



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

April 12, 2021

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

EVALUATION TEAM:
Valerie Hardcastle
Gary Ozanich
Steve Howe
Xiaoni Zhang
Dayna Schambach

TABLE OF CONTENTS

EXECUTIVE SUMMARY	iv
Background	1
Evaluation Activities	1
Midpoint Evaluation.....	3
Methodology	3
Understanding the 1115 Demonstration in Context.....	3
Cascade of Care Model Framework	4
SWOT Framework	5
Stakeholder Interviews.....	5
Stakeholder Reviews	5
Results: Cascade of Care Analysis	6
Results: SWOT Analysis	18
Mechanism 1: Implement Opioid Prescribing Guidelines	18
Mechanism 2: Use Evidence-Based, SUD/ODU-Specific Placement Criteria.....	21
Mechanism 3: Protocol for Placing Patients at Appropriate Level of Care (LOC).....	22
Mechanism 4: Nationally Recognized SUD/ODU-Specific Program Standards for Provider Qualifications	24
Mechanism 5: Use Process of Reviewing Providers to Ensure Standards of Care.....	24
Mechanism 6: Provide Access to Critical Levels of Care for SUD/ODU.....	25
Mechanism 7: Ensure Sufficient Provider Capacity	26
Mechanism 8: Waiving the IMD Exclusion.....	27
Mechanism 9: Implement Policies to Ensure Inpatients Are Linked to Community-Based Services.....	28
Conclusions	30
Policies and Regulation	30
Justice-Involved Persons with SUD/ODU.....	30
Education and Training	30
Reducing Complexity	31
Reimbursement.....	31
Appendix A. MIDPOINT EVALUATION METHODOLOGY	32
Appendix B. Kentucky Opioid Response Effort (KORE) Primary Funding Priorities	36
Appendix C. 1115 Demonstration Metrics by Stage of SUD/ODU Cascade of Care	38
Appendix D. Statement of Evaluator Independence	39

List of Tables

Table 1. SUD/ODU Cascade of Care in Kentucky 7
Table 2. Crosswalk between SUD/ODU Cascade of Care and Kentucky Initiatives 13
Table 3. Demonstration Mechanisms and Cascade of Care Summary Chart 17
Table 4. Mechanisms and Secondary Driver Mapping 19
Table 5. SWOT Analysis on Implementing Opioid Prescribing Guidelines..... 20
Table 6. SWOT Analysis on Evidence-Based SUD/ODU-Specific Placement Criteria 22
Table 7. SWOT Analysis on Appropriate Level of Care (LOC)..... 23
Table 8. SWOT Analysis on Using Nationally Recognized SUD/ODU-Specific Program Standards for
Provider Qualifications 24
Table 9. SWOT Analysis on Reviewing Providers to Ensure Standards of Care 25
Table 10. SWOT Analysis on Access to Critical Levels of Care for SUD/ODUs 26
Table 11. SWOT Analysis on Ensuring Sufficient Provider Capacity 27
Table 12. SWOT Analysis Waiving the IMD Exclusion 28
Table 13. SWOT Analysis on Implementing Policies to Ensure Inpatients Are Linked to Community-Based
Services 29

List of Figures

Figure 1. Driver Diagram..... 2
Figure 2. Cascade of Care Model 4
Figure 3. Project Timeline 32
Figure 4. Interview Overview 34
Figure 5. Qualitative Analysis Diagram..... 35

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 of 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
OD	Opioid Use Disorder
PAs	Prior Authorizations
RCSU	Residential Crisis Stabilization Units
RTCs	Residential Treatment Centers
SAMHSA	Substance Abuse and Mental Health Services Administration
SBIRT	Brief Intervention and Referral to Treatment
SPA	State Plan Amendment
SUD	Substance Use Disorder
SWOT	Strength, Weakness, Opportunity and Threat

EXECUTIVE SUMMARY

The Department of Medicaid Services (DMS) within the Kentucky Cabinet for Health & Family Services (CHFS) proposed a Substance Use Disorder (SUD/OD) 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/OD 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/OD providers offering treatment services and (2) expand SUD/OD treatment benefits available to enrollees, thereby increasing utilization of SUD/OD treatment services.

The goals of the 1115 Demonstration are:

- Improve access to critical levels of care for OUD and other SUD/ODs for Medicaid beneficiaries
- Increase the use of evidence-based SUD/OD screening criteria for patient placement in outpatient or residential care
- Establish standards for residential treatment provider qualifications that meet nationally-recognized SUD/OD-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/OD 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/OD-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/OD 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/OD 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/OD activities across Kentucky
- Review of documents and data from departments within CHFS
- Two waves of stakeholder interviews
- Stakeholder reviews of early drafts of this Midpoint Evaluation

Results

The implementation of the demonstration and the collection of data concerning performance under the waiver have been constrained by the COVID-19 pandemic. There is also evidence that behaviors during this period changed, which complicates longitudinal analyses and other comparisons across time periods.

Common themes and issues that became apparent in evaluating the 1115 Demonstration within both the Cascade of Care Model and SWOT analysis frameworks are listed below, along with (where appropriate) accompanying recommendations for consideration for implementation:

1. *Policies and regulation* - the comprehensive response by the Commonwealth in addressing evidence-based treatment through public policies and evolving regulation was a consistent theme throughout the evaluation. This includes changes to prior authorization requirements, changes to regulations, policies supporting engagement and education, and standardization and coordination of actions across departments and cabinets. Kentucky should be applauded for thoroughness in which it has implemented complementary supports for the 1115 Demonstration. Resource constraints for the implementation of these supporting activities were the principal concern identified by stakeholders. However, it appears that at least some of these concerns have been addressed through additional DMS actions; hence, additional communication to providers around reimbursement and related changes might be advised.
2. *Justice-involved persons with SUD/ODD* - Key informants from multiple systems believe there is a gap for persons involved in the criminal justice system between the SUD/ODD 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 ASAM and other standards. A central issue is how these new criteria will be folded into current accreditations. Possible suggested solutions include coordinating DMS accreditations with those of Commission on Accreditation of Rehabilitation Facilities (CARF) and COA to reduce demands on providers and to subsidize a standardized ASAM consistent six-dimensional tool.
5. *Reimbursement* - A final theme that emerged was the issue of reimbursement for providers who serve large numbers of Medicaid clients. We appreciate that this is an on-going issue and not specific to this 1115 Demonstration project. However, several stakeholders did raise the possibility that reimbursement and payment challenges disincentivized providers from participating more fully. It might be worth investigating whether some small changes in reimbursement schedules might make wider adoption of these measures more palatable.

Conclusions

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

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

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

Background

The Department of Medicaid Services (DMS) within the Kentucky Cabinet for Health & Family Services (CHFS) proposed a Substance Use Disorder (SUD/OD) demonstration project as a Section 1115 Demonstration Waiver project to expand ongoing efforts to address the opioid crisis. The proposal for the 1115 SUD/OD 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/OD 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/OD providers offering treatment services and (2) expand SUD/OD treatment benefits available to enrollees, thereby increasing utilization of SUD/OD treatment services.

The central features of this demonstration are:

1. increased access to SUD/OD providers by assessing Medicaid SUD/OD provider capacity at critical levels of care and certifying residential treatment providers according to nationally recognized standards for SUD/OD treatment.
2. waiver of the Medicaid Institutions for Mental Disease (IMD) exclusion, allowing reimbursement for SUD/OD 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.

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:

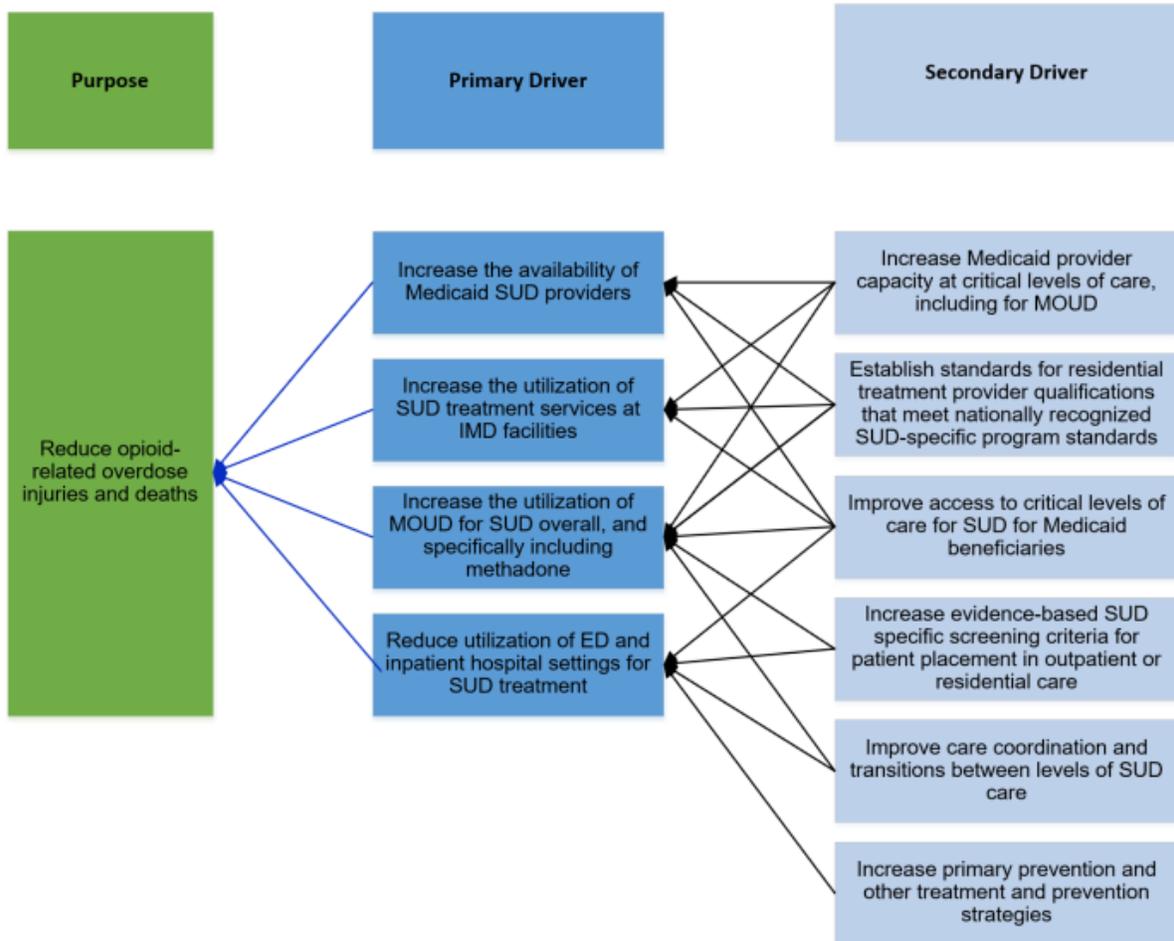
- Midpoint Evaluation (April 2021)
- Interim Assessment (January 2022)
- Final Assessment (July 2025)

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/OD 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/OD providers offering residential treatment, especially IMDs, to beneficiaries.

Figure 1. Driver Diagram



H1c: The demonstration will increase the utilization of SUD/ODU services.

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

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

H2b: Among beneficiaries receiving care for SUD/ODU, the demonstration will reduce hospital readmissions for SUD/ODU 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/ODD and non-SUD/ODD expenditures (with SUD/ODD expenditures disaggregated into IMD and non-IMD expenditures)
- Expenditures disaggregated by source of treatment—namely, inpatient expenditures, emergency department (ED) expenditures, non-ED outpatient expenditures, pharmacy expenditures, and long-term care expenditure.

Midpoint Evaluation

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

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

Methodology

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

Methodological Limitations

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

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

Understanding the 1115 Demonstration in Context

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

To do this, two analyses were developed:

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

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

Two different methodological frameworks were used to develop the analyses. The Cascade of Care Model provides insight into Kentucky’s global response to SUD/ODU 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/ODU. 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/ODU 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/ODU 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 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/ODU 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/ODU who are in recovery be significantly impacted.

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.

Results: Cascade of Care Analysis

Table 1 below documents the goals for each stage in the SUD/OD 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/OD prevention, treatment, and recovery strategies and to develop evidence-based standards that can serve as a national model for reducing opioid mortality. As of 1 March 2021, selection of the particular strategies for each of the counties was not yet completed and full implementation of the strategies had not yet launched.

Table 1. SUD/OD Cascade of Care in Kentucky

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

	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)	<i>Untrained or poorly trained providers (PCP's) or first responders</i> 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	<i>Lack of diagnostic capability or expertise</i> <i>Failure to use evidence-based assessment tools</i> Lack of access to assessment Lack of understanding around billing Stigma Lack of time in medical appointments Lack of administrative support

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

	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	<i>Lack of treatment capacity</i> 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	<i>Fragmented care system</i> Lack of transportation Lack of insurance/ability to pay MOUD inconvenience Lack of availability Dual diagnoses Incarceration/detention Homelessness/unstable housing Interference with jobs/family responsibilities

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

Table 2 crosswalks the stages in the SUD/ODU 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/ODU 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 the 1115 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/ODU 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/ODU-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/ODU morbidity and mortality remains unchanged, and that the 1115 Demonstration project remains a significant initiative embedded with others.

Table 2. Crosswalk between SUD/ODU Cascade of Care and Kentucky Initiatives

STAGE	REQUIRED 1115 MECHANISMS	GOALS OF MECHANISMS	KY DMS 1115 SUPPORT EFFORTS	ADDITIONAL INITIATIVES
<p style="text-align: center;">Prevention and Harm Reduction</p>	<p>Implement opioid prescribing guidelines</p>	<p>Increase primary prevention</p> <p>Disrupt inappropriate prescribing</p> <p>Impede “doctor shopping”</p> <p>Encourage responsible prescribing</p> <p>Reduce opioid intake</p> <p>Reduced adverse consequences of accidental poisonings</p> <p>Increase awareness of OUD</p>	<p>Encourage use of SAMHSA prescribing guidelines</p> <p>KASPER (Kentucky All Schedule Prescription Monitoring) user-interface enhancement</p> <p>Efforts to integrate interstate data</p>	<p><i>Educational outreach to physicians, pharmacists, and community (KORE)</i></p> <p><i>Trainings to improve opioid prescribing safety and disposal (HEAL)</i></p> <p>Promote community engagement through coalitions (HEAL)</p> <p>Public health campaign to increase awareness of OUD (HEAL)</p> <p>Naloxone education and distribution (KORE, HEAL)</p> <p>Syringe exchange access programs (SAEP) (KY Health Departments [HD])</p> <p>Education about harm (KY HD)</p> <p>Testing for complications for PWID (KY HD)</p> <p>State pharmacy map for naloxone (Ky Office of Drug Control Policy [ODCP])</p> <p>Care coordination (KORE, HEAL)</p> <p>Annual Harm Reduction Summit</p>

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

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

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

Table 3. Demonstration Mechanisms and Cascade of Care Summary Chart

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

Results: SWOT Analysis

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

- Improve access to critical levels of care for OUD and other SUD/ODDs for Medicaid beneficiaries
- Increase the use of evidence-based SUD/ODD screening criteria for patient placement in outpatient or residential care
- Establish standards for residential treatment provider qualifications that meet nationally recognized SUD/ODD-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/ODD 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/ODD Cascade of Care Model.

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

- Implement prescribing guidelines and other treatment and prevention strategies.

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

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

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

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

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

Table 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/ODU-Specific Placement Criteria		X	X			
Mechanism 3: Protocol for Placing Patients at Appropriate Level of Care		X	X			
Mechanism 4: Nationally Recognized SUD/ODU-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/ODU		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
<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • Under the radar pill-mills • Increased use of other drugs, especially methamphetamines • Increased use of fentanyl • Removing PAs restricts ability to steer patients/providers to the options with the best clinical evidence

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

The use of evidence-based, SUD/OD-specific placement criteria is a mechanism for impacting Engagement with Care (Stage 4) in the SUD/OD 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/ODs for Medicaid beneficiaries.
- Increase the use of evidence-based SUD/OD screening criteria for patient placement in outpatient or residential care.

The research undertaken for this evaluation indicates performance improvement in evidence-based, SUD/OD-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/OD 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/OD 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/OD.

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/OD-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/OD throughout the Kentucky Judicial College.

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

Table 6. SWOT Analysis on Evidence-Based SUD/OD-Specific Placement Criteria

Strengths	Weaknesses
<ul style="list-style-type: none"> • More ASAM-certified treatment facilities • Pilot programs integrating mental health/SUD/OD screening into primary care practices • Increased participation in the initial phases of treatment • Increased referrals from ED for patients diagnosed with SUD/OD • 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 	<ul style="list-style-type: none"> • 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/OD to seek treatment • Drug courts overburdened and hard to scale
Opportunities	Threats
<ul style="list-style-type: none"> • Incentivizing programs to create increased provider interest • Including follow-up post-ED as metric for those with SUD/OD • Training providers regarding criteria, and how to utilize and support organizational change • Developing checklists for referring parties • Special training on persons with SUD/OD for Kentucky Judicial College 	<ul style="list-style-type: none"> • 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/OD 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/OD for Medicaid beneficiaries.
- Increase use of evidence-based SUD/OD 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/OD. Challenges appear consistent with other mechanisms: economic/financial, regional differences, care coordination, and justice-involved individuals/corrections.

Respondents indicated that training offered by DMS in understanding level of care requirements and reimbursements as being important in addressing the financial challenges. Consistent with other mechanisms, Medicaid reimbursement was identified as the primary economic challenge, particularly for providers with large Medicaid populations. The MCO requirement of using ASAM criteria be applied to utilization management when determining medical necessity and prior authorization (PA) for services is addressing the economic and associated capacity issues. However, inconsistencies in authorizations due to lack of standardized assessment tools and prior authorization requirements continues to be reported.

In addition, the elimination of Prior Authorizations (PA) due to COVID has made monitoring protocols for placing patients at appropriate LOC difficult; depth of clinical updates is limited. Since elimination of PAs, MCOs have seen increase in inpatient stays that are 28 days or longer without clear evidence of clinical need.

Other identified actions that can support LOC appropriateness were:

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

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

Table 7. SWOT Analysis on Appropriate Level of Care (LOC)

Strengths	Weaknesses
<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Persisting notion that abstinence is best • Providers unwilling to live in high need communities • Difficult clients • Inconsistencies in authorizations • COVID-19 impacts on PAs

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/ODU-Specific Program Standards for Provider Qualifications

Using nationally recognized SUD/ODU-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/ODU Cascade of Care Model.

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

- Increase use of evidence-based SUD/ODU screening criteria for patient placement in outpatient or residential care.
- Establish standards for residential treatment provider qualifications that meet nationally recognized SUD/ODU-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/ODU-Specific Program Standards for Provider Qualifications

Strengths	Weaknesses
<ul style="list-style-type: none"> • Increased reimbursement of services • Requirement for ASAM criteria added to SPA • Good DMS communication with MCOs 	<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • Additional training for providers • Updating regulations to reference to ASAM criteria. 	<ul style="list-style-type: none"> • 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:

- Increase use of evidence-based SUD/ODU screening criteria for patient placement in outpatient or residential care.
- Increase provider capacity at critical levels of care, including MOUD for OUD.
- 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
<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • Ongoing communication with providers • Enhanced rates for providers 	<ul style="list-style-type: none"> • 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/OD

Providing access to critical levels of care for SUD/OD is a mechanism for addressing Withdrawal (Stage 5) and Treatment (Stage 6) in the SUD/OD Cascade of Care Model.

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

- Improve access to critical levels of care for OUD and other SUD/ODs for Medicaid beneficiaries.

- Increase the use of evidence-based SUD/OD screening criteria for patient placement in outpatient or residential care.
- 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/OD 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/ODs

Strengths	Weaknesses
<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Long-term stays covered for maximum of 90 days • Difficult to access to capital for expansion • Varying licensure and DMS regulations requirements
Opportunities	Threats
<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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/OD Cascade of Care Model.

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

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

- Establish standards for residential treatment provider qualifications that meet nationally recognized SUD/OD-specific program standards.
- 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
<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Low response rates to data gathering activities by providers • Too few qualified providers to meet demand
Opportunities	Threats
<ul style="list-style-type: none"> • Incentivizing programs for increased provider enrollment by KY MCOs • Including transitional living or recovery housing in LOC • Expanding prescribing to physician assistants 	<ul style="list-style-type: none"> • Lack of counselors and licensed clinicians • Enrollment deterred by stigma or previous experience treating SUD/OD 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/OD Cascade of Care Model.

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

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

Waiving the IMD exclusion allows for reimbursement for crisis stabilization, withdrawal management, and SUD/OD 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
<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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" 	<ul style="list-style-type: none"> • Unscrupulous providers • High turn-over among providers • Misinformation within court systems leading to detrimental outcomes • Focus on abstinence may lead to early termination of treatment services. • Difficult to ensure that individual can remain on their treatment medication choice • Limited ability to monitor facilitation within inpatient facilities

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

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

- Improve care coordination and transitions between levels of SUD/ODU 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
<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Some ancillary support programs lack evaluation • Difficult to measure a successful recovery • Mismatch between billing codes and services provided
Opportunities	Threats
<ul style="list-style-type: none"> • Advocating for SUD/ODU 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 	<ul style="list-style-type: none"> • Lack of adequate recovery support systems • Time-limited supports • Transient population • Compassion fatigue/burnout • Correctional employees unfamiliar with resources • Suspension of Medicaid during incarceration • Pandemic made follow-through more difficult • Duplication of services • No monitoring mechanism; claims data do not include discharge data.

Conclusions

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

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

Policies and Regulation

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

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

Justice-Involved Persons with SUD/OD

Key informants from multiple systems believe there is a gap for persons involved in the criminal justice system between the SUD/OD 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/OD, the promise of MOUD, and innovative models for connecting inmates to services pre-release.

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

Education and Training

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

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

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

Reducing Complexity

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

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

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

Reimbursement

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

APPENDIX A. MIDPOINT EVALUATION METHODOLOGY

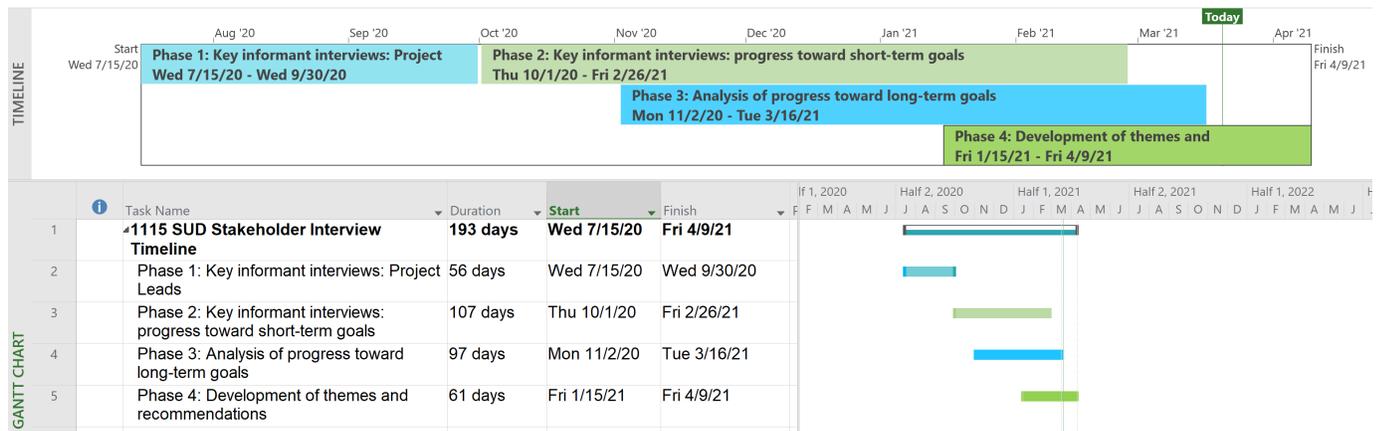
The purpose of this evaluation is to provide an early assessment of the implementation of the demonstration and a foundation for longer-term evaluation activities. It is a formative evaluation that examines both action steps and any short-term outcomes. The results of this evaluation should be used to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

Table 14: Implementation Actions

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

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

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

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

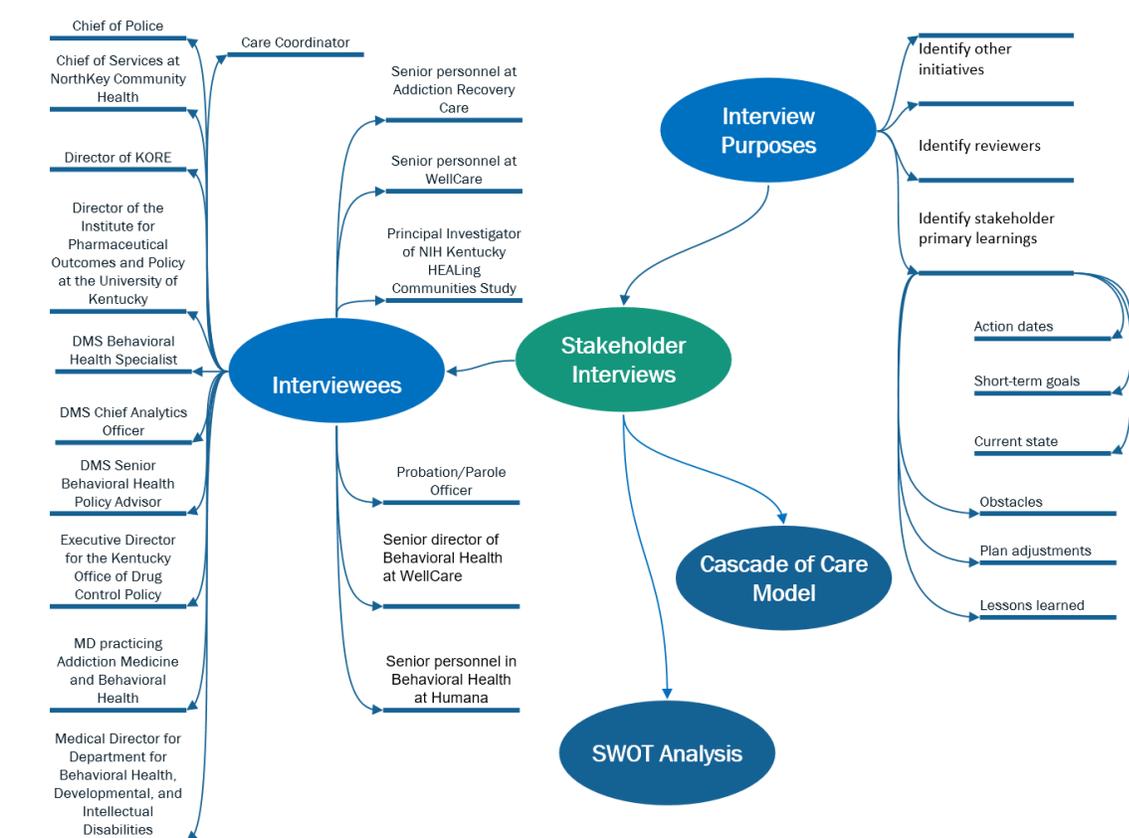
- Care Coordinator
- Chief of Police
- Chief of Services at NorthKey Community Health
- Director of KORE
- Director of the Institute for Pharmaceutical Outcomes and Policy at the University of Kentucky
- DMS Behavioral Health Specialist
- DMS Chief Analytics Officer
- DMS Senior Behavioral Health Policy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

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

- What is your role/s within your agency?
- In the last 2 years, how has the 1115 Demonstration impacted your services in terms of:
 - Opioid prescribing guidelines?
 - Use of evidence-based placement criteria like SBIRT Assessments and ASAM Criteria?
 - Utilizing Appropriate Levels of Care?
 - Use of SUD/OD-Specific Standards (ASAM, CARF)?
 - Reviewing providers to ensure standards of care?
 - Access to critical levels of care for OUD/SUD/ODs?
 - 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/OD 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 is provided in Figure 4.

Figure 4. Interview Overview

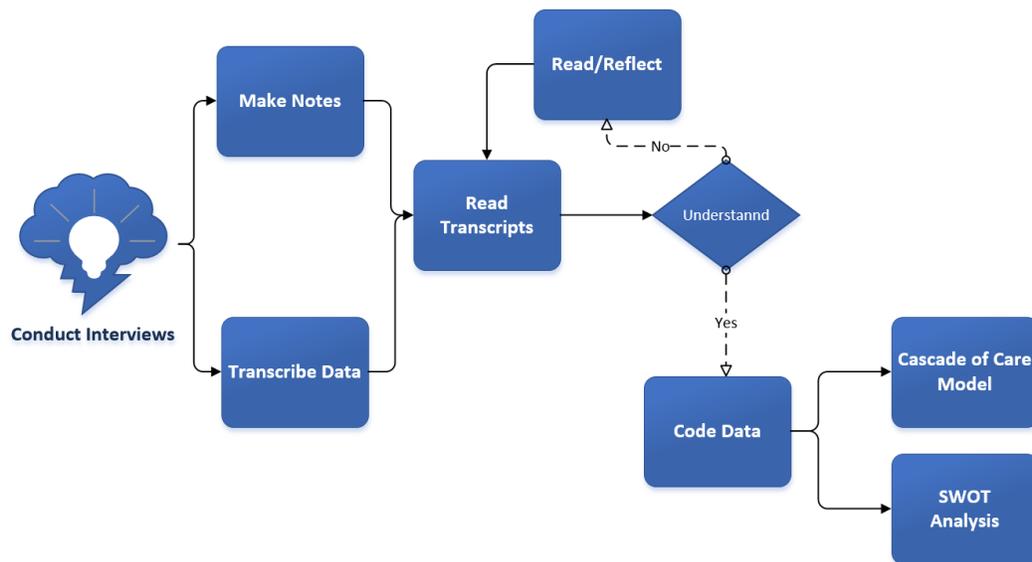


Phase 3: Analysis of progress toward long-term goals (November 2, 2020 to March 16, 2021)

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

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

Figure 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

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/OD CASCADE OF CARE

Stage	1115 Outcome Metrics
Prevention	<ul style="list-style-type: none"> • % 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	<ul style="list-style-type: none"> • % 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/OD per 1,000 beneficiaries • % beneficiaries with SUD/OD with ambulatory or preventive care visit.
Engagement with Care	<ul style="list-style-type: none"> • Beneficiaries screened for SUD/OD treatment needs • Beneficiaries with a SUD/OD diagnosis • Beneficiaries with a SUD/OD-related service • % beneficiaries with a new episode of abuse or dependence who began treatment • Beneficiaries receiving residential or inpatient treatment for SUD/OD • Beneficiaries using early intervention services • Beneficiaries using outpatient services for SUD/OD • Beneficiaries using intensive outpatient or partial hospitalization services for SUD/OD • Beneficiaries using residential or inpatient services for SUD/OD • Beneficiaries using withdrawal management services • Beneficiaries using MOUD for SUD/OD • Inpatient stays for SUD/OD per 1,000 beneficiaries • Hospital readmission rate for beneficiaries with SUD/OD • Medicaid SUD/OD spending • Medicaid SUD/OD spending on residential or inpatient treatment • Per capita SUD/OD spending during the measurement period • Number beneficiaries with OD deaths
Withdrawal and Treatment	<ul style="list-style-type: none"> • Providers enrolled in Medicaid and qualified to deliver SUD/OD services • Providers enrolled in Medicaid and qualified to deliver SUD/OD services and who met standards to provide MOUD • Length of stay for beneficiaries discharged from IMD inpatient or residential treatment for SUD/OD • Beneficiaries using MOUD for SUD/OD • Inpatient stays for SUD/OD per 1,000 beneficiaries • Hospital readmission rate for beneficiaries with SUD/OD • Medicaid SUD/OD spending • Medicaid SUD/OD spending on residential or inpatient treatment • Per capita SUD/OD spending during the measurement period • Grievances filed related to SUD/OD treatment services • Appeals filed related to SUD/OD treatment services • Critical incidents filed related to SUD/OD treatment services
Retention Remission and Recovery	<ul style="list-style-type: none"> • Beneficiaries using MOUD for SUD/OD • % beneficiaries with pharmacotherapy for OUD with 180+ days of continuous treatment • Medicaid SUD/OD spending • Per capita SUD/OD spending during the measurement period • Grievances filed related to SUD/OD treatment services • Appeals filed related to SUD/OD treatment services • Critical incidents filed related to SUD/OD 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.