admissions for SUD-related diagnoses remains ambiguous. More data will need to be collected before we can accurately assess this metric.
6. While significant improvements are shown regarding self-reported life outcomes after treatment, a third report continued illicit drug usage.
7. Expenses for demonstration-related health services have steadily increased, as have the number of beneficiaries with SUD.

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.

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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, about 40% of adults with opioid addiction are within the Medicaid-insured population (MACPAC, 2017), 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.

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The implementation plan for the demonstration was initially approved on October 5, 2018, with an amendment granted on November 4, 2019.[1]

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 amendment approved November 4, 2019
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.

[1] 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.

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The Approval date for the KY 1115 SUD waiver was 11/20/2018; its effective date was 04/01/2019, and the **e**xpiration data is 12/31/2023. The fiscal years (FY) July 2017-June 2018 and July 2018-June 2019 were used as baseline years. Table B.2.1 below outlines the demonstration year (DY) periods for the project. This interim report covers DY 1 only.

Table B.2.1 Demonstration Year Periods

DY	Periods
DY 1	April 1, 2019 - December 31, 2020
DY 2	January 1, 2021 - December 31, 2021
DY 3	January 1, 2022 - December 31, 2022
DY 4	January 1, 2023 - December 31, 2023

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:

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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; and
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.

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

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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-specific program standards	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
	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	

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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

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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

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

B.4 Renewals, Amendments, and Major Operational Changes

There have been no changes to the demonstration during the approval period.

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 million based upon counts by the US Census Bureau. As of May 2020, the unduplicated count for Medicaid beneficiaries in the Commonwealth was 1,434,288, or 32% 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.

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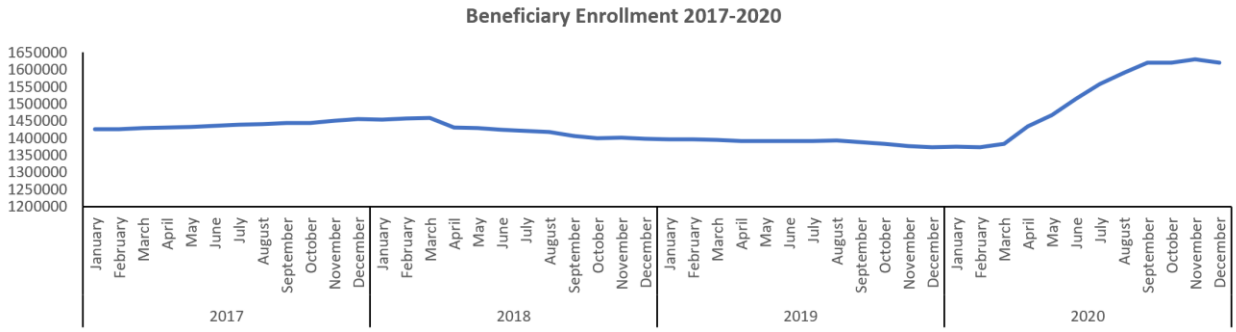
Table B.5.1 Kentucky Medicaid Beneficiary Plans (2020)

Plan Type	Unduplicated Member Count
Aetna	211,021
Anthem	139,091
Fee for Service	185,399
Humana	149,581
Passport by Molina	306,200
Wellcare	442,936
Grand Total	**1,434,288**

(Kentucky for Department Medicaid Services, 2020)

The chart below in Figure B.5.1 shows the four-year Medicaid enrollment trend in Kentucky starting January 2017 and ending December 2020. There was a significant increase in enrollment.

Figure B.5.1 Four-Year Medicaid Enrollment Trend



While in 2017 there was little variation, 2018 and 2019 saw slight decreases and then between March 2020 and December 2020 there was a sharp increase. We note that this increase corresponds with the advent of COVID-19. This report will attempt to highlight periods in which the pandemic might impact evaluation analysis.

As shown in Table B.5.2 below, reimbursement claims also increased by 10% from 2017-2020, which parallels enrollment increases seen in Figure B.5.1 above. As enrollment in Medicaid increased, so did the number of Kentucky residents who also engaged in its services, though we note that less than a quarter of eligible enrollees (23.8%) filed a claim in 2020.

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Table B.5.2 MCO Claims Data 2017-2020

MCOs	2017	2018	2019	2020
Aetna	36,820	33,175	31,114	29,328
Anthem	25,439	26,584	27,454	27,334
FFS	108,691	108,923	111,355	122,660
Humana	36,146	36,728	36,205	34,880
MCO Unknown	20,503	20,820	22,234	27,497
Passport	62,106	62,805	61,755	58,130
Wellcare	83,367	81,304	77,974	76,053
Grand Total	**373,072**	**370,339**	**368,091**	**375,882**

Kentucky's SUD population as of December 2017 included 104,131 beneficiaries, or just over 7% of the enrolled Medicaid population (1,455,211); similarly, its SUD population as of December 2020 included 115,856 beneficiaries, or just over 7% of the enrolled Medicaid population (1,620,820).

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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.

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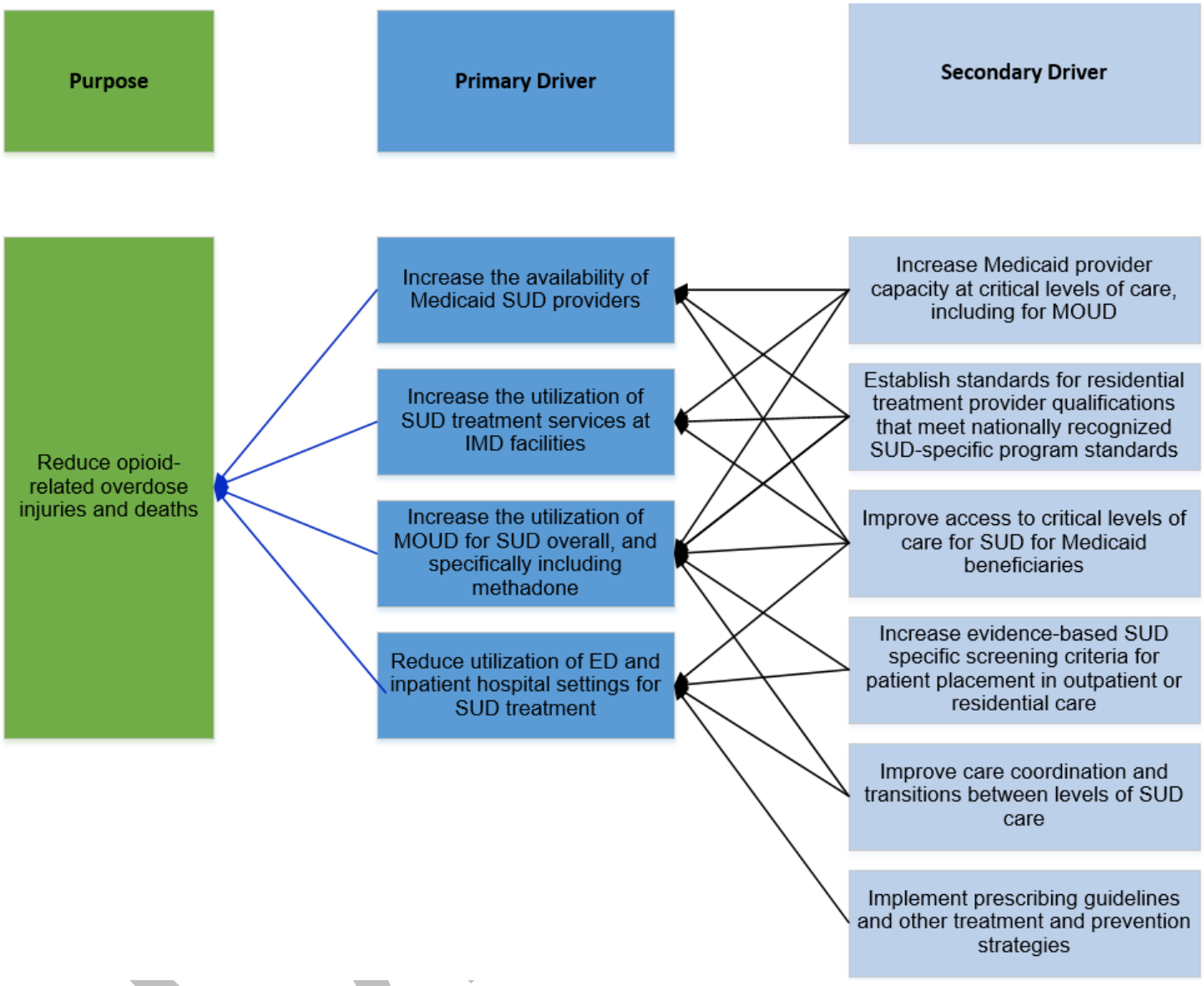
Figure C.1 Driver Diagram



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 analyses will be conducted at three levels in evaluating the costs associated with the 1115 Waiver:

A1a: Total SUD/OUD expenditures;

A1b: SUD/OUD and non-SUD/OUD expenditures, with SUD/OUD expenditures disaggregated into IMD and non-IMD expenditures;

A1c: 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.

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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		

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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 MAT 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		

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Primary Driver (Increase the utilization of MAT for SUD, especially methadone)	Percentage of beneficiaries with SUD (OUD) diagnosis who used MAT	N/A	Number of beneficiaries with SUD diagnosis who used MAT	Total number of beneficiaries	Claims data	Descriptive statistics Interrupted time series without comparison group
	Percentage of beneficiaries with SUD (OUD) diagnosis who received methadone	N/A	Number of beneficiaries with SUD diagnosis who received methadone as part of MAT	Total number of beneficiaries		
	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

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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

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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 MAT 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 use within past 6 months (KORTOS) / 12 months (KTOS)	N/A	Substance use within past 6 months	N/A		

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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 MAT 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]	

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

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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 was performed to provide an early assessment of the implementation of the demonstration and a foundation for longer-term evaluation activities (attached at 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

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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.

As a result of the Midpoint Assessment, the Statement of Work for evaluation was amended to reflect new information and to 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?

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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 in appropriate inpatient hospital admission of Medicaid beneficiaries for SUD care?
c. The degree to which Medicaid beneficiaries in each CC stages 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 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.2.1 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 (1) 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.

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The first primary evaluation question:

1. To what extent has access by Medicaid beneficiaries for 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

explores 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

explores 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

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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 had 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

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analyze these longitudinal data owing to complexities in their interrelationships. Here, however, we are restricted to descriptive statistics 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.

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,

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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 in process with both beneficiaries with active SUD and SUD treatment providers. As of June 30, 2022, 90 beneficiaries and 44 providers had been interviewed. These were divided into two data sets: Batch 1 and Batch 2. Batch 1 data, which are included in this report, are comprised of the one-time interview responses for 40 beneficiaries and 13 providers.

The case study interviews have been initiated and contact with these case study groups continue. As of June 30, 2022, Time 1 interviews have been completed for the Central Quadrant case study group; the North and Southeast Quadrant case study groups are in progress but currently incomplete. We anticipate that the Southwest Quadrant case study group will be launched in late summer 2022.

D.3 Evaluation Period

Data for the period July 2017 to September 2023 are being used for the analysis of the demonstration. The state fiscal years of July 2017 to June 2018 (SFY 18) and July 2018 to June 2019 (SFY 19) are used for baseline comparisons. This Interim Evaluation compares these baseline years to data from June 2019 to July 2020 (SFY 20). Administrative data from July 2020 to June 2021 (SFY 21) were not made available for this draft of the Interim Evaluation. Adjudicated administrative data may have a six-to-nine-month lag relative to their availability. Therefore, these comparative timelines are appropriate for the Interim Assessment.

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.

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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 with 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)

Table D.4.2 Evaluation Measures – Provider-Related

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

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)

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)*

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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*

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 (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 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.

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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**		

Table D.4.8 Counties with Largest Populations with No SUD Treatment Facilities

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
Kentucky Comparison	**N/A**		

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, results will be reported for all counties for relevant metrics, and 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).

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Figure D.4.1 Access to Medicaid

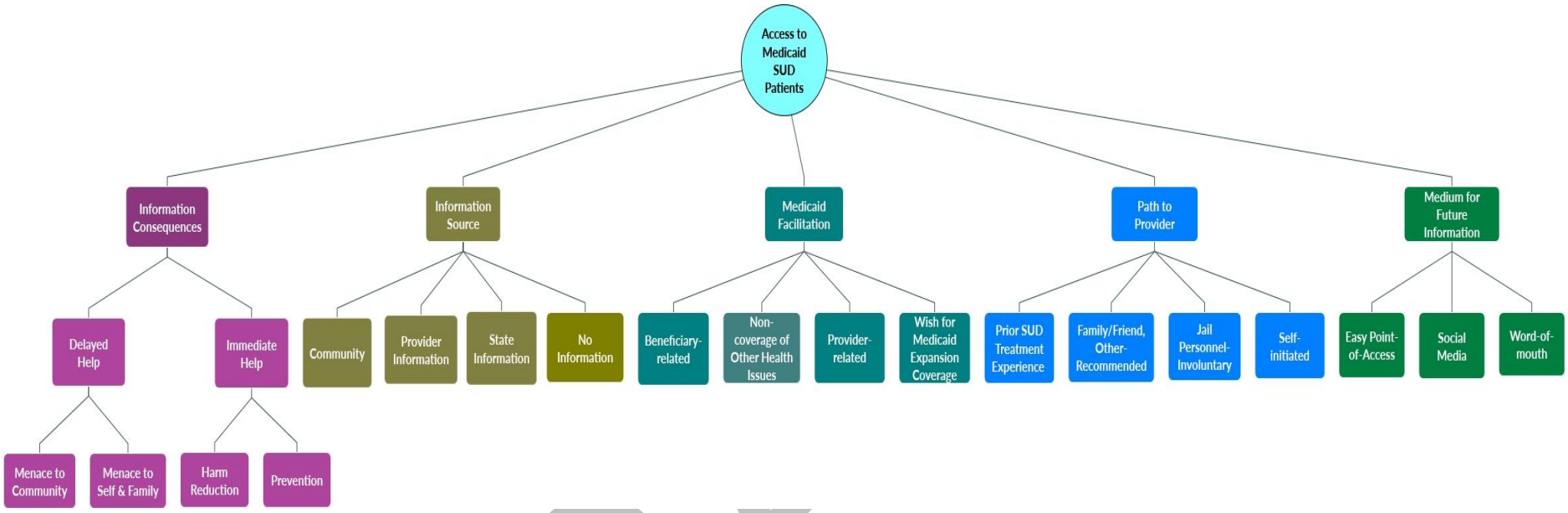


Figure D.4.2 Medicaid

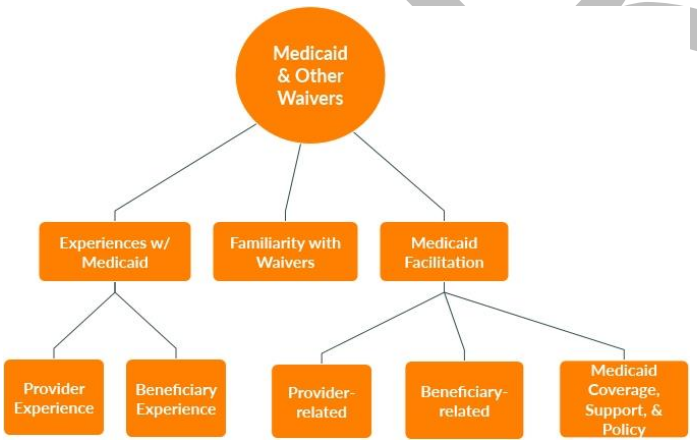


Figure D.4.3 Treatment Provided

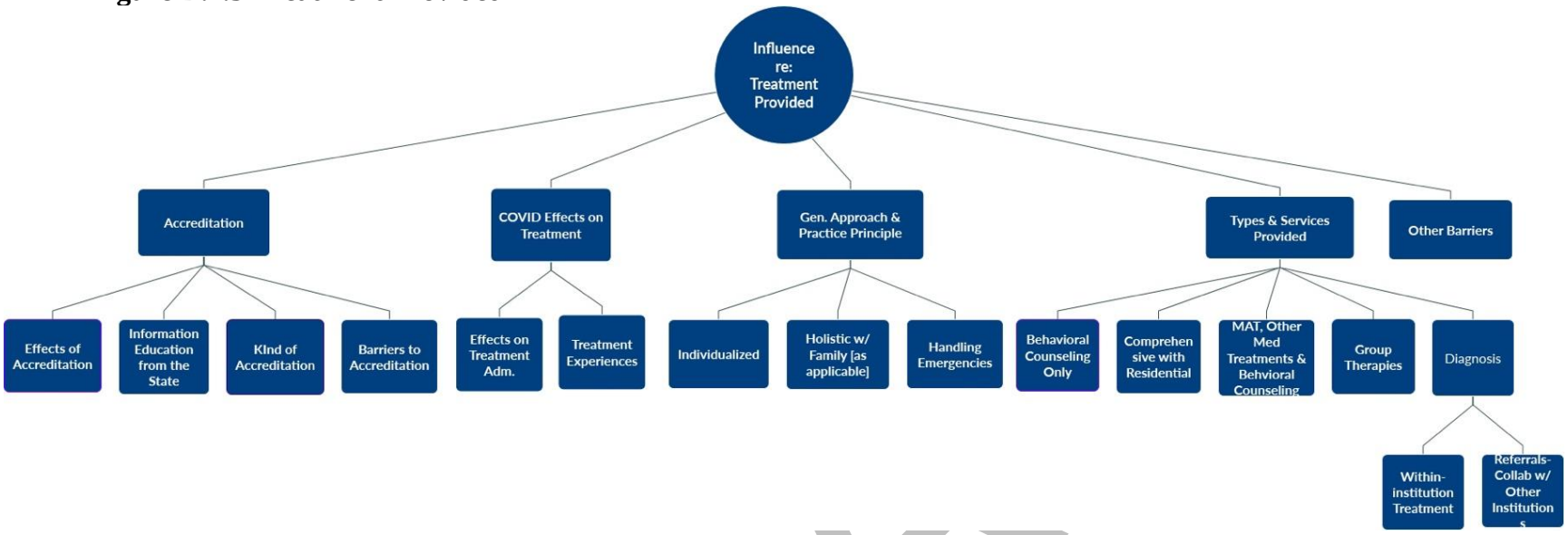


Figure D.4.4 Treatment Received

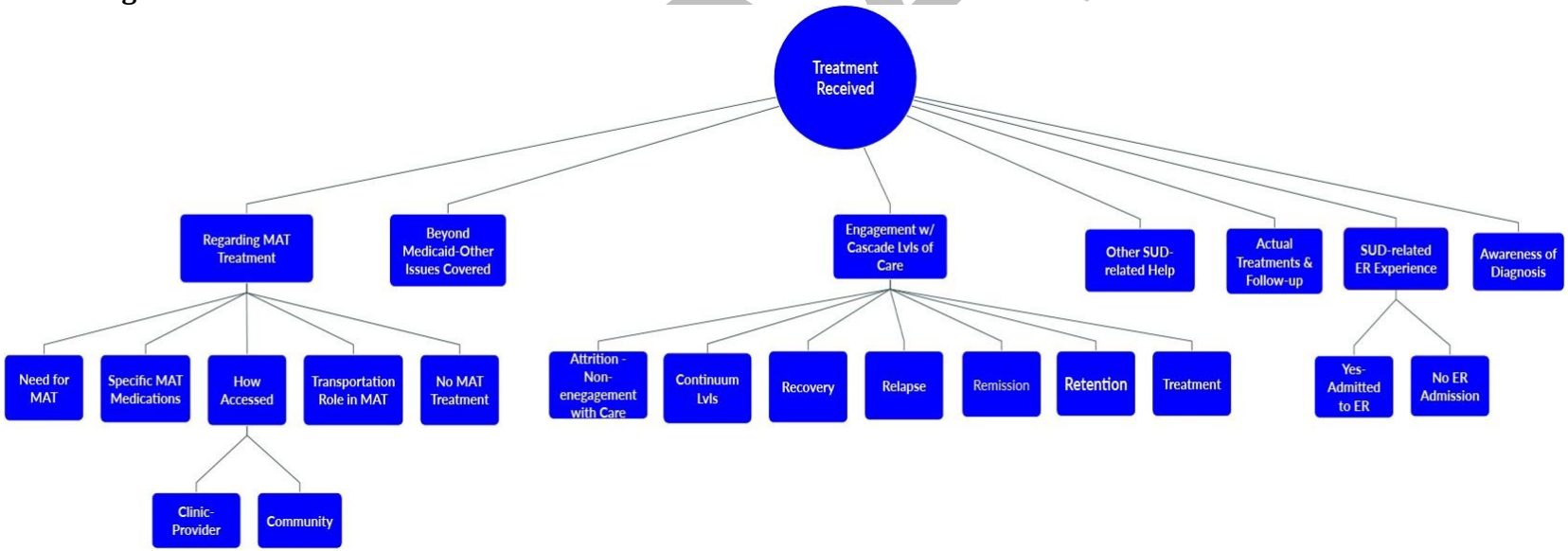
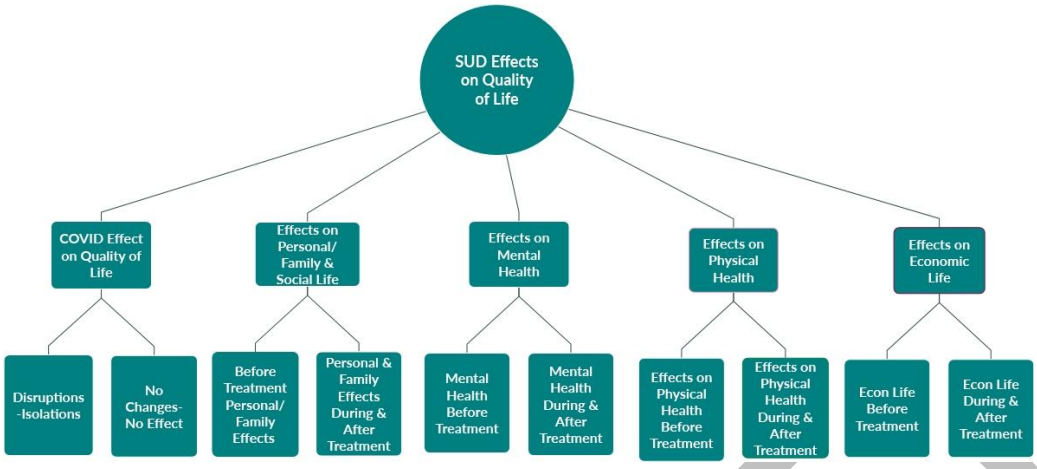


Figure D.4.5 Quality of Life



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

Because most of Kentucky's Medicaid beneficiaries receive benefits administered by managed care organizations (MCOs), the quantitative analysis will rely on Kentucky Medicaid encounter data 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 follows 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."[6] 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.

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.

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D.5.3 SUD-related expenditure data

These data provide information on health care services provided to beneficiaries and information on 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 MCO s— they are used by the state Medicaid program, in combination with other factors, to determine capitated MCO rates. For this reason, they can provide a useful if imperfect measure of costs incurred by the Medicaid program.

For this Interim Evaluation, data were not available for mean capitated rates for services. In lieu of their absence counts of the services are used to provide a comparison and initial trend analyses. The expectation is that for the Final Summative Report either the mean capitated rates will be provided, or a valid proxy will be determined under the Independent Evaluator's Business Associate Agreement with the Commonwealth.

D.5.4 Provider enrollment data

Kentucky Medicaid launched the Kentucky Medicaid Partner Portal Application (KY MPPA), a Medicaid provider enrollment system, was established in mid-2019. Data from KY 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 KY MPPA, provider enrollment was done through a manual reporting process. A limitation of this data source is that data on provider enrollment prior to implementation.

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.

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Table D.5.5.1 Interview Distribution for Interim Evaluation

Quadrant	Beneficiaries (N=40)			Providers (N=13)		
	Health District	Number of Beneficiaries	Percentage by Quadrant	Health District	Number of Providers	Percentage By Quadrant
Central [N=7]	5	7	17.50%	5	2	15.38%
North [N=10]	3	4	25.00%	3	1	15.38%
	6	5		6	1	
	5*	1				
Southeast [N=16]	7	4	40.00%	7	1	53.85%
	8	6		8	6	
	5**	2				
	4**	1				
	3**	3				
Southwest [N=7]	1	1	17.50%	1	1	15.38%
	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.5.6. Kentucky Treatment Outcome Study (KTOS) and Kentucky Opiate Replacement Treatment Outcome Study (KORTOS)

KTOS and KORTOS are two ongoing studies conducted by the University of Kentucky Center on Drug and Alcohol Research in collaboration with the Kentucky Department of Behavioral Health, Developmental, and Intellectual Disabilities. KTOS is a study of patients enrolling in SUD treatment programs (including outpatient, residential, and inpatient programs), and KORTOS is a study of patients enrolling in opiate treatment programs. KTOS enrolled 1,1066 patients in 2019 and 836 patients in 2020 (of whom approximately 79% (842) and 70% (585) respectively were Medicaid-insured) who completed surveys at intake and at 12 months; KORTOS enrolled about 114 patients in 2019 and 21 patients in 2020 (of whom approximately 61% (70) and 62% (13) respectively were Medicaid-insured) who completed surveys at intake and at 6 months. We will use self-reported measures of physical health, mental health, and substance use from KTOS and KORTOS to evaluate the effect of the demonstration on improvements in beneficiary health and care.

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The major limitations of these surveys are the voluntary participation in the surveys, the 35%-40% attrition rates for Medicaid-insured respondents, the relatively 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. Because of these limitations, evaluation of these measures should be viewed with caution. An additional limitation relative to the evaluation is the lag time between survey completion and final report.

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). 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 the trend of a given metric. For year-to-year comparison, line charts were used. In addition, maps were created showing metrics for each of defined Quadrants. Deviation analyses on metrics using visuals were conducted.

Time-series analysis modeling will be applied to specific measures (e.g., provider capacity and utilization) in the Final Summative Report. There are insufficient data for this Interim Evaluation to perform any meaningful time-series analysis. In addition, data during the collection period were substantially perturbed by the COVID epidemic.

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.

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- 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. Instead, we will be reporting the relevant data for all counties.

To assess the number of providers at IMDs, the first five diagnosis codes were used. Given the complexity of SUD and potential comorbidities and other diagnoses, the study expanded beyond using the first diagnosis code and treatment.

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.

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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 rich set of covariates, but there remains a chance of bias due to factors we are unable to include in our model.

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 understate the 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. Therefore, a total of 20 months of waiver implementation data can be used to perform analysis, and this 20-month data is not sufficient to observe changes introduced by the waiver, with year one serving as the benchmark period. It is expected that not all metrics included in the study will show in the desired trending direction. Therefore, findings from the Interim Evaluation are tentative; with more longitudinal data available, the Final Summative Report will conduct statistical tests on the impact of this 1115 demonstration. 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 and reliability, data 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 four sample replacements from the initial sample drawn from each of the quadrant due to provider and beneficiary non-participation.

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3. The Kentucky Medicaid Partner Portal Application (MPAA portal) was used to validate provider enrollment, facility-type, and provider affiliations. The data were limited based upon multiple providers billing under a unique facility Medicaid Provider Number and multiple locations of facility being listed under a single central license.

4. Administrative Vital Statistics data were not made available for this Interim Evaluation. Assurances have been made that necessary data use agreements will be in place for the Final Summative Report. Data from other sources were used in lieu of the Vital Statistics data when valid.

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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.[2] At

[2] 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

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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.

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 prescribing 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 prescribing 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

Metric #14. Additional filtering criteria were applied to answer our specific research questions shown in section F.2.2.1.

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 2020. Working from claims data, the number of unique performing, prescribing, and billing SUD providers during the measurement period, as well as the number of methadone providers, were calculated.

Table F.2.2.1 Provider Statistics

Calendar Year	Yearly Cumulative Unique Performing Providers	Yearly Cumulative Unique Prescribing Providers	Yearly Cumulative Unique Billing Providers	Yearly Cumulative Unique Methadone Providers
2017	8,821	1,401	3,476	
2018	9,566	1,692	3,781	
2019	9,981	2,022	3,819	597
2020	10,461	2,175	3,974	712

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 has increased from a baseline of 8,821 in January 2017 to 10,461 in December 2020. This represents an increase of 18.6%. Because the billing provider distinction is an administrative function and the provider entity typically determines its designation, the count may not reflect a consistent methodology. However, the number of billing providers did increase from 2017 to 2020.

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?

The number of providers prescribing MOUD increased by 55.2% during the period 2017 to 2020. The number initially declined during 2019; this could be due to issues related to the shutdown during the initial phase of the COVID-19 pandemic.

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, 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.”

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

Methadone was a not reimbursable by Kentucky Medicaid until 2019. The statistics shown in Table F.2.2.1 are derived from claims data and are best used as an approximation of a trend owing to the administrative issues of billing versus prescribing providers and what could be a slow conversion from a client-paid service to billing an MCO. However, the total number of methadone prescribers who started accepting Medicaid at the start of the waiver through 2020 clearly increased.

We note that only three beneficiaries interviewed received methadone; the most common MOUD mentioned was suboxone.

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

As seen in Table F.2.2.2 below**,** 79.2% (95/120) of the counties had an increase in the number of billings from providers for SUD treatment from 2017 to 2020. Counties that did not are highlighted in yellow. (One of those counties did not change number of providers.)

Table F.2.2.2 Providers by County

County	2017	2018	2019	2020
Adair	1235	1340	1400	1843
Allen	898	964	1019	960
Anderson	1283	1326	1338	1326
Ballard	478	514	539	532
Barren	1484	1602	1545	1456
Bath	1052	983	1055	1151
Bell	1364	1491	1509	1483
Boone	1716	1822	1873	1892
Bourbon	1178	1204	1223	1307
Boyd	2046	2047	1880	2020
Boyle	1410	1353	1381	1459
Bracken	598	566	602	570
Breathitt	1211	1303	1293	1313
Breckenridge	1296	1415	1331	1283
Bullitt	2141	2357	2376	2154
Butler	929	907	957	847
Caldwell	759	769	834	818
Calloway	897	901	911	917
Campbell	1585	1558	1484	1555
Carlisle	375	435	388	394
Carroll	905	926	938	918

County	2017	2018	2019	2020
Carter	1332	1355	1281	1341
Casey	1125	1215	1231	1272
Christian	1667	1794	1810	1773
Clark	1749	1827	1755	1925
Clay	1462	1608	1592	1623
Clinton	842	928	926	877
Crittenden	604	655	557	568
Cumberland	666	625	635	618
Daviess	2148	2418	2520	2525
Edmonson	948	956	927	848
Elliott	729	687	665	606
Estill	1046	1134	1140	1174
Fayette	4020	4330	4347	4506
Fleming	1174	1146	1126	1137
Floyd	1918	2019	1982	1948
Franklin	2647	3053	2974	2862
Fulton	462	462	487	477
Gallatin	633	603	698	616
Garrard	1172	1291	1233	1319
Grant	1155	1302	1248	1240
Graves	1038	1276	1200	1054

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County	2017	2018	2019	2020
Grayson	1492	1655	1630	1509
Green	924	929	940	945
Greenup	1167	1231	1206	1296
Hancock	555	584	588	558
Hardin	2674	3014	3067	3037
Harlan	1796	1828	1797	1801
Harrison	1047	1097	1108	1109
Hart	1129	1189	1112	1045
Henderson	1525	1562	1494	1512
Henry	1084	1162	1116	1128
Hickman	425	401	392	416
Hopkins	1345	1590	1554	1514
Jackson	1282	1336	1287	1290
Jefferson	5783	6439	6266	6354
Jessamine	1942	2091	2095	2259
Johnson	1229	1262	1366	1348
Kenton	2232	2341	2346	2374
Knott	1424	1422	1412	1407
Knox	1627	1714	1798	1719
Larue	956	1078	1097	990
Laurel	2154	2306	2373	2345
Lawrence	1364	1503	1436	1404
Lee	1008	1032	994	977
Leslie	1080	1048	1069	1027
Letcher	1319	1423	1382	1380
Lewis	771	776	880	916
Lincoln	1483	1468	1328	1495
Livingston	588	630	610	599
Logan	1004	1087	1094	1070
Lyon	485	555	508	520
Madison	1454	1715	1720	1692
Magoffin	1184	1255	1213	1225
Marion	697	751	738	653
Marshall	2608	2911	2725	2770
Martin	1014	1143	1081	1077
Mason	1184	1326	1264	1084
McCracken	885	943	1023	1040
McCreary	951	933	923	956
McLean	815	966	885	987

County	2017	2018	2019	2020
Meade	1292	1474	1453	1337
Menifee	697	766	809	854
Mercer	1267	1324	1384	1452
Metcalfe	688	762	762	767
Monroe	690	666	707	688
Montgomery	1670	1766	1741	1737
Morgan	987	970	943	932
Muhlenberg	1238	1262	1240	1245
Nelson	1682	1886	2119	1971
Nicholas	677	696	766	690
Ohio	1184	1137	1081	1135
Oldham	1579	1616	1707	1997
Owen	895	964	972	916
Owsley	726	786	835	804
Pendleton	892	946	1038	1036
Perry	1830	2017	1894	1924
Pike	2002	2117	2115	2183
Powell	1208	1302	1261	1212
Pulaski	2512	2519	2543	2566
Robertson	307	347	325	401
Rockcastle	1206	1196	1210	1254
Rowan	1450	1601	1544	1701
Russell	1108	1186	1224	1219
Scott	1654	1742	1836	1989
Shelby	1591	1780	1765	1607
Simpson	770	869	809	861
Spencer	907	1073	1000	972
Taylor	1771	1911	1832	1785
Todd	689	672	622	631
Trigg	671	736	765	705
Trimble	713	756	710	618
Union	692	671	734	774
Warren	2463	2677	2515	2619
Washington	1429	1434	1536	1791
Wayne	1159	1264	1305	1306
Webster	675	733	844	897
Whitely	2003	2018	2053	2021
Wolfe	1036	1014	1036	984
Woodford	1252	1314	1255	1252

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

Table F.2.2.3 below uses procedure codes plus medication codes, including both buprenorphine and methadone, to estimate the number of Medicaid prescriptions for MOUD by county. Only four counties (3.3%) did not have an increase in the number of prescriptions for MOUD by SUD treatment providers from 2017 to 2020 (highlighted in yellow below), and only one of the four decreased in the number of prescriptions; the rest remained constant.

Table F.2.2.3 MOUD prescriptions by County

County	2017	2018	2019	2020
Adair	53	49	71	124
Allen	20	39	54	50
Anderson	58	86	102	100
Ballard	20	26	29	36
Barren	38	60	76	85
Bath	73	69	82	97
Bell	78	95	88	106
Boone	80	97	136	152
Bourbon	105	120	110	109
Boyd	124	130	128	157
Boyle	66	102	93	105
Bracken	30	38	38	48
Breathitt	89	110	105	89
Breckenridge	30	63	65	63
Bullitt	99	126	141	139
Butler	18	34	47	49
Caldwell	15	27	32	48
Calloway	26	35	41	49
Campbell	88	83	119	124
Carlisle	14	20	21	28
Carroll	43	50	50	65
Carter	70	81	89	113
Casey	58	73	80	89
Christian	48	50	64	90
Clark	134	178	148	165
Clay	79	99	97	121
Clinton	27	36	36	39
Crittenden	20	34	32	39
Cumberland	29	35	30	33
Daviess	60	100	123	132

County	2017	2018	2019	2020
Edmonson	30	37	38	52
Elliott	49	56	43	48
Estill	89	99	109	94
Fayette	232	329	380	440
Fleming	78	80	97	86
Floyd	135	160	162	175
Franklin	117	160	169	154
Fulton	18	20	24	25
Gallatin	31	35	49	50
Garrard	65	100	100	107
Grant	84	89	104	119
Graves	33	54	52	55
Grayson	38	47	56	72
Green	29	41	48	59
Greenup	60	69	79	85
Hancock	16	13	16	19
Hardin	112	144	192	230
Harlan	140	157	152	147
Harrison	53	76	90	92
Hart	25	42	47	50
Henderson	39	52	61	76
Henry	64	66	54	73
Hickman	7	12	17	18
Hopkins	43	59	64	86
Jackson	64	85	98	117
Jefferson	311	375	390	452
Jessamine	135	167	184	191
Johnson	79	82	85	112
Kenton	109	144	183	229
Knott	103	134	110	123

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County	2017	2018	2019	2020
Knox	92	115	110	114
Larue	35	40	52	45
Laurel	148	168	173	201
Lawrence	78	116	113	112
Lee	55	58	65	73
Leslie	90	100	85	90
Letcher	93	112	108	119
Lewis	43	53	59	68
Lincoln	90	122	108	126
Livingston	23	30	35	45
Logan	27	40	48	52
Lyon	14	19	22	42
Madison	50	65	71	104
Magoffin	57	78	79	94
Marion	17	27	32	32
Marshall	163	208	232	260
Martin	70	85	77	84
Mason	50	52	66	71
McCracken	44	46	54	69
McCreary	66	71	71	76
McLean	54	65	67	83
Meade	39	58	58	83
Menifee	49	56	52	68
Mercer	86	112	108	113
Metcalfe	31	34	44	46
Monroe	18	29	33	38
Montgomery	112	151	147	155
Morgan	63	66	58	68
Muhlenberg	58	70	83	84
Nelson	88	120	156	158

County	2017	2018	2019	2020
Nicholas	57	61	57	60
Ohio	30	38	56	47
Oldham	38	65	97	146
Owen	49	71	74	86
Owsley	35	46	42	54
Pendleton	47	67	92	109
Perry	139	163	143	174
Pike	159	193	206	227
Powell	102	107	91	109
Pulaski	166	169	171	199
Robertson	17	13	14	17
Rockcastle	77	88	74	85
Rowan	85	107	98	112
Russell	54	60	73	76
Scott	110	149	134	175
Shelby	85	95	112	116
Simpson	19	26	38	49
Spencer	28	56	65	73
Taylor	81	97	110	108
Todd	9	19	23	17
Trigg	15	27	37	33
Trimble	21	48	41	47
Union	2	11	24	31
Warren	73	78	117	143
Washington	84	103	124	175
Wayne	41	69	79	84
Webster	15	29	37	49
Whitely	93	122	135	133
Wolfe	48	57	52	50
Woodford	94	117	115	103

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

Table F.2.2.4 below uses procedure codes plus performing provider to estimate the number of methadone providers by county. Twelve counties (10%) did not increase the number of methadone prescribers from 2019 to 2020. They are highlighted in yellow; two of those counties had no methadone prescribers at all in 2019 or in 2020.

Table F.2.2.4 Methadone Prescribers by County

County	2019	2020
Adair	3	4
Allen	1	4
Anderson	4	8
Ballard	1	4
Barren	2	3
Bath	1	4
Bell	2	2
Boone	9	9
Bourbon	6	8
Boyd	5	9
Boyle	6	7
Bracken	3	4
Breathitt	4	5
Breckenridge	2	5
Bullitt	5	6
Butler		2
Caldwell	2	5
Calloway	2	3
Campbell	6	9
Carlisle	1	2
Carroll	3	4
Carter	3	6
Casey	2	3
Christian	4	4
Clark	7	7
Clay	3	5
Clinton	2	1
Crittenden	2	3
Cumberland	3	5
Daviess		2
Edmonson	2	3
Elliott	2	3
Estill	12	16
Fayette	4	5
Fleming	7	6
Floyd	7	6
Franklin		3
Fulton	3	4

County	2019	2020
Gallatin	4	5
Garrard	4	8
Grant	3	3
Graves		1
Grayson		1
Green	6	6
Greenup		2
Hancock	3	6
Hardin	4	3
Harlan	9	9
Harrison		1
Hart	2	4
Henderson	5	5
Henry	2	3
Hickman	2	4
Hopkins	4	4
Jackson	9	20
Jefferson	9	9
Jessamine	3	7
Johnson	9	13
Kenton	3	3
Knott	5	4
Knox	1	1
Larue	4	8
Laurel	4	5
Lawrence	4	5
Lee	5	4
Leslie	4	4
Letcher	2	3
Lewis	4	6
Lincoln	1	3
Livingston	3	3
Logan	3	3
Lyon	3	6
Madison	2	2
Magoffin	3	3
Marion	10	9
Marshall	6	6

County	2019	2020
Martin	2	3
Mason	2	4
McCracken	2	3
McCreary	3	4
McLean		5
Meade	2	2
Menifee	2	5
Mercer		1
Metcalfe		1
Monroe	6	8
Montgomery	4	6
Morgan	4	3
Muhlenberg	1	3
Nelson	3	4
Nicholas	3	4
Ohio	1	5
Oldham	5	6
Owen	2	2
Owsley	4	7
Pendleton	5	5
Perry	6	9
Pike	5	6
Powell	5	6
Pulaski	7	6
Robertson	5	8
Rockcastle	3	3
Rowan	7	10
Russell	1	4
Scott	2	2
Shelby	3	4
Simpson		2
Spencer	1	2
Taylor	2	2
Todd	3	5
Trigg	1	3
Trimble	3	4
Union	1	3
Warren	2	2

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County	2019	2020
Washington		1
Wayne	3	5

County	2019	2020
Webster	1	3
Whitely	7	9

County	2019	2020
Wolfe		
Woodford		

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

Owing to the requirements for billing and reimbursement as established by DMS, an IMD entity that operates multiple locations does not have to report location specific information but may do centralized billing. While it is recommended and data elements support location reporting, this is relatively new and has not been broadly adopted. Therefore, facilities billing for treatment cannot be reliably determined and licensed facilities derived from the Kentucky Medicaid Provider Portal Application (KY MPPA) are used as a proxy measure are used as a proxy measure.

As indicated in Table F.2.2.5 below, the number of providers billing for residential SUD treatment increased, from 4,183 in 2017 to 6,266 in 2020, an increase of 49.8%.

Table F.2.2.5 Number of Providers and IMD Facilities Billing for SUD Services

FY	Number of Providers Billing for Residential SUD Treatment	Number of IMD facilities licensed for SUD Treatment
2017	4,183	1,993
2018	4,848	2,503
2019	5,393	2,981
2020	6,266	3,932

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

As indicated in Table F.2.2.5 above, the number of IMD facilities licensed by the state increased from 1,993 to 3,932 from 2017 to 2020. This represents a nearly doubling of IMD facilities treating SUD.

Only one of the 13 providers interviewed and coded as part of Batch 1 was not affiliated with an IMD.

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

Table F.2.2.6 below uses billing provider claims related to residential and inpatient services to estimate the number of providers billing for residential treatment for SUD. Only five counties did not experience an increase in billing provider claims related to residential services. Of those counties, four decreased in the number of providers and one remained constant (highlighted in yellow below).

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Table F.2.2.6 Number of Billing Provider Claims for Residential Treatment

County	2017	2018	2019	2020
Adair	35	40	53	74
Allen	26	34	31	34
Anderson	38	42	49	55
Ballard	13	13	16	21
Barren	42	40	48	54
Bath	28	32	42	55
Bell	39	62	70	69
Boone	54	55	63	80
Bourbon	28	36	44	48
Boyd	53	61	61	82
Boyle	39	46	54	67
Bracken	22	20	22	18
Breathitt	31	37	41	53
Breckenridge	26	34	41	35
Bullitt	48	49	61	69
Butler	26	29	35	32
Caldwell	25	30	33	32
Calloway	28	25	35	41
Campbell	56	53	51	69
Carlisle	11	9	9	7
Carroll	34	30	31	39
Carter	34	35	35	44
Casey	29	40	43	47
Christian	47	39	55	56
Clark	46	64	64	77
Clay	37	50	53	66
Clinton	22	29	23	32
Crittenden	23	20	17	28
Cumberland	17	19	17	28
Daviess	52	59	72	82
Edmonson	14	27	20	25
Elliott	17	17	19	27
Estill	32	39	44	54
Fayette	99	120	122	154
Fleming	40	34	44	46
Floyd	47	55	60	73
Franklin	64	75	80	90
Fulton	15	13	9	14

County	2017	2018	2019	2020
Gallatin	23	21	20	23
Garrard	32	40	43	46
Grant	33	43	44	49
Graves	36	41	44	44
Grayson	32	42	45	47
Green	28	27	33	35
Greenup	30	36	38	42
Hancock	14	10	13	19
Hardin	72	71	90	101
Harlan	60	63	62	82
Harrison	35	42	52	58
Hart	26	44	39	48
Henderson	40	42	46	52
Henry	20	31	30	39
Hickman	9	8	8	11
Hopkins	42	57	54	54
Jackson	39	42	46	51
Jefferson	146	151	173	198
Jessamine	58	59	71	87
Johnson	36	37	43	48
Kenton	73	77	81	108
Knott	30	32	44	54
Knox	48	63	65	75
Larue	16	22	33	28
Laurel	48	67	74	98
Lawrence	31	49	57	64
Lee	23	33	46	41
Leslie	26	34	40	36
Letcher	30	43	47	63
Lewis	27	32	30	40
Lincoln	42	46	50	66
Livingston	12	16	23	24
Logan	31	40	40	41
Lyon	17	11	16	18
Madison	45	57	68	71
Magoffin	27	39	41	36
Marion	12	13	18	16
Marshall	72	81	82	98

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County	2017	2018	2019	2020
Martin	30	35	38	42
Mason	29	42	43	47
McCracken	23	27	35	33
McCreary	27	29	38	46
McLean	35	42	39	47
Meade	27	35	37	44
Menifee	13	24	26	37
Mercer	35	47	52	69
Metcalfe	16	23	20	19
Monroe	26	20	19	23
Montgomery	44	54	60	79
Morgan	27	26	29	33
Muhlenberg	36	41	46	48
Nelson	47	47	68	69
Nicholas	18	22	27	23
Ohio	26	24	41	40
Oldham	42	46	68	72
Owen	23	32	30	39
Owsley	24	25	35	37
Pendleton	32	41	45	53
Perry	41	64	69	66
Pike	51	59	73	92

County	2017	2018	2019	2020
Powell	29	43	48	51
Pulaski	64	77	73	101
Robertson	9	14	10	14
Rockcastle	35	38	42	56
Rowan	42	52	49	64
Russell	33	31	45	48
Scott	50	54	69	77
Shelby	35	43	48	56
Simpson	26	25	31	27
Spencer	17	34	31	34
Taylor	52	64	63	71
Todd	19	19	20	27
Trigg	18	19	21	23
Trimble	17	18	24	24
Union	21	16	17	26
Warren	64	78	84	94
Washington	47	48	55	79
Wayne	37	38	34	48
Webster	17	26	27	31
Whitely	50	57	71	82
Wolfe	26	32	31	36
Woodford	45	43	46	51

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

Because facilities information is not contained in the claims data, we used the billing provider to extract IMD-related claims. As shown in Table F.2.2.7, only three counties had fewer IMD-related claims in 2020 than they did in 2017 (highlighted in yellow below), and no counties' counts remained constant.

Table F.2.2.7 Number of Providers and IMD Facilities Billing for SUD Services

County	2017	2018	2019	2020
Adair	11	19	37	46
Allen	8	13	16	24
Anderson	22	26	34	37
Ballard	5	5	7	12
Barren	18	18	28	36
Bath	12	15	23	40
Bell	14	33	33	43

County	2017	2018	2019	2020
Boone	26	26	38	51
Bourbon	17	22	26	32
Boyd	27	33	31	60
Boyle	16	24	31	43
Bracken	8	10	11	9
Breathitt	13	20	20	27
Breckenridge	16	16	27	25

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County	2017	2018	2019	2020
Bullitt	24	29	36	48
Butler	12	15	14	20
Caldwell	6	13	17	21
Calloway	13	20	18	25
Campbell	32	29	26	48
Carlisle	3	3	4	5
Carroll	17	19	20	26
Carter	16	24	19	36
Casey	12	20	29	31
Christian	17	17	23	36
Clark	26	38	45	52
Clay	21	25	26	35
Clinton	7	8	13	22
Crittenden	7	5	7	14
Cumberland	4	7	4	13
Daviess	26	27	40	60
Edmonson	8	12	11	15
Elliott	9	8	11	15
Estill	20	21	26	40
Fayette	53	66	67	98
Fleming	20	18	22	28
Floyd	26	28	28	40
Franklin	36	37	45	64
Fulton	5	1	4	4
Gallatin	12	11	12	14
Garrard	18	24	28	24
Grant	16	25	23	30
Graves	18	19	25	31
Grayson	15	25	25	29
Green	9	11	17	18
Greenup	13	19	18	30
Hancock	9	4	8	8
Hardin	42	44	55	72
Harlan	31	33	38	44
Harrison	16	20	30	39
Hart	12	21	28	33
Henderson	19	18	26	34
Henry	11	17	19	28
Hickman	3	3	3	7

County	2017	2018	2019	2020
Hopkins	18	29	24	28
Jackson	19	25	26	30
Jefferson	74	78	92	110
Jessamine	35	39	50	66
Johnson	19	16	21	26
Kenton	40	42	51	74
Knott	12	17	26	32
Knox	25	36	37	42
Larue	6	10	18	19
Laurel	27	40	40	64
Lawrence	16	26	29	35
Lee	8	17	27	17
Leslie	13	16	20	17
Letcher	15	23	23	40
Lewis	10	14	16	24
Lincoln	19	23	34	43
Livingston	5	9	10	20
Logan	12	14	19	26
Lyon	8	5	6	11
Madison	17	33	33	50
Magoffin	12	20	15	24
Marion	5	6	9	13
Marshall	36	40	46	64
Martin	18	13	17	26
Mason	13	25	20	25
McCracken	7	15	17	19
McCreary	15	14	17	25
McLean	19	23	20	26
Meade	13	13	17	34
Menifee	6	9	15	22
Mercer	25	30	41	49
Metcalfe	8	12	10	10
Monroe	9	9	7	11
Montgomery	25	28	41	56
Morgan	13	11	13	15
Muhlenberg	15	17	20	22
Nelson	23	29	47	48
Nicholas	8	14	17	16
Ohio	14	13	22	26

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County	2017	2018	2019	2020
Oldham	14	19	30	38
Owen	11	15	15	23
Owsley	7	12	14	19
Pendleton	16	17	30	36
Perry	21	36	35	34
Pike	30	35	45	50
Powell	16	21	25	33
Pulaski	32	45	42	66
Robertson	1	8	3	6
Rockcastle	17	19	23	27
Rowan	21	23	32	46
Russell	13	13	26	32
Scott	30	30	45	55
Shelby	15	22	33	44

County	2017	2018	2019	2020
Simpson	8	11	17	17
Spencer	8	16	19	22
Taylor	25	37	42	44
Todd	3	5	9	14
Trigg	2	11	6	11
Trimble	8	6	11	17
Union	5	8	5	15
Warren	30	46	41	51
Washington	24	31	34	52
Wayne	17	20	20	31
Webster	4	10	12	21
Whitely	19	26	38	46
Wolfe	9	17	14	19
Woodford	28	27	30	36

In sum, relative to provider availability and access to care, the results show overwhelmingly positive trends. While not all counties have experienced increased provider availability and access, nor have they all increased treatment options, the vast majority have.

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. 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 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.

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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. 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. (We also will not be able to evaluate question #6 until the final report.)

Table F.3.1.1 Access to Care: SUD-Diagnosed Individuals

FY	Number of beneficiaries with a new SUD diagnosis or newly initiated SUD-related services	Number of beneficiaries with an SUD diagnosis who used outpatient services	Number of beneficiaries with an SUD diagnosis who used residential treatment services	Number of beneficiaries with an OUD diagnosis who used MOUD	Number of beneficiaries with an OUD diagnosis who received methadone
2017		40,057	11,657	30,686	0
2018	96,092	45,816	15,632	35,993	0
2019	104,141	52,091	18,108	44,964	2990
2020	110,153	59,496	20,118	53,976	7544

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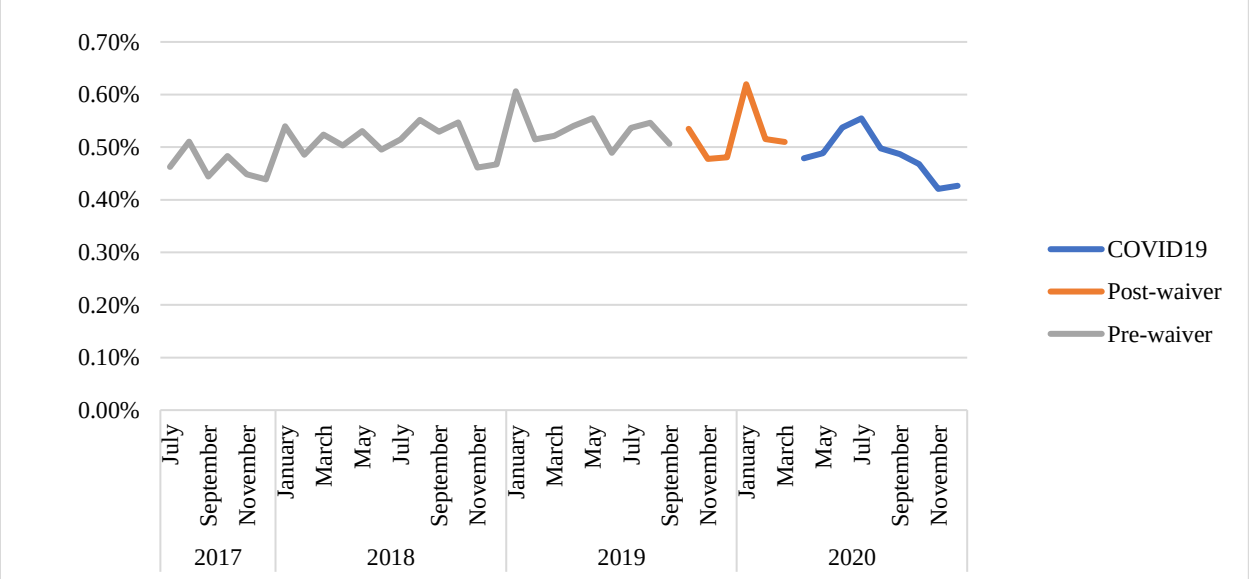
1. Did the number of beneficiaries with a new SUD diagnosis or newly initiated SUD-related services increase after the waiver implementation?

There has been an overall increase over the years for number of beneficiaries with a new SUD diagnosis or newly initiated SUD service, from 96,092 in 2018 to 104,141in 2020 (data for 2017 are still forthcoming) or 8.4% over that two-year period. Table F.3.2.1 above provides a summary of newly diagnosed beneficiaries with SUD or those who initiated treatment.[3]

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.3.2.1 breaks out the data into three periods: Pre-Waiver, Post-Waiver, and 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 32.5% (13/40) of beneficiaries in treatment who were interviewed as part of this evaluation project had new SUD diagnosis. Over two-thirds (27/40) 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.

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

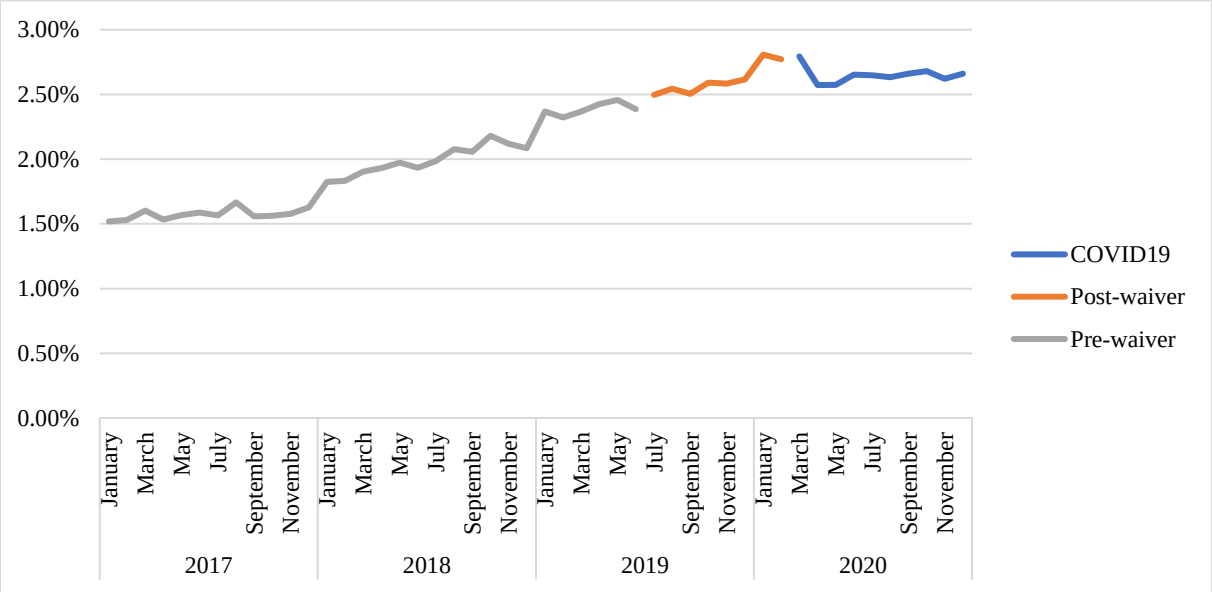


2. Did the number of beneficiaries with an SUD diagnosis who used outpatient services for SUD increase after the waiver implementation?

[3] We note that the definition for a new SUD diagnosis or newly initiated services includes unenrollment in Medicaid for at least three months prior to these actions. It is therefore theoretically possible for double-counting, if any beneficiaries dropped and added Medicaid over the course of the year while first receiving an SUD diagnosis and then later accessing treatment.

There has been an overall increase over the 2017-2020 for outpatient SUD services, from 271,685 to 485,560 or a 79% increase. Figure F.3.2.2 below shows the SUD diagnoses rate trends pre-waiver vs post-waiver between 2018 and 2020. 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 sharp downward trend that slowly starts to recover in the remainder of 2020.

Figure F.3.2.2 Outpatient Service Use Rate for SUD



It is clear that providers are working to transition beneficiaries to outpatient care: "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" (a provider from the Southeast Quadrant).

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 15,506 to 39,953 from 2017 to 2020, an increase of 258%.

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 shows a consistent increase from January 2017 to July 2020 in a month-by-month comparison. The 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.

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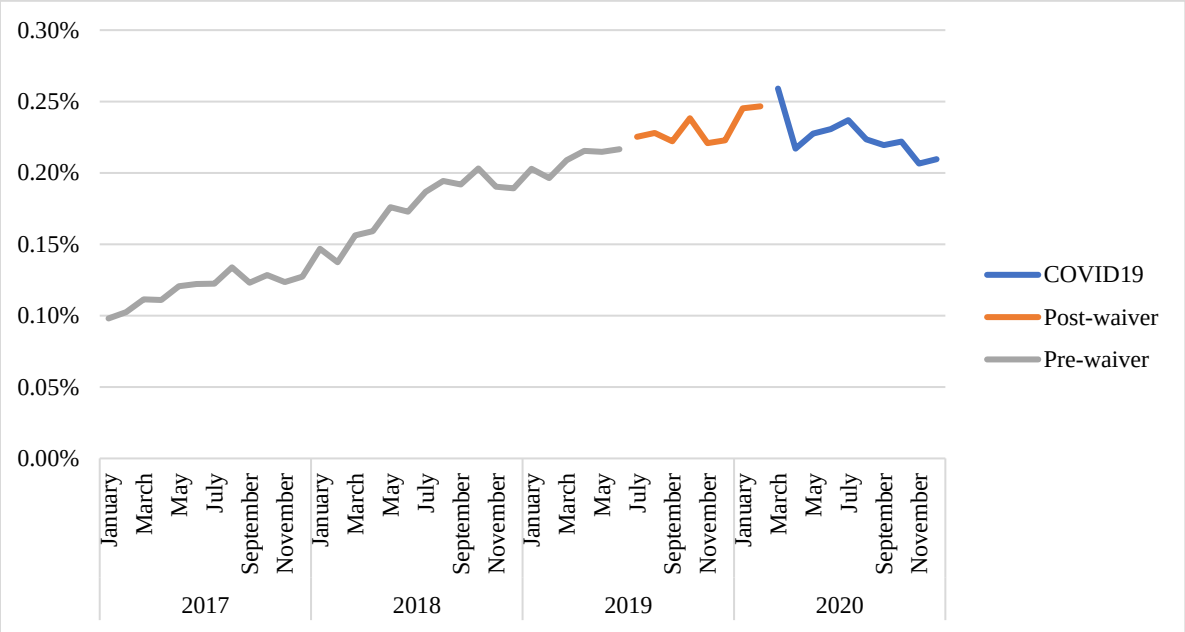
Figure F.3.2.3 Percentage of Beneficiaries with SUD Diagnosis Used Residential Services



We note that in our interviews, all but one of the 40 beneficiaries used SUD services through an IMD. Almost a third (62.5%) 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 by themselves.) Over half of those referred were in the Northern Quadrant.

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

As depicted in Table F.3.2.1 above, the number of individuals with a primary OUD diagnosis who used MOUD increased from 202,638 to 406,168 from 2017 to 2020, just over double.

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 steady increase in medication for OUD from 2017 to 2020. There is an overall increase in the rate during post-waiver, but there was a slight decrease in utilization March through November 2020, again corresponding to the advent of COVID-19 in the region, and then a trend recovery in December 2020.

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).

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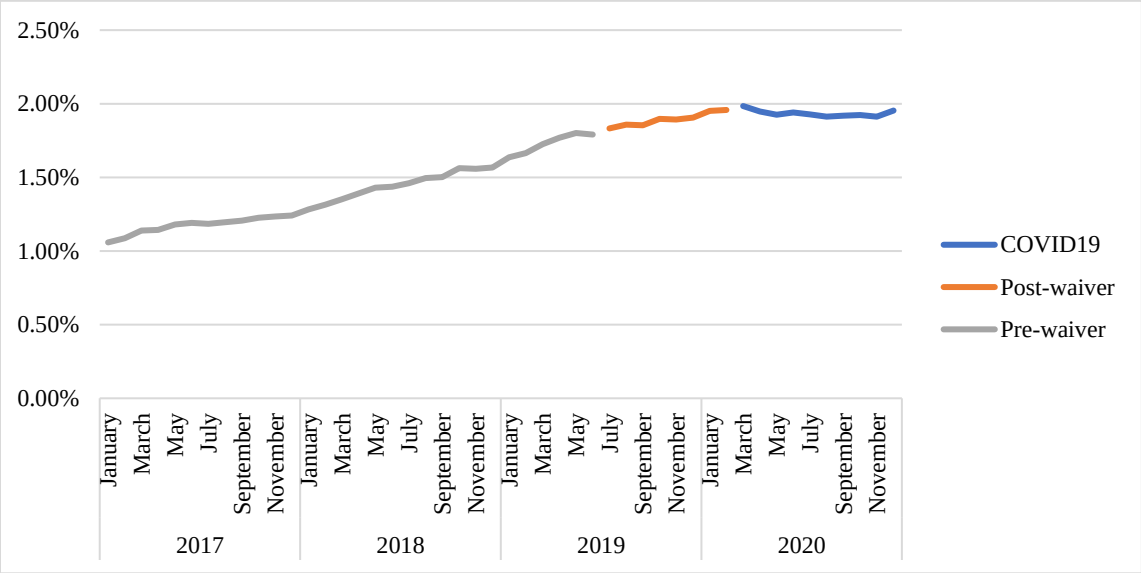
Figure F.3.2.4 Percentage of Beneficiaries with OUD Diagnosis Who Used MOUD



5. Did the number of beneficiaries with an OUD diagnosis who used methadone increase after waiver implementation?

As depicted in Table F.3.2.1 above, the number of individuals with a primary OUD diagnosis who used methadone increased from 10,232 to 54,112 from 2019 to 2020. The year 2019 represents only 6 months of data, due to the timing of the start of Medicaid covering methadone treatments.

Figure F.3.2.5 Percentage of Beneficiaries with SUD Diagnosis Who Used Methadone

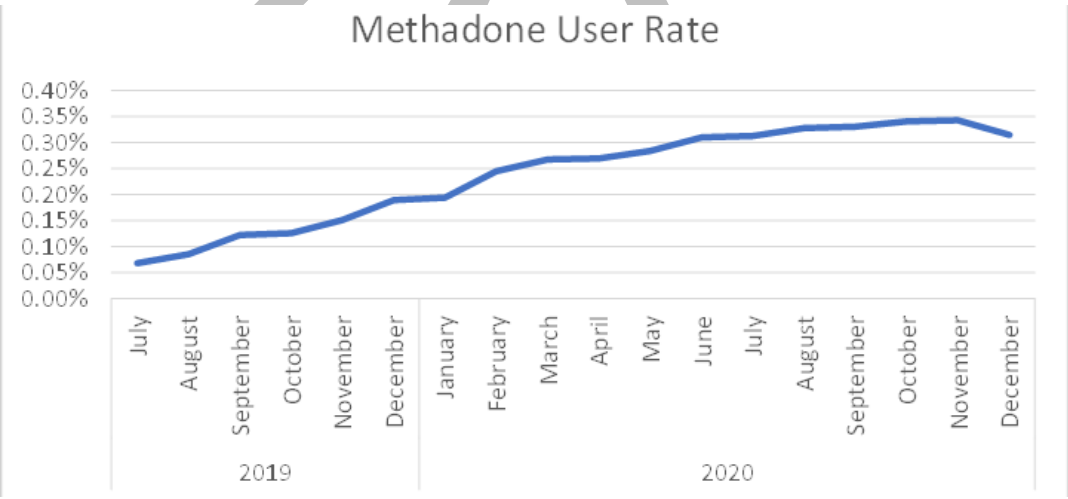


Figure F.3.2.5 above controls for the changes in the number of Medicaid beneficiaries by showing the proportion of beneficiaries diagnosed with OUD using methadone as a percentage of the total number of beneficiaries. It shows a steady increase in the percentage of beneficiaries who accessed methadone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

We note, however, that only three of the beneficiaries we interviewed were currently taking methadone; in contrast, 42.5% (17) were taking buprenorphine or suboxone. Providers interviewed indicated a preference for non-methadone MOUD treatments; however, some beneficiaries preferred methadone.

We also note that over half (23) of the beneficiaries interviewed were not receiving any MOUD at all.

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.

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.

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Table F.4.1.1 Hospital Utilization: SUD-Diagnosed Beneficiaries

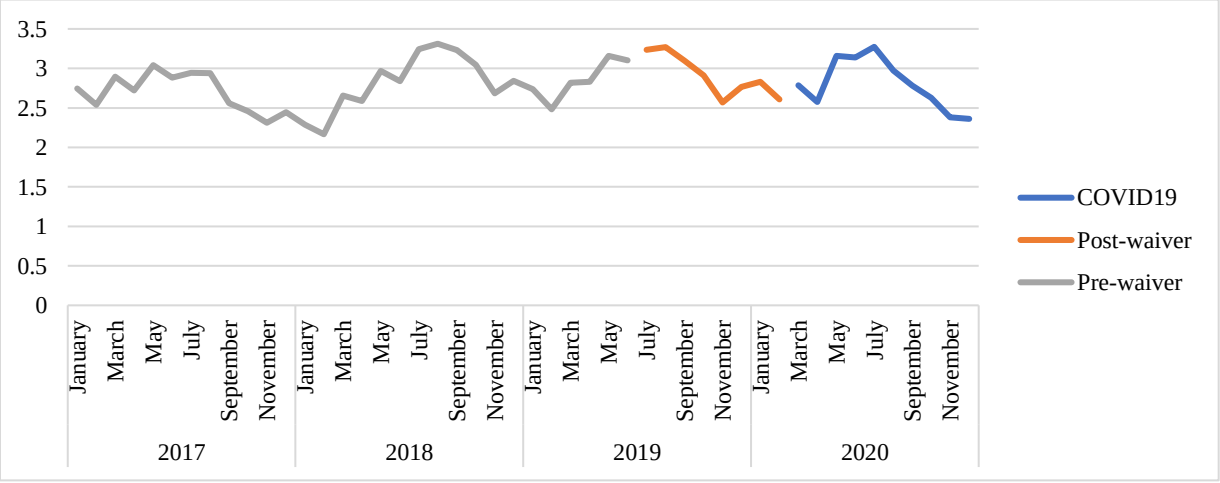
FY	Number of ED visits for an SUD-related diagnosis	Number ED visits with a primary SUD diagnosis with SUD service follow-up within 30 days	Number of hospital admissions with an SUD diagnosis
2017	46,684	11,475	29,232
2018	48,191	16,427	35,065
2019	48,584	22,336	34,866
2020	50,701	27,343	39,349

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 not decrease but increased from 46,684 to 50,701 from 2017 to 2020, an increase of 8.6%.

In the past four years, the ED visits for SUD-related diagnoses followed a similar pattern over the course of the year, as shown below in Figure F.4.1.1. Between July to December, 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 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.

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



Almost half of the beneficiaries interviewed (18/40) 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).

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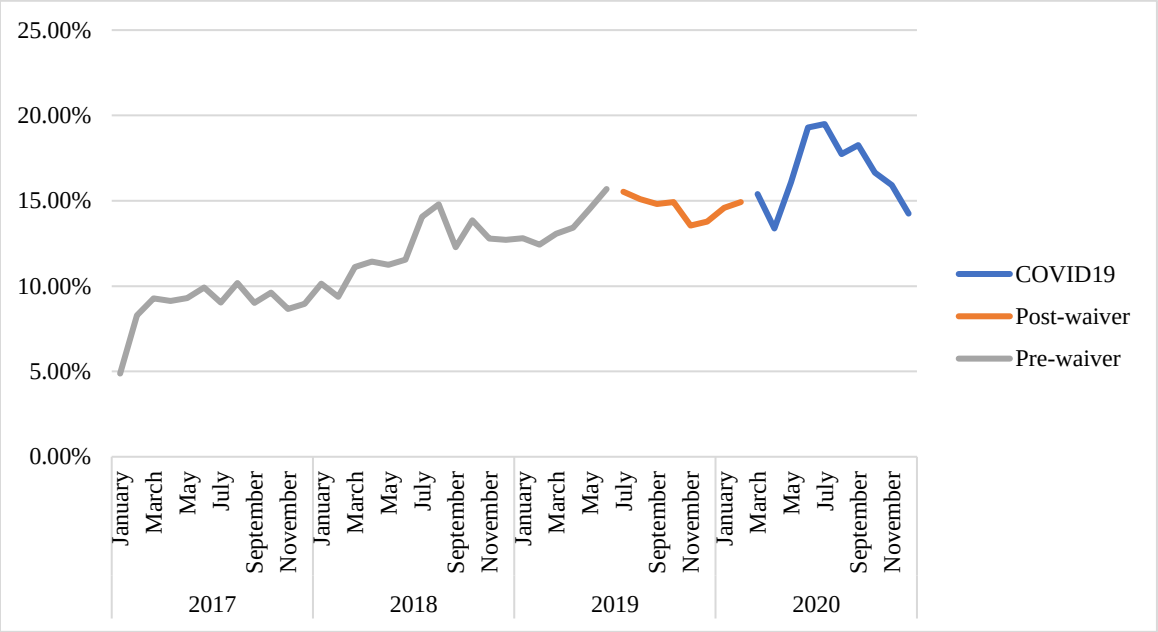
Importantly, as seen in Figure F.4.1.2 below, there is a steady upward trend for the ED visits beneficiaries with a primary SUD diagnosis who then accessed SUD services within 30 days after visiting the ED for both pre- and post- waiver implementation, with a decrease occurring in the latter half of 2020. This indicates that those diagnosed with SUD through an ED visit were seeking treatment in ever greater numbers. As depicted in Table F.4.1.1 above, the number of ED visits with a primary SUD diagnosis with SUD service follow-up within 30 days rose from 11,475 in 2017 to 27,343 in 2020, an increase of over 138%.

Figure F.4.1.2 ED Visits for Beneficiaries with a Primary SUD Diagnosis Who Accessed SUD Services within 30 Days



Likewise, as shown in Figure F.4.1.3 below, ED visitation rates for those who had received SUD services in the past 30 days had a decreasing trend over the past four years.

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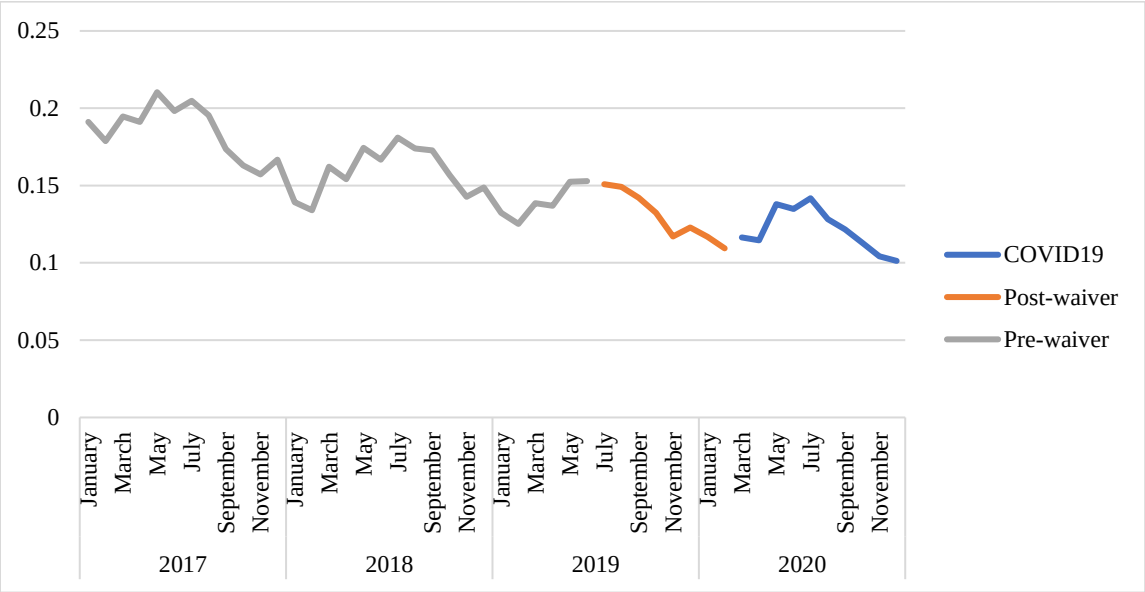
Figure F.4.1.3 ED Visits for Beneficiaries with a Primary SUD Diagnosis Who Received SUD Services within 30 Days of Visiting the ED

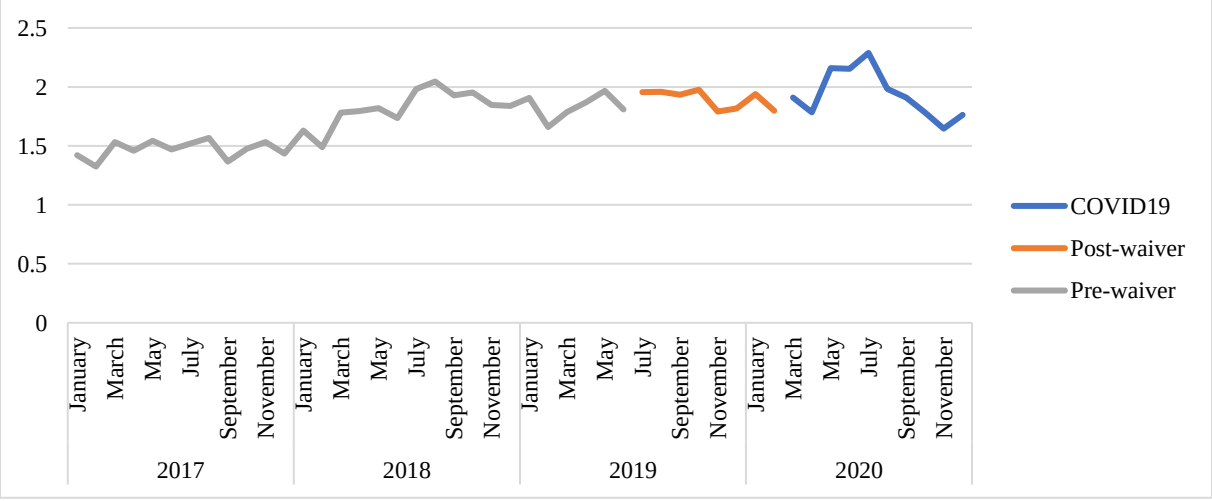


2. Did the rate of hospital admissions for SUD-related diagnoses decrease after the waiver implementation?

As depicted in Table F.4.1.1 above, the number of hospital admissions for SUD-related diagnoses increased from 29,232 to 39,349 from 2017 to 2020, an increase of 34.6%.

As shown in Figure F.4.1.4 below, the rate of admissions is ambiguous. 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 October of 2020.

Figure F.4.1.4 ED Visits with Inpatient Admission for Beneficiaries with SUD



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F.5 Changes in Beneficiary Quality of Life

F.5.1 KORTOS and KTOS Surveys

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 for OUD and then at the 6-month point after continuous program participation.

As shown in Figure F.5.1.1 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. (However, the number of participants was extremely low (21), so it is questionable whether the survey represents the entire population of those participating in OUD treatment.) At the same time, while significant 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); KORTOS indicated self-reported improvements in quality of life.

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

Table F.5.1.1 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

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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**
depression	71	28	67	14
anxiety	78	35	71	19
co-morbid	65	20	67	10
suicidal ideation	18	4	15	0
chronic pain	54	35	48	19
# poor physical health days (past 30 days)	14	8	5	2
# poor mental health days (past 30 days)	18	8	13	4
self-reported good health	9	39	24	43
employed FT	34	47	38	43
homeless	25	9	29	7
difficulty meeting basic living needs	54	35	48	48
difficulty meeting basic health needs	35	24	48	29
arrested	17	7	5	10
illicit drug use	96	37	100	62
opioid drug use	73	11	52	5
heroin usage	66	13	71	38

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

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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-related Expenditures

Table F.6.1 below provides a count of the services provided for SUD services for the baseline years of 2018-19 and the demonstration year of 2020. Based upon the number of medical claims paid, the costs across all reported demonstrated-related health services have increased. While the analyzed data are only for the first year of the demonstration, this interpretation is subject to the complications associated with the COVID-19 pandemic, including the fact that the number of persons with SUD in Kentucky dramatically increased from 2018 through 2020.

Table F.6.1 Total SUD Services County (Proxy for Expenditures)

Year	Total SUD Service Claim Payments	SUD Outpatient Service Payments	SUD Inpatient Service Payments	SUD ED Service Payments
DY2018	109,639	45,816	15,632	48,191
DY2019	118,783	52,091	18,108	48,584
DY2020	130,315	59,496	20,118	50,701

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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 for 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—namely, inpatient expenditures, emergency department (ED) expenditures, non-ED outpatient expenditures, and pharmacy expenditures?[4]

we draw the following preliminary 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 though 2020.

H1b: The number of Medicaid providers billing for residential SUD treatment increased from 2017 though 2020, as did the number of licensed IMD facilities.

H1a and H1b county-by-county analysis: While we were unable to identify the Kentucky counties with greatest need using accepted multi-dimensional attributes, we can identify those counties who, as of 2020, have been unable to utilize the opportunities found in the Kentucky Medicaid 1115 Demonstration waiver.

[4] A fourth primary evaluation question: To what extent did rates of opioid-related overdose death decrease? will be fully analyzed in the final Summative Report.

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As seen in Table G.1 below, there are 26 counties who did not increase service availability for at least one of the presumed outcomes. However, it is possible for these counties that the proffered increase was not reflective of community needs. However, there were10 counties that were not able to increase service availability for two out of the four presumed outcomes (italicized below). We are taking these 10 counties to reflect opportunities for further investigation or potential investment by the state. Of those, four appear on our criteria list for counties of greatest need: Gallatin, Knott, Lee, and Wolfe (italicized and bolded below; three of which are in our defined Southeast Quadrant, and one is in the North).

Table G.1 Counties in Potential Need

County	Did not increase # providers	Did not increase # MOUD prescribers	Did not increase # methadone prescribers	Did not increase # residential providers
Bourbon			x	
Boyd	x			
Bracken	x			x
Breathitt		x		
Breckinridge	x			
Butler	x			
Campbell	x			
Carlisle			x	
Clinton				
Crittendan	x			
Cumberland	x			
Edmonson	x			
Elliot	*x*	*x*		
Fleming	*x*		*x*	
Floyd			x	
Fulton			x	x
Gallatin	***x***			***x***
Hancock				x
Hardin			x	
Henderson	x			
Hickman	x			
Johnson				x
Knott	***x***		***x***	
Lee	***x***		***x***	
Leslie	x	x		
Marion	x		x	
Mason	x			

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Monroe	*x*			*x*
Morgan	*x*		*x*	
Ohio	x			
Pulaski			x	
Robertson		x		
Todd	x			
Trimble	x			
Wolfe	***x***		***x***	
Woodford	*x*		*x*	

H1c: Definitive answers regarding utilization of services are unavailable at this time. While the number of beneficiaries newly diagnosed with SUD and those receiving treatment for the first time both increased from 2017 through 2020, the rate as a percentage of beneficiaries ultimately did not show an increase, due largely, we believe, to the impact of COVID-19. Similarly, while there was an increase in the number of beneficiaries receiving residential treatment for SUD from 2017-2020, the rate as a percentage of beneficiaries ultimately did not show an increase either. However, there was an increase in the number of beneficiaries receiving outpatient treatment for SUD from 2017-2020, and, while the rate as a percentage of beneficiaries declined with the advent of COVID-19, it did not completely erase the gains seen after the waiver started. Similarly, there was both an increase in the total numbers and the rate of beneficiaries with OUD who received MOUD as well as those receiving methadone as their MOUD (though the rates did taper slightly during the pandemic). More data will need to be collected before we will be able to accurately assess these metrics.

H1d/H2a: The number of ED visits for SUD-related diagnoses among beneficiaries did not decrease, but it increased from 2017 to 2020. However, the rate of visits followed roughly the same cyclical pattern from 2017 to 2020. These outcomes appear to be impacted by the dramatic increase in the number of beneficiaries with SUD seen across the same study period. For, the number of beneficiaries with a primary SUD diagnosis who then accessed SUD services within 30 days after visiting the ED increased from 2017 through July 2020. As well, the number of beneficiaries with a primary SUD diagnosis who then had accessed SUD services within 30 days prior to visiting the ED decreased steadily from 2017 through 2020.

H2b: The rate of hospital admissions for SUD-related diagnoses remains ambiguous. 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 October of 2020. More data will need to be collected before we can accurately assess this metric.

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

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

Expenditures: Based upon the claims data we utilized, there is no evidence of cost savings at the end of the first year of the Demonstration. Expenses for demonstration-related health services have steadily increased. However, we also recognize the number of beneficiaries with SUD have already increased during our period of data analysis, which will negatively impact expenses.

Evaluation Question 1: Access by Medicaid beneficiaries for SUD treatment services has increased. The full extent of which will be analyzed in the Final Summative Report.

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.

Evaluation Question 3: All categories of Medicaid expenditures relevant to this report appear to have increased during the period examined. We anticipate a more determinative analysis in the Final Summative Report.

However, 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.

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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 currently in the process of updating the MCQS. The updated strategy will reflect the complementarity of the 1115 Demonstration and considered 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.

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Specific OUD measures included in the updated MCQS, currently in review, 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.

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.

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

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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 (or 2 waves) counties has 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.

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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.

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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 Interim Evaluation, it is premature to suggest changes in policy, procedures, or practices.

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References

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

Bonell, C.P., Hargreaves, J., Cousens, S. et al. (2009). Alternatives to randomization in the evaluation of public health interventions: design challenges and solutions. *Journal of Epidemiology and Community Health* 65:582-587.

Bunn, T.L., Quesinberry, D., Jennings, T., Kizewski, A., Jackson, H., McKee, S., Eustice, S. (2019). Timely linkage of individuals to substance use disorder treatment: development, implementation, and evaluation of FindHelpNowKY.org. *BMC Public Health*. 11:177. doi: 10.1186/s12889-019-6499-5. PMID: 30744608; PMCID: PMC6371481.

Bradley, K., Heeringa, J., Pohl, R.V., et al. (2020). *Selecting the Best Comparison Group and Evaluation Design: A Guidance Document for State Section 1115 Demonstration Evaluations*. https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/comparison-grp-eval-dsgn.pdf

Campbell, M., Fitzpatrick, R., Haines, A., Kinmonth, A.L., Sandercock, P., Spiegelhalter, D., et al. (2000). Framework for design and evaluation of complex interventions to improve health. *BMJ* 321:694.

Center for Disease Control and Prevention (CDC). (2022). *Overdose Mortality by State.* https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm

Centers for Disease Control and Prevention. *U.S. Opioid Prescribing Rate Maps*. (2019). https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html

Clarke, V., and Braun, V. (2017). Thematic analysis. *The Journal of Positive Psychology* 12:297-298. http://dx.doi.org/10.1080/17439760.2016.1262613

Creswell, J.W. & Plano Clark, V.L. (2011). *Designing and conducting mixed methods research* (2nd ed.). Thousand Oaks, CA: Sage. DOI: 10.1177/1609406919899220

Foundation for Healthy Kentucky. (2019). *Kentucky Health Issues Poll: 54 Percent of Kentucky Adults with Drug Use Problem Enter Treatment*. https://www.interactforhealth.org/whats-new/263/substance-use-in-ohio-and-kentucky/

Guest, G., MacQueen, K.M., and Namey, E. E. (2012). *Applied thematic analysis.* Thousand Oaks, CA: Sage.

Harvey, K., and Ingram, V. (2021). *2021 Overdose Fatality Report*. Kentucky Justice and Public Safety Cabinet. https://odcp.ky.gov/Reports/2021%20Overdose%20Fatality%20Report%20%28final%29.pdf

Healthcare Cost and Utilization Project (HCUP). (2019). Neonatal Abstinence Syndrome (NAS) Among Newborn Hospitalizations. https://www.hcup-us.ahrq.gov/faststats/nas/nasquery.jsp?

Kentucky Cabinet for Health and Family Services (2021). Kentucky All Schedule Prescription Electronic Monitoring Quarterly Trend Report, 3rd Quarter 2021. https://chfs.ky.gov/agencies/os/oig/dai/deppb/Documents/KASPERQuarterlyTrendReportQ32021.pdf

Kentucky Department for Public Health Division of Maternal and Child Health (2021). *Neonatal Abstinence Syndrome Reporting Registry – Annual Report 2021*. https://chfs.ky.gov/agencies/dph/dmch/Documents/NASReport.pdf

DRAFT

Kentucky Injury Prevention and Research Center (2021). Drug Overdose and Comorbidity County Profiles. https://kiprc.uky.edu/programs/overdose-data-action/county-profiles.

Kentucky Substance Use Research & Enforcement (2022). *Six Major Overdose-Related Substances and General Overdose-Related Events in Kentucky, January 1, 2017–December 31, 2021. K- SURE Brief (No.19).* https://kiprc.uky.edu/sites/default/files/2022-07/K.SURE%20Product%2019_FINAL.pdf

McHugh ML. (2012). Interrater reliability: the kappa statistic. *Biochem Med* (Zagreb). 22: 276-82. PMID: 23092060; PMCID: PMC3900052.

Medicaid and CHIP Payment and Access Commission (MACPAC). (2017). *Medicaid and the Opioid Epidemic.* https://www.macpac.gov/publication/medicaid-and-the-opioid-epidemic/

Noble, M. C., and Ingram, V. (2021). *2020 Overdose Fatality Review.* https://odcp.ky.gov/Documents/2020%20KY%20ODCP%20Fatality%20Report%20%28final%29.pdf

O'Conner, C & Joffe, H. (2020). Intercoder reliability in qualitative research: Debates and practical guidelines. *International Journal of Qualitative Methods*. 19: 1-13.

Penfold, R. B., and Zhang, F. (2013). Use of interrupted time series analysis in evaluating health care quality improvements. Academic Pediatrics, 13: S38–S44.

Soumerai SB. (2015). How do you know which health care effectiveness research you can trust? A guide to study design for the perplexed. *Prev Chronic Dis*. 12: E101.

Steel, M., and Mirzaian, M. (2021). *Kentucky Resident Drug Overdose Deaths, 2016–2020.* Kentucky Injury Prevention and Research Center. https://kiprc.uky.edu/sites/default/files/2022-01/OD%20Death%20Annual%20Report.pdf

Victora, C.G. , Habicht, J.-P., and Bryce, J. (2004). Evidence-based public health: moving beyond randomized trials. *Am J PublicHealth* 94:400–05.

Wagner, A.K., Soumerai, S.B., Zhang, F., and Ross-Degnan, D. (2002). Segmented regression analysis of interrupted time series studies in medication use research. *J Clin Pharm Ther* 27:299-309.

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

April 12, 2021

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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

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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

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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.

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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.

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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.

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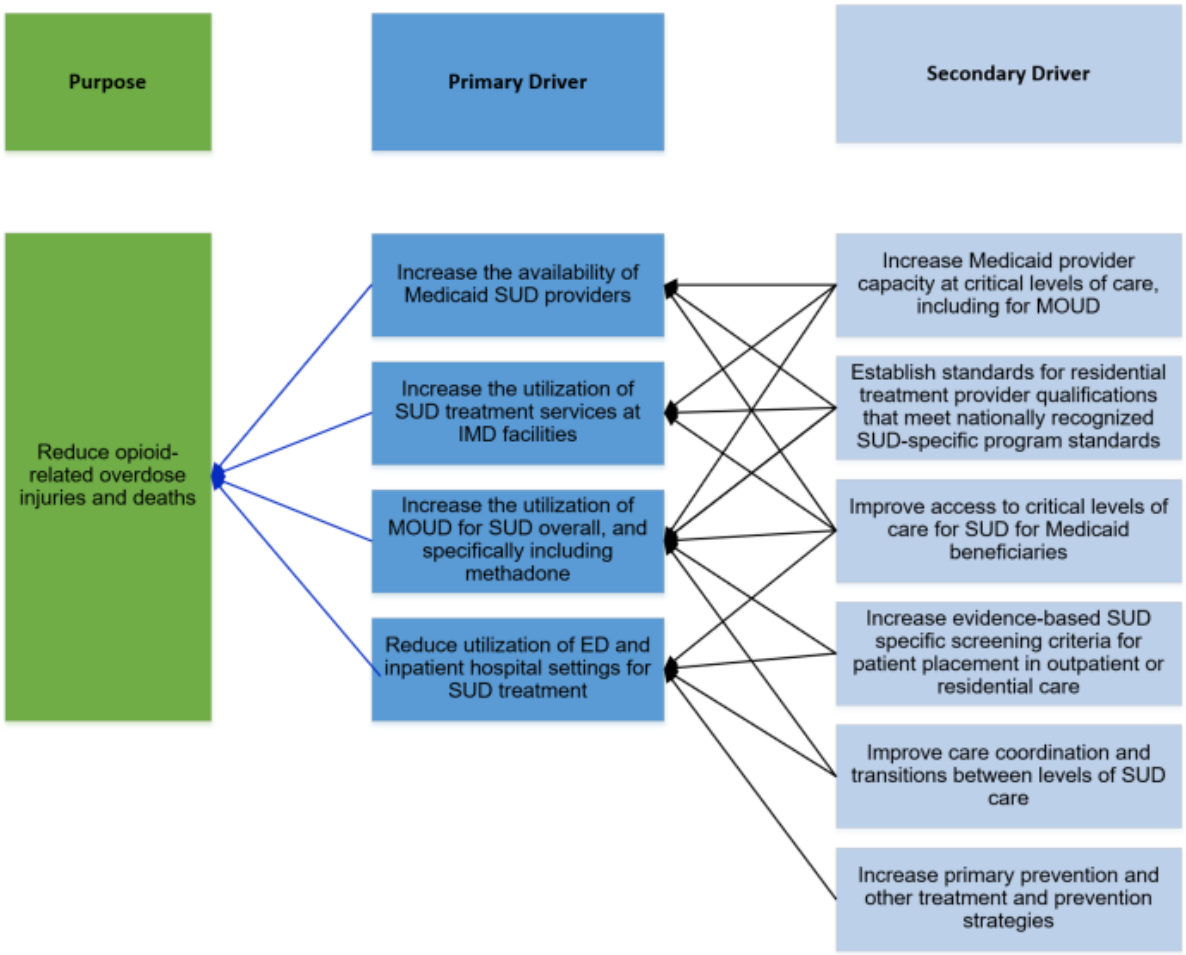
Figure 1. Driver Diagram



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.

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- 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.

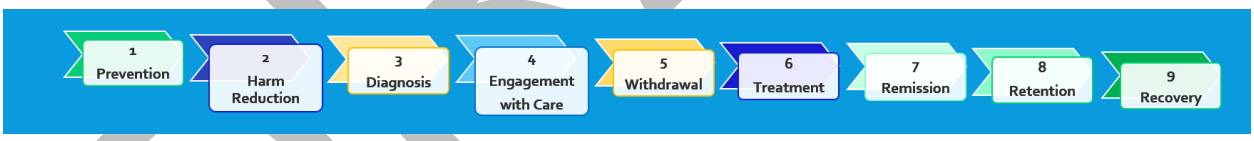
Two different methodological frameworks were used to develop the analyses. The Cascade of Care Model provides insight into Kentucky's global response to SUD/OUD and how the 1115 Demonstration project is embedded within the wide range of state, regional, and local initiatives. A SWOT Analysis (Strengths, 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 2. 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.

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SWOT Framework

A SWOT framework is an assessment tool that can be used to evaluate the relative positioning of an entity or project relative to complimentary and competing services, and relationships with stakeholder groups. A SWOT analysis is designed to be fact-based and data-driven while providing evidence relative to performance, competition, risk, and the potential of an initiative. This approach is particularly suitable for this Midpoint Evaluation given the variety of OUD activities and complex stakeholder environment within the Commonwealth. While the Cascade of Care framework provides an understanding of how the 1115 Demonstration was intertwined with and yet distinct from many other statewide initiatives, the SWOT framework provides a systematic method of understanding how stakeholders viewed the efforts to implement the Demonstration.

There were two initiatives capturing external data for the SWOT analysis. Interviews took place from December 2020 through February 2021, during which respondents were asked to share views of the strengths and weaknesses associated with the 1115 Demonstration in Kentucky during this early stage of implementation. Respondents were also asked to identify opportunities for and threats to Kentucky's efforts. The second source of data was drawn from the interviews originally conducted for the development of the Cascade of Care model.

Stakeholder Interviews

Stakeholder interviews accorded in two somewhat overlapping waves. The focus of the first set of interviews was the establishment of the Cascade of Care Model components and the second was specifically focused on the SWOT analysis. The accrual methodology consisted of a snowball sampling technique built from an initial purposive sample group. The interviews consisted of 24 individuals. Their backgrounds and affiliations consisted of state government, corrections or law enforcement, payer organizations, or healthcare. The research protocols used for these interviews are available in Appendix A.

Stakeholder Reviews

The Midpoint Evaluation is distinct from the Program Assessments. This evaluation is to provide insight at a time critical to the success of the program so that an understanding of early implementation allows for mid-course corrections, enhancements, or necessary changes. The Midpoint Evaluation will also provide a platform for broader stakeholder buy-in and engagement to support the success of the program, as well as providing a context for the Interim and Final Assessment Reports. Thus, 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.

Stakeholder engagement in reviewing Midpoint Evaluation drafts consisted of three waves of feedback:

- In early March 2021, we shared a preliminary report with staff in the Kentucky Department for Medicaid Services (DMS). Comments and issues were considered and incorporated into the analysis if appropriate.

- A revised draft was shared with all stakeholders who had contributed to the development of this report in mid-March 2021 and, again, comments and issues were considered and incorporated into the analysis if appropriate.

- Finally, the evaluation was circulated more broadly within the Kentucky Cabinet for Health and Family Services. Comments and insights were incorporated as appropriate. This process provided the final set of contributions to the material presented in this report.

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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.

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Table 1. 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

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	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

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	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

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	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

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	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

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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 2. 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

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STAGE	REQUIRED 1115 MECHANISMS	GOALS OF MECHANISMS	KY DMS 1115 SUPPORT EFFORTS	ADDITIONAL INITIATIVES
Diagnosis **and** **Engagement with Care**	Use of evidence-based, SUD/OUD-specific placement criteria Protocol for placing patients at appropriate level of care	Improve access to critical levels of care Improve patient placement Increase treatment retention Increase diversion from incarceration	Added exception to Peer Support Specialist Service 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	***ASAM trainings (KORE*)** ***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

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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

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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)

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Table 3. 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

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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.

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Table 4. 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 5. 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

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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.

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Table 6. 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

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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 7. 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 • Extending medical supervision of prisoners to short-term jails • Medicaid availability for persons in custody	• Persisting notion that abstinence is best • Providers unwilling to live in high need communities • Difficult clients • Inconsistencies in authorizations • COVID-19 impacts on PAs

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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 8. 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.

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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 9. 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 • Self-evaluation by providers allowed • Effective partnership with MCOs	• Limited responses to surveys • Difficult to access data on provider networks • Lack of rigor in provisional process • 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.

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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 10. 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:

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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 11. 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.

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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 12. 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

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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 13**. 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.

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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.

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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.

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APPENDIX A. MIDPOINT EVALUATION METHODOLOGY

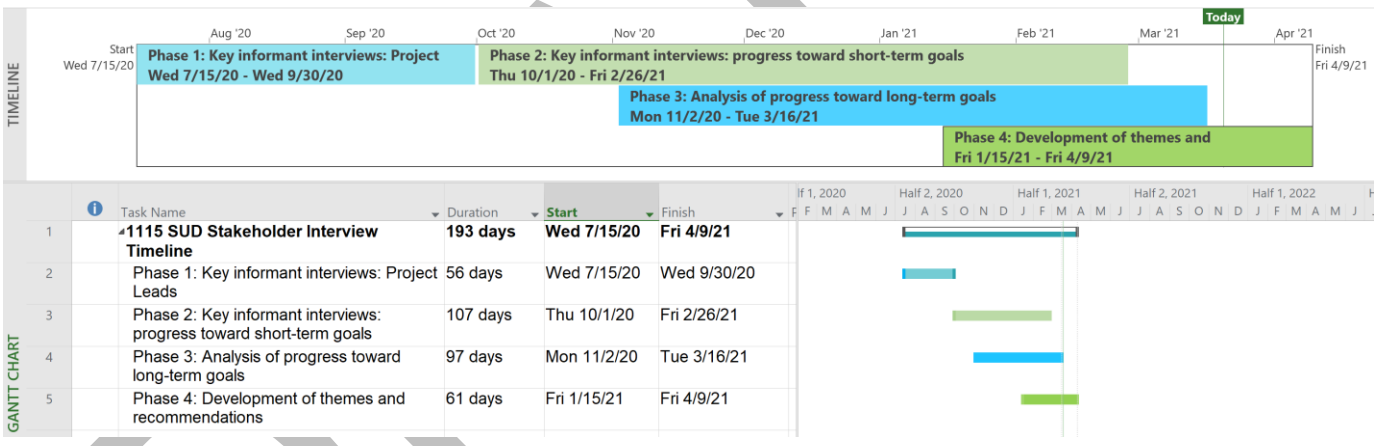
The purpose of this evaluation is to provide an early assessment of the implementation of the demonstration and a foundation for longer-term evaluation activities. It is a formative evaluation that examines both action steps and any short-term outcomes. The results of this evaluation should be used to 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 3. 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.

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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.

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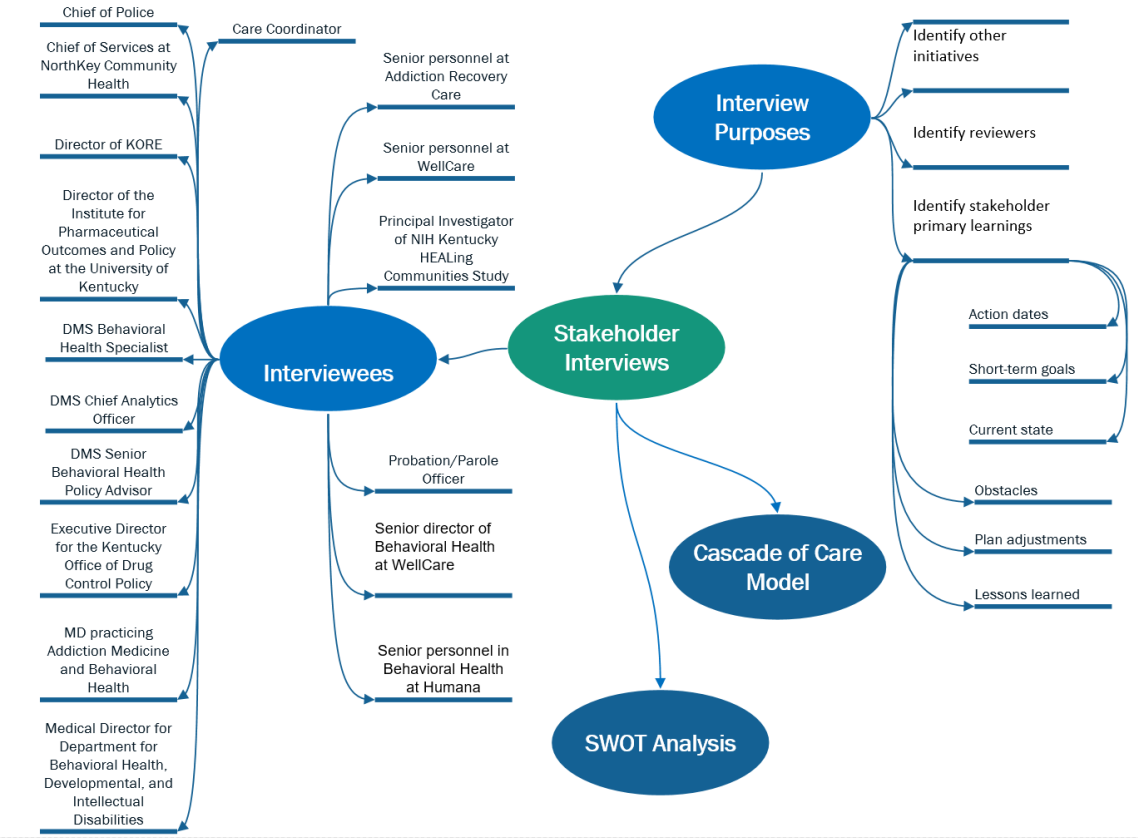
While queries and conversations varied depending on the respondent's relationship to the 1115 Demonstration, core questions included:

- 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 4. Interview Overview



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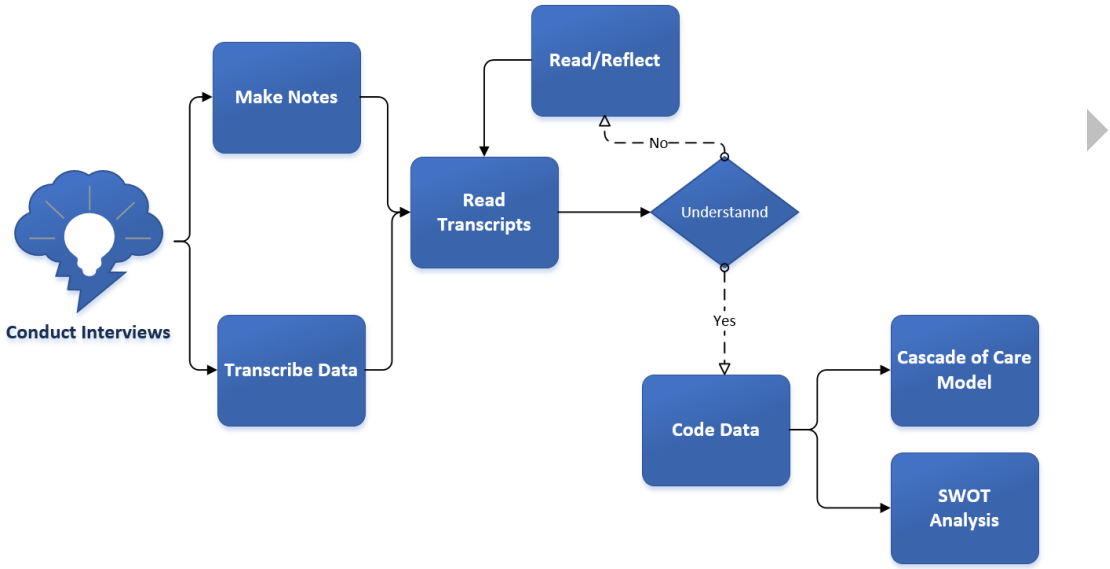
Phase 3: Analysis of progress toward long-term goals (November 2, 2020 to March 16, 2021)

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 5. 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.

APPENDIX B. 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

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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

APPENDIX C. 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

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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

APPENDIX D. 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.

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