Evaluation Design

West Virginia Continuum of Care for Medicaid Enrollees with Substance Use Disorders

09/24/2019

A. General Background Information

West Virginia (WV) has the highest age-adjusted rate of drug overdose deaths in the country (52.2 deaths per 100,000 residents in 2016)[1], more than 2.5 times the national average. Between 2012 and 2016, the death count increased 58.4%, from 558 to 884[2]. Additionally, 31 of every 1,000 births in the state involve babies born with Neonatal Abstinence Syndrome (NAS) resulting from substance use among pregnant women[3]. The WV Medicaid program currently provides health coverage to more than 660,000 residents on an annual basis with nearly 70% of members served through the state's managed care delivery system. More than one-third of WV's population is covered by Medicaid at some point during the year.

The WV Bureau for Medical Services (BMS) received approval for a 5-year (from January 2018 to December 2022) section 1115 waiver demonstration entitled "Creating a Continuum of Care for Medicaid Enrollees with Substance Use Disorders" on October 6, 2017 (referred to as the "waiver" throughout the remainder of this evaluation plan). This demonstration has the potential to address some of the state's most serious health problems. The program is intended to achieve the following objectives stated in the approved special terms and conditions:

- Improve **quality of care** and **population health outcomes** for Medicaid enrollees with SUD;
- Increase enrollee **access to and utilization of** appropriate SUD treatment services based on the ASAM Criteria or comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines;
- Decrease medically inappropriate and avoidable **utilization of high-cost emergency department and hospital services** by enrollees with SUD; and
- Improve **care coordination and care transitions** for Medicaid enrollees with SUD.

Summary of Demonstration/Implementation Plan

West Virginia began implementation of waiver activities in January 2018. The waiver approach centers upon three reimbursement mechanisms designed to address gaps in the SUD care continuum and thought to be cost-neutral. The waiver will also establish standards of care for SUD services that incorporate industry standard benchmarks from the American Society of Addiction Medicine (ASAM) criteria for patient assessment and placement. The three main treatment options to be expanded through Medicaid are peer recovery support services, adult residential treatment, and methadone treatment, described in more detail below:

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[1] Centers for Disease Control and Prevention WISQARS (Web-based Injury Statistics Query and Reporting System). Available at: http://www.cdc.gov/injury/wisqars/index.html.
[2] Centers for Disease Control and Prevention. Drug Poisoning Mortality Report. Available at: https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm
[3] Centers for Disease Control and Prevention, "Incidence of Neonatal Abstinence Syndrome, 28 States, 1999-2013", August 12, 2016. Available at http://www.cdc.gov/mmwr/volumes/65/wr/mm6531a2.htm?s_cid=mm6531a2_w.

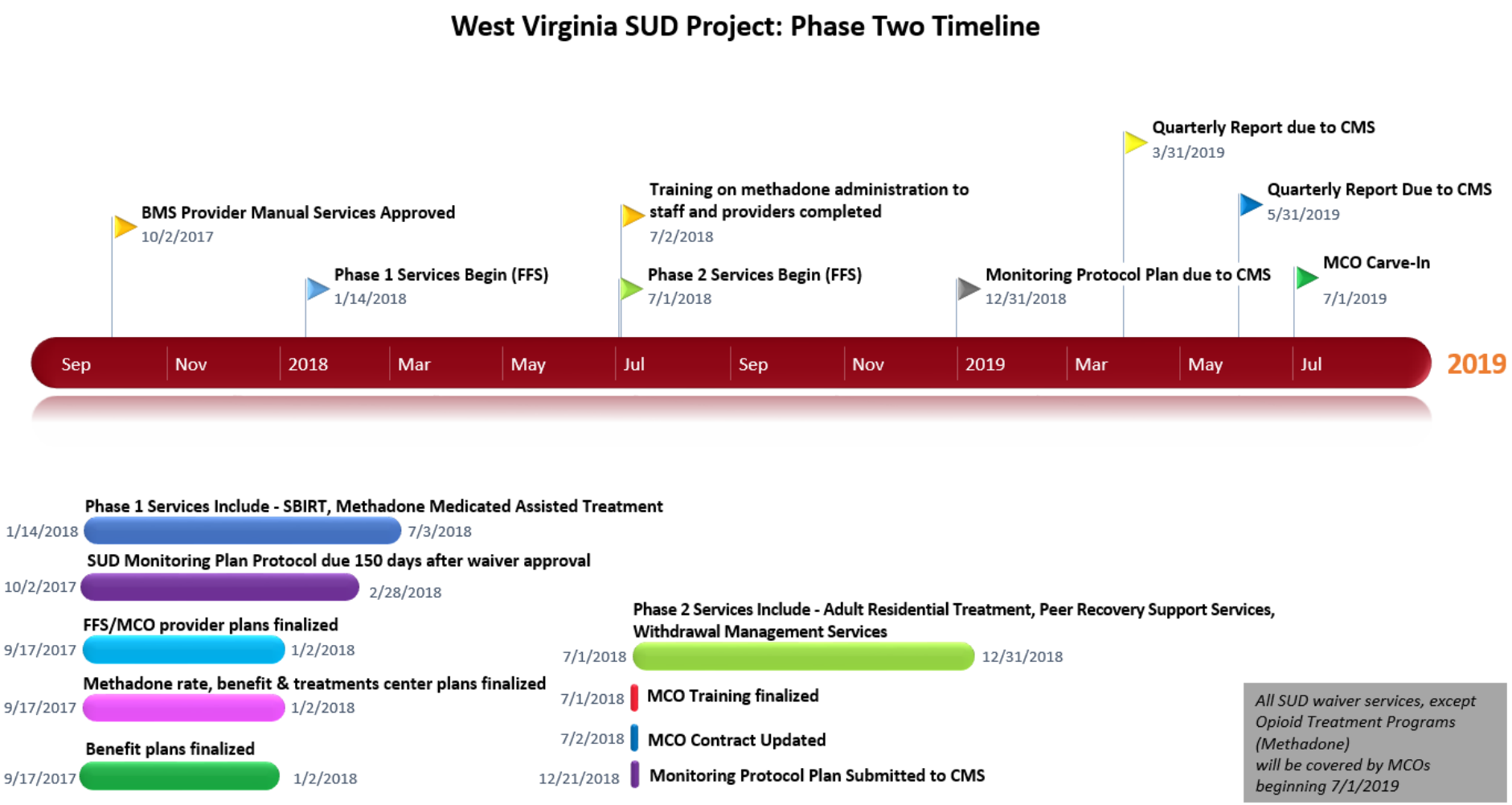
1. **Peer Recovery Support Services (PRSS):** These services are designed and delivered by individuals in recovery from SUD (peer recovery coaches), who provide counseling support to help prevent relapse and promote recovery. Services are provided by appropriately trained staff employed by Licensed Behavioral Health Centers. Peer recovery coaches must be certified through a WV Department of Health and Human Resources approved training program. This service became officially available for Medicaid reimbursement beginning on July 1st, 2018.

2. **Residential treatment services**: These services are available to adult Medicaid beneficiaries with SUD who are residents in facilities that meet the definition of an Institution for Mental Disease (IMD). Facilities must be enrolled as Medicaid providers and must deliver care consistent with ASAM Levels 3.1, 3.3, 3.5, and/or 3.7, as assessed by BMS staff. These services can be provided in settings of any size. The average length of stay for individuals receiving these services must be 30 days or less. Covered services include withdrawal management, addiction pharmacotherapy, drug screening, motivational enhancement, counseling, clinical monitoring, and recovery support services. This service was implemented on July 1st, 2018.

3. **Methadone treatment:** This service bundle benefit includes physician-supervised daily opioid agonist medication and counseling services provided to maintain multidimensional stability for Medicaid beneficiaries with OUD. This service can be provided by BMS-licensed Opioid Treatment Programs (OTPs, methadone clinics) in accordance with an individualized service plan determined by a licensed physician or prescriber. Covered services include use of opioid agonist pharmacotherapy (methadone), drug screening, linkage to psychological and medical consultation, cognitive or behavioral therapy, and referral for infectious disease screening. This service was implemented on January 14th, 2018.

Additionally, BMS has continued to work with providers to help them understand current best practices in, and expand their capacity to treat, SUD. BMS also offers regularly scheduled training workshops to ensure that providers are appropriately billing for these services. When waiver services were initially rolled-out, all services were reimbursed via the traditional fee-for-service delivery system. On July 1, 2019, adult residential services and peer recovery support services were 'carved-in' to contracts with the three Medicaid Managed Care Organizations (MCOs) operating in WV. The MCOs are now responsible for providing necessary authorizations as well as paying claims for these services.

Figure 1. Demonstration Timeline



Population Groups Impacted by the Demonstration

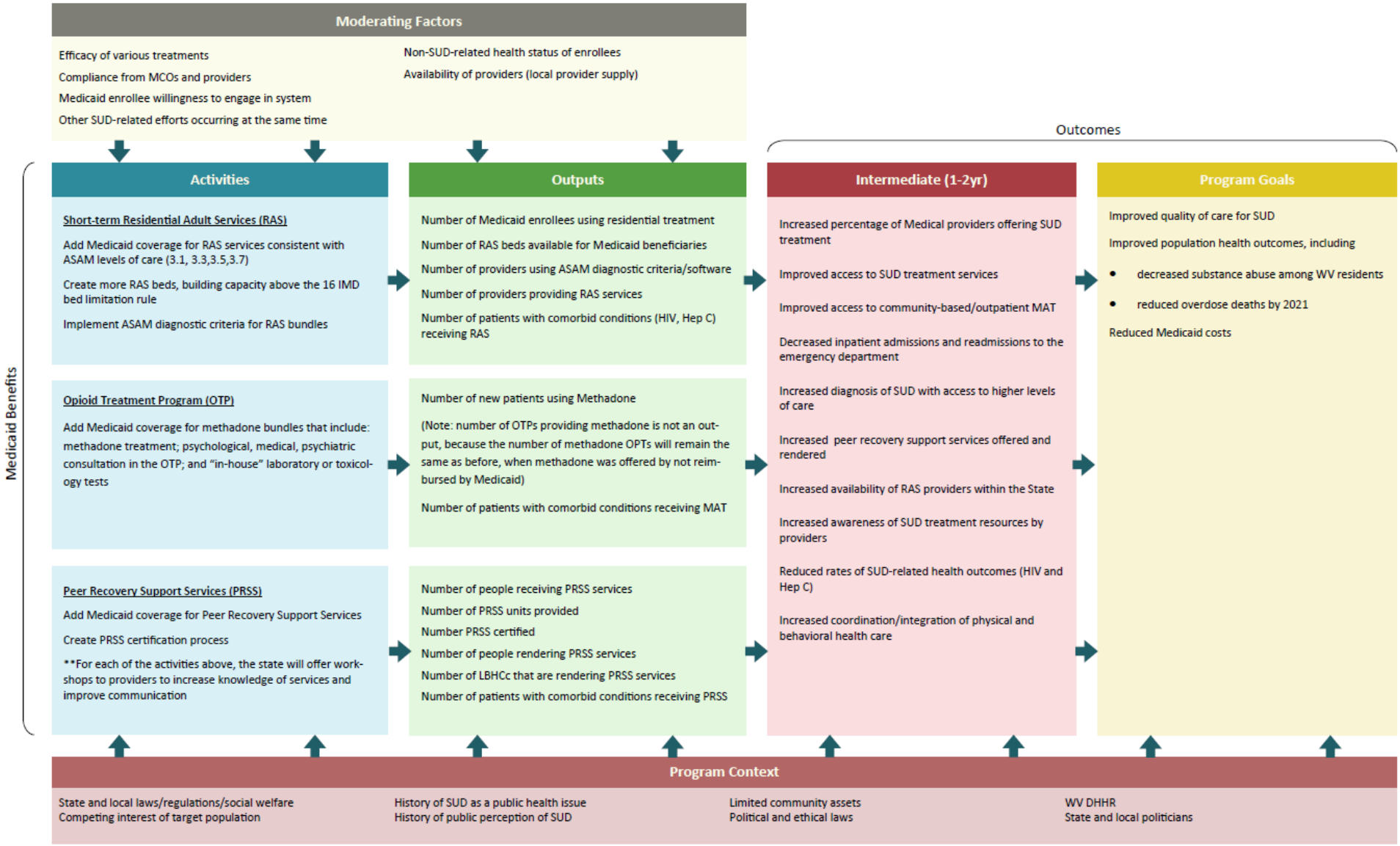
This demonstration is intended to impact West Virginia residents with SUD who are enrolled in Medicaid. In particular, the policy will target those who need services meeting ASAM levels of care 3.1-3.7, and those who were previously unable to afford methadone or PRSS services.

B. Evaluation Questions and Hypotheses

Logic Model

The following logic model is submitted in lieu of a driver diagram, with permission from CMS. A logic model is a visual tool that is used in project planning and evaluation to identify, record, and visualize the relationships between daily program activities and their outputs. Logic models often outline a projects inputs (such as funding), activities (what is done), outputs (result of an activity), and their impact toward change (outcomes such as initial, intermediate, and long-term).

Figure 2. Demonstration Logic Model



Questions and Hypotheses

The demonstration's core evaluation questions, hypotheses, data sources, and analytic approaches are provided in **Table 1.** As part of the evaluation design process, the WVU Evaluation Team worked with WV BMS to create a series of evaluation questions. These questions are directly based on the four stated goals outlined in the waiver special terms and conditions (presented on Page 2). For each evaluation question, the team developed hypotheses about the impact of the waiver, informed by state partners and evidence from clinical providers and the peer-reviewed literature. Each overarching state goal was developed into two to three research questions. Each research question has between two and five associated hypotheses. The bulk of these hypotheses are outcomes-based although there may be some overlap with process evaluation within a few. Outcomes include quality of care, population health changes, access to care, service utilization, and costs. There is also a fourth goal with hypotheses revolving around care coordination and transitions between levels and types of care. We feel these research questions represent a way to capture all the major outcomes we would predict to be associated with WV's Waiver. They are tied directly to the state goals in the waiver evaluation and also allow us to assess the possibility of some spill-over effects of increased treatment options (i.e. reduced ED Utilization).

We used the measure sets suggested by CMS to operationalize our metrics. When a CMS recommended measure set did not exist for our outcome, we looked for measure specifications from other nationally recognized data stewards (e.g. National Quality Forum). The denominators for certain measures – as defined by the data stewards – in **Table 1** specify the population of interest as "all Medicaid beneficiaries." However, we are limiting the denominator for each of these measures to include only Medicaid beneficiaries with SUD. Claims with a diagnosis code (any diagnosis on the claim) listed under one the following HEDIS 2019 Value Sets denotes an SUD diagnosis: (1) Alcohol Abuse and Dependence, (2) Opioid Abuse and Dependence, and (3) Other Drug Abuse and Dependence.

Table 1. Evaluation Design Table

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
Demonstration Goal 1: Improve quality of care and population health outcomes for Medicaid enrollees with SUD.						
Evaluation Question 1.1: What is the impact of the demonstration on quality of care for Medicaid enrollees?						
Evaluation Hypothesis 1.1.1: The demonstration will improve the quality of SUD services delivered to Medicaid enrollees.						
Intermediate Outcome	Initiation of alcohol and other drug (AOD) dependence treatment	2019 Medicaid Adult Core Set, NQF #0004	Initiation: Percentage of beneficiaries who initiated treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or medication treatment within 14 days of the diagnosis. If the Index Episode was an inpatient discharge (or an ED/observation visit that resulted in an inpatient stay), the inpatient stay is considered initiation of treatment and the beneficiary is compliant. If the Index Episode was not an inpatient discharge, the beneficiary must initiate the treatment on the start date of the Index Episode or in the 13 days after the Index Episode (14 total days). Any of the following code combinations meet criteria for initiation: • An acute or nonacute inpatient admission with a diagnosis matching the IESD diagnosis cohort using one of the following: Alcohol Abuse and Dependence Value Set, Opioid Abuse and Dependence Value Set, Other Drug Abuse and Dependence Value Set. To identify acute and nonacute inpatient admissions: 1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).	Beneficiaries who were diagnosed with a new episode of alcohol or drug dependency during the first 10 and ½ months (January 1 – November 14) of the measurement year •The total AOD abuse or dependence rate is not a sum of the diagnosis cohorts. Count beneficiaries in the total denominator rate if they had at least one alcohol, opioid, or other drug abuse or dependence diagnosis during the measurement period. Report beneficiaries with multiple diagnoses on the Index Episode claim only once for the total rate for the denominator. • Exclude beneficiaries from the denominator for both rates (initiation of AOD treatment and engagement of AOD treatment) if the initiation of treatment event is an inpatient stay with a discharge date after November 27 of the measurement year. • Beneficiaries in hospice are excluded from the eligible population.	Medicaid Claims	Difference-in-differences

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
			2. Identify the admission date for the stay. • IET Stand Alone Visits Value Set with a diagnosis matching the IESD diagnosis cohort using one of the following: Alcohol Abuse and Dependence Value Set, Opioid Abuse and Dependence Value Set, Other Drug Abuse and Dependence Value Set, with or without a telehealth modifier (Telehealth Modifier Value Set) • Observation Value Set with a diagnosis matching the IESD diagnosis cohort using one of the following: Alcohol Abuse and Dependence Value Set, Opioid Abuse and Dependence Value Set, Other Drug Abuse and Dependence Value Set • IET Visits Group 1 Value Set with IET POS Group 1 Value Set and a diagnosis matching the IESD diagnosis cohort using one of the following: Alcohol Abuse and Dependence Value Set, Opioid Abuse and Dependence Value Set, Other Drug Abuse and Dependence Value Set with or without a telehealth modifier (Telehealth Modifier Value Set) • IET Visits Group 2 Value Set with IET POS Group 2 Value Set and a diagnosis matching the IESD diagnosis cohort using one of the following: Alcohol Abuse and Dependence Value Set, Opioid Abuse and Dependence Value Set, Other Drug Abuse and Dependence Value Set with or without a telehealth modifier (Telehealth Modifier Value Set)A telephone visit (Telephone Visits Value Set) with a diagnosis			

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
			matching the IESD diagnosis cohort using one of the following: Alcohol Abuse and Dependence Value Set, Opioid Abuse and Dependence Value Set, Other Drug Abuse and Dependence Value Set • An online assessment (Online Assessments Value Set) with a diagnosis matching the IESD diagnosis cohort using one of the following: Alcohol Abuse and Dependence Value Set, Opioid Abuse and Dependence Value Set, Other Drug Abuse and Dependence Value Set • If the Index Episode was for a diagnosis of alcohol abuse or dependence (Alcohol Abuse and Dependence Value Set) a medication treatment dispensing event (Medication Treatment for Alcohol Abuse or Dependence Medications List, see link to Medication List Directory in Guidance for Reporting above) or medication treatment during a visit (AOD Medication Treatment Value Set) • If the Index Episode was for a diagnosis of opioid abuse or dependence (Opioid Abuse and Dependence Value Set) a medication treatment dispensing event (Medication Treatment for Opioid Abuse or Dependence Medications List, see link to Medication List Directory in Guidance for Reporting above) or medication treatment during a visit (AOD Medication Treatment Value Set)			
Intermediate Outcome	Engagement of alcohol and other	2019 Medicaid Adult Core Set, NQF #0004	Engagement: Percentage of beneficiaries who initiated treatment and who had two or	Beneficiaries who were diagnosed with a new episode of alcohol or drug	Medicaid Claims	Difference-in-differences

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
	drug dependence treatment		more additional AOD services or medication treatment within 34 days of the initiation visit. Step 1. Identify all beneficiaries compliant for the Initiation of AOD Treatment numerator. For beneficiaries who initiated treatment via an inpatient admission, the 34-day period for the two engagement visits begins the day after discharge. Step 2. Identify beneficiaries whose initiation of AOD treatment was a medication treatment event (AOD Medication Treatment Value Set; Medication Treatment for Alcohol Abuse or Dependence Medications List; Medication Treatment for Opioid Abuse or Dependence Medications List). These beneficiaries are numerator compliant if they have two or more engagement events where only one can be an engagement medication treatment event. Step 3.Identify the remaining beneficiaries whose initiation of AOD treatment was not a medication treatment event (beneficiaries not identified in step 2). These beneficiaries are numerator compliant if they meet either of the following: • At least two engagement visits • At least one engagement medication treatment event Two engagement visits can be on the same date of service but they must be with different providers in order to count as two events. An engagement visit on the same date of service as an engagement medication treatment event meets	dependency during the first 10 and ½ months (January 1 – November 14) of the measurement year •The total AOD abuse or dependence rate is not a sum of the diagnosis cohorts. Count beneficiaries in the total denominator rate if they had at least one alcohol, opioid, or other drug abuse or dependence diagnosis during the measurement period. Report beneficiaries with multiple diagnoses on the Index Episode claim only once for the total rate for the denominator. • Exclude beneficiaries from the denominator for both rates (initiation of AOD treatment and engagement of AOD treatment) if the initiation of treatment event is an inpatient stay with a discharge date after November 27 of the measurement year. • Beneficiaries in hospice are excluded from the eligible population.		

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
			criteria (there is no requirement that they be with different providers). Any of the following meet criteria for an engagement visit: • An acute or nonacute inpatient admission with a diagnosis matching the IESD diagnosis cohort using one of the following: Alcohol Abuse and Dependence Value Set, Opioid Abuse and Dependence Value Set, Other Drug Abuse and Dependence Value Set. To identify acute and nonacute inpatient admissions: 1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set). 2. Identify the admission date for the stay. • IET Stand Alone Visits Value Set with a diagnosis matching the IESD diagnosis cohort using one of the following: Alcohol Abuse and Dependence Value Set, Opioid Abuse and Dependence Value Set, Other Drug Abuse and Dependence Value Set, with or without a telehealth modifier (Telehealth Modifier Value Set) • Observation Value Set with a diagnosis matching the IESD diagnosis cohort using one of the following: Alcohol Abuse and Dependence Value Set, Opioid Abuse and Dependence Value Set, Other Drug Abuse and Dependence Value Set • IET Visits Group 1 Value Set with IET POS Group 1 Value Set with a diagnosis matching the IESD diagnosis cohort using one of the following: Alcohol Abuse and Dependence Value Set, Opioid			

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
			Abuse and Dependence Value Set, Other Drug Abuse and Dependence Value Set, with or without a telehealth modifier (Telehealth Modifier Value Set) • IET Visits Group 2 Value Set with IET POS Group 2 Value Set with a diagnosis matching the IESD diagnosis cohort using one of the following: Alcohol Abuse and Dependence Value Set, Opioid Abuse and Dependence Value Set, Other Drug Abuse and Dependence Value Set, with or without a telehealth modifier (Telehealth Modifier Value Set) • A telephone visit (Telephone Visits Value Set) with a diagnosis matching the IESD diagnosis cohort using one of the following: Alcohol Abuse and Dependence Value Set, Opioid Abuse and Dependence Value Set, Other Drug Abuse and Dependence Value Set • An online assessment (Online Assessments Value Set) with a diagnosis matching the IESD diagnosis cohort using one of the following: Alcohol Abuse and Dependence Value Set, Opioid Abuse and Dependence Value Set, Other Drug Abuse and Dependence Value Set Either of the following meets criteria for an engagement medication treatment event:• If the IESD diagnosis was a diagnosis of alcohol abuse or dependence (Alcohol Abuse and Dependence Value Set), one or more medication treatment dispensing events or medication treatment during a visit (AOD Medication Treatment Value Set),			

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
			beginning on the day after the initiation encounter through 34 days after the initiation event (total of 34 days), meets criteria for Alcohol Abuse and Dependence Treatment. • If the IESD diagnosis was a diagnosis of opioid abuse or dependence (Opioid Abuse and Dependence Value Set), one or more medication dispensing events (Medication Treatment for Opioid Abuse or Dependence Medications List) or medication treatment during a visit (AOD Medication Treatment Value Set), beginning on the day after the initiation encounter through 34 days after the initiation event (total of 34 days), meets criteria for Opioid Abuse and Dependence Treatment.			
Intermediate Outcome	Medication Assisted Treatment use	Mathematica Policy Research Technical Specifications for Monitoring Metrics	The number of unique beneficiaries (de-duplicated total) who have a claim for a MAT dispensing event for SUD during the measurement period Step 1. Identify claims with a code from the following HEDIS 2018 medications lists: • MAT for Alcohol Abuse or Dependence Medications List • MAT for Opioid Abuse or Dependence Medications List Step 2. Determine the total number of unique beneficiaries (de-duplicated) with claims that meet the criteria in Step 1.	All Medicaid beneficiaries enrolled for any amount of time during the measurement period	Medicaid claims	Difference-in-differences
Evaluation Hypothesis 1.1.2: The demonstration will increase provider knowledge of appropriate SUD treatment options.						
Activities	Provider knowledge		Degree to which focus group members (providers) demonstrate changes in ability to correctly		Focus group data	

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
			identify the expanded treatment mechanisms as a result of state-run trainings			
Evaluation Question 1.2: What is the impact of the demonstration on population health outcomes among Medicaid enrollees?						
Evaluation Hypothesis 1.2.1: The demonstration will decrease morbidity and mortality among Medicaid enrollees and their children.						
Program Goal	Mortality rate among beneficiaries with SUD		Number of all-cause deaths among beneficiaries diagnosed with SUD during the measurement period	All Medicaid beneficiaries with SUD, enrolled for any amount of time during the measurement period	Medicaid claims data supplemented with Death certificate data	Difference-in-differences Interrupted time series for death certificate data
Program Goal	Drug-related mortality (due to any drug and also due to opioids alone)	Mathematica Policy Research Technical Specifications for Monitoring Metrics	Number of drug poisoning deaths during the measurement period among Medicaid beneficiaries. As recommended by Mathematica, we will report the cause of overdose death as specifically as possible using underlying and contributing cause of death codes where available (for example, prescription vs. illicit opioid) Identify beneficiaries with the following ICD-10 underlying cause of death codes: • X40 – X44 (unintentional drug poisonings) • X60-X64 (suicidal drug poisonings) • X85 (homicide drug poisoning) • Y10-Y14 (drug poisoning of undetermined intent) Opioid-related drug overdoses can be reported separately as follows: Among all drug poisoning deaths identify those with the following ICD-10 contributing cause of death codes:: • T40.1 (heroin) • T40.2 (natural and semisynthetic opioids) • T40.3 (methadone)	Beneficiaries enrolled in Medicaid for at least one month (30 consecutive days) during the measurement period.	Medicaid claims data, supplemented with vital statistics mortality data, which contain underlying and contributing cause of death codes. Prior to 2018 these data only include underlying cause of death codes. For all deaths occurring after 1/1/18, these data include both underlying and contributing cause of death codes	Difference-in-differences Interrupted time series for death certificate data

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
			• T40.4 (synthetic opioids other than methadone)"			
Program Goal	Medicaid Beneficiaries with SUD Diagnosis (monthly and annually)	Mathematica Policy Research Technical Specifications for Monitoring Metrics	The number of unique beneficiaries (de-duplicated total) enrolled in the measurement period who receive MAT or have qualifying facility, or professional claims with a SUD diagnosis and a SUD-related treatment during the measurement period and/or in the 11 months before the measurement period Step 1. Identify claims for MAT, defined in one of the following HEDIS 2018 IET value sets or medications lists: • Medication Assisted Treatment Value Set • MAT for Alcohol Abuse or Dependence Medications List • MAT for Opioid Abuse or Dependence Medications List Step 2. Identify claims with a diagnosis code (any diagnosis on the claim) listed under one of the following HEDIS 2018 Value Sets: • Alcohol Abuse and Dependence • Opioid Abuse and Dependence • Other Drug Abuse and Dependence In addition to a diagnosis code above, the claim must also have a procedure code from any of the following HEDIS 2018 IET value set for identifying SUD treatment: • IET Stand Alone Visits • IET Visits Group 1 with IET POS Group 1 • IET Visits Group 2 with IET POS Group 2 • Detoxification • ED	All Medicaid beneficiaries enrolled for any amount of time during the measurement period	Medicaid claims	Difference-in-differences

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
			• Inpatient Stay • Telephone Visits • Online Assessments Step 3. Determine the total number of unique beneficiaries (de-duplicated) with claims that meet the criteria in Step 1 or Step 2.			
Program Goal	Neonatal abstinence syndrome morbidity		Number of infants meeting NAS criteria, born to Medicaid enrollees during measurement period	Infants born to Medicaid enrollees during the measurement period	Medicaid claims WV Birth Score Data	Difference-in-differences
Program Goal	HIV morbidity		Number of Medicaid enrollees with a diagnosis of HIV during the measurement period	All Medicaid beneficiaries enrolled for any amount of time during the measurement period	Medicaid claims	Difference-in-differences
Program Goal	Hepatitis C morbidity		Number of Medicaid enrollees with a diagnosis of Hepatitis C during the measurement period	All Medicaid beneficiaries enrolled for any amount of time during the measurement period	Medicaid claims	Difference-in-differences
Demonstration Goal 2: Increase enrollee access to and use of appropriate SUD treatment services based on the ASAM Criteria..						
Evaluation Question 2.1: What is the impact of the demonstration on access to SUD treatment among Medicaid enrollees?						
Evaluation Hypothesis 2.1.1: The demonstration will increase the supply of residential, MAT, and PRSS care available for Medicaid enrollees.						
Output	Supply of SUD providers	N/A	Providers who were enrolled in Medicaid and delivered SUD treatment services during the measurement period. This will be calculated as the count of distinct providers who either prescribed MAT or delivered behavioral health treatment services with a primary diagnosis of SUD listed on the professional claim	Total number of providers enrolled with Medicaid during the measurement period	Medicaid claims and provider enrollment data	Interrupted time series
Output	Supply of SUD residential treatment facilities	N/A	Number of residential SUD treatment facilities that have been credentialed to deliver services consistent with ASAM Levels 3.1, 3.5, and/or 3.7		Monthly internal reports submitted to the Bureau for Medical Services	Interrupted time series
Output	Supply of SUD residential treatment beds	N/A	Number of residential SUD treatment beds that have been certified as delivering care consistent with ASAM Levels 3.1, 3.5, and/or 3.7		Monthly internal reports submitted to the Bureau for Medical Services	Interrupted time series

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
Intermediate Outcome	Buprenorphine prescriber availability		The total number of Medicaid enrolled providers who have a DEA x-license and have also been approved by BMS to prescribe buprenorphine	N/A	BMS approved buprenorphine prescriber list	Interrupted time series
Output	Peer recovery support specialist availability		Percentage of peer recovery coaches that are certified through a West Virginia Department of Health and Human Resources-approved training program that provides peer support providers with a basic set of competencies necessary to perform the peer support function.		Monthly internal reports submitted to BMS	Interrupted time series
Evaluation Question 2.2: What is the impact of the demonstration on use of SUD treatment among Medicaid enrollees?						
Evaluation Hypothesis 2.2.1: The demonstration will increase the use of residential, MAT, and PRSS care available by Medicaid enrollees.						
Intermediate Outcome	Outpatient services for SUD treatment	Measure Set/Endorsement: Mathematica Policy Research Technical Specifications for Monitoring Metrics	The number of unique beneficiaries (de-duplicated total) with a service or pharmacy claim for outpatient services for SUD (such as outpatient counseling or motivational enhancement therapies, step-down care, and monitoring for stable patients) during the measurement period Step 1. Identify claims with a diagnosis code (any diagnosis on the claim) listed under one of the following HEDIS 2018 Value Sets: • Alcohol Abuse and Dependence • Opioid Abuse and Dependence • Other Drug Abuse and Dependence Step 2. Retain claims with a procedure code from any of the following IAD HEDIS 2018 Value Sets: • IAD Stand-Alone Outpatient Value Set • Observation Value Set • BH Visit Setting Unspecified Value Set with a corresponding			Difference-in-differences

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
			code from Outpatient POS Value Set • BH Visit Setting Unspecified Value Set with a corresponding code from POS 53 Value Set o States should ensure that the visit was in an outpatient setting • Note: be sure to include any of the above services billed with a code from the Telehealth Modifier Value Set. Step 3. Exclude any claims with a code in the Detoxification HEDIS 2018 Value Set. Step 4. Determine the total number of unique beneficiaries (de-duplicated) with claims that meet the criteria in Steps 1, 2 and 3.			
Intermediate Outcome	Residential services for SUD treatment	N/A	The total number of unique beneficiaries (de-duplicated total) who receive residential treatment services consistent with ASAM Levels 3.1, 3.5, and/or 3.7 Step 1. Identify claims for residential treatment using CPT codes: • H2036 U1 HF : ASAM Level 3.1 residential services • H2036 U5 HF : ASAM Level 3.5 residential services • H2036 U7 HF : ASAM Level 3.7 residential services Step 2. Determine the total number of unique beneficiaries (de-duplicated) with claims that meet the criteria in Steps 1.	All Medicaid beneficiaries enrolled for any amount of time during the measurement period	Medicaid Claims	Difference-in-differences

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
Intermediate Outcome	Methadone use among beneficiaries with OUD (Adapted from "Use of pharmacotherapy for opioid use disorder (OUD)")	NQF #3400 (Steward: CMS)	Beneficiaries ages 18 to 64 with an OUD who filled a prescription for or were administered or ordered a methadone prescription for the disorder during the measure year.	Number of Medicaid beneficiaries with at least one encounter with a diagnosis of opioid abuse, dependence, or remission (primary or other) at any time during the measurement year.	Medicaid claims	Difference-in-differences
Output	Peer recovery support specialist use		Number of Medicaid enrollees with SUD diagnosis (appropriate for peer recovery treatment) receiving peer recovery treatment	Number of Medicaid enrollees with SUD diagnosis (appropriate for peer recovery treatment)	Medicaid Claims	Time series
Demonstration Goal 3: Decrease emergency department and hospital services by enrollees with SUD.						
Evaluation Question 3.1: What is the impact of the demonstration on emergency department (ED) utilization by Medicaid enrollees with SUD?						
Evaluation Hypothesis 3.1.1: The demonstration will decrease the rate of ED use and the percentage of ED visits that are non-emergent among Medicaid enrollees with SUD.						
Intermediate Outcome	All-cause ED use among beneficiaries with SUD	Adapted from Mathematica Policy Research Technical Specifications for Monitoring Metrics, Metric #23	Number of ED visits among beneficiaries with SUD during the measurement period Step 1. Identify all claims for ED visits during the measurement period using the HEDIS 2018 ED Value Set. Count each visit to an ED once, regardless of the intensity or duration of the visit. Step 2. Identify the date of service for each visit identified in Step 1. Retain only visits with dates of service that fall within the measurement period. Count multiple ED visits on the same date of service as one visit.	All Medicaid beneficiaries enrolled for any amount of time during the measurement period	Medicaid claims	Difference-in-differences
Intermediate Outcome	ED Utilization for SUD per 1,000 Medicaid Beneficiaries	Measure Set/Endorsement: Mathematica Policy Research Technical Specifications for Monitoring Metrics	The number of ED visits for SUD during the measurement period Step 1. Identify all claims for ED visits during the measurement period using the HEDIS 2018 ED Value Set. Count each visit to an ED once, regardless of the intensity or duration of the visit.	Beneficiaries enrolled in Medicaid for at least one month (30 consecutive days) during the measurement period.	Medicaid claims	Difference-in-differences

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
			Step 2. Identify the date of service for each visit identified in Step 1. Retain only visits with dates of service that fall within the measurement period. Count multiple ED visits on the same date of service as one visit. Step 3. Identify the subset of claims with a diagnosis code (any diagnosis on the claim) listed under one of the following HEDIS 2018 Value Sets: • Alcohol Abuse and Dependence • Opioid Abuse and Dependence • Other Drug Abuse and Dependence Step 4. Calculate the number of visits using all visits identified in Steps 1, 2 and 3.			
Intermediate Outcome	Non-SUD non-emergent ED use	NYU ED Algorithm	Percentage of ED visits classified as non-emergent using the NYU ED Algorithm. The algorithm reports a percentage of total visits. Note: Because all drug and alcohol visits are carved out from the algorithm, we are only able to measure non-drug related ED visits.	Because the algorithm reports a percentage of total visits, we do not include a denominator here. Instead, we highlight our population of interest, on whose claims we will run the algorithm: all Medicaid beneficiaries enrolled for any amount of time during the measurement period	Medicaid claims	Difference-in-differences
Evaluation Question 3.2: What is the impact of the demonstration on inpatient hospital use by Medicaid enrollees with SUD?						
Evaluation Hypothesis 3.2.1: The demonstration will decrease hospital admissions among Medicaid enrollees with SUD.						
Intermediate Outcome	Inpatient stays for SUD	Mathematica Policy Research Technical Specifications for Monitoring Metrics	Number of inpatient hospital stays among Medicaid enrollees with SUD during the measurement period Step 1. Identify all inpatient stays (acute and nonacute) during the measurement period using the HEDIS 2018 Inpatient Stay Value Set.	All Medicaid beneficiaries enrolled for any amount of time during the measurement period		Difference-in-differences

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
			Step 2. Identify the discharge date for the stay. Retain only stays with discharge dates that fall within the measurement period.			
Demonstration Goal 4: Improve care coordination and care transitions for Medicaid enrollees with SUD						
Evaluation Question 4.1: What is the impact of the demonstration on the integration of physical and behavioral health care among Medicaid enrollees with SUD and comorbid conditions?						
Evaluation Hypothesis 4.1.1: The demonstration will increase the rate of Medicaid enrollees with SUD-related physical health conditions who are also receiving behavioral care.						
Output	Separate analyses for each of the following measures, as defined above: Medication Assisted Treatment Initiation of Alcohol and Other Drug Treatment Engagement of Alcohol and Other Drug Treatment	See above	See above	Medicaid enrollees with SUD diagnosis and co-morbid hepatitis C	Medicaid Claims	Difference-in-differences analysis
Output	Separate analyses for each of the following measures, as defined above: Medication Assisted Treatment Initiation of Alcohol and Other Drug Treatment	See above	See above	Medicaid enrollees with SUD diagnosis and co-morbid HIV	Medicaid Claims	Difference-in-differences analysis

Logic Model Component	Measure Description	Steward	Numerator	Denominator	Data Source	Analytic Approach
	Engagement of Alcohol and Other Drug Treatment					
Evaluation Question 4.2: What is the impact of the demonstration on care transitions among Medicaid enrollees with SUD?						
Evaluation Hypothesis 4.2.1: The demonstration will improve communication among providers who transition patients to other providers.						
Activities	Communication among providers		Degree to which focus group members (providers) express in levels of communication difficulties with other providers.		Focus group data	

C. Methodology

1. Evaluation design

In 2018, the Government Accountability Office (GAO) released a comprehensive report examining state efforts to evaluate Medicaid waivers. The report had three major findings; 1) CMS should require a final report after the conclusion of waiver implementation, 2) CMS should issue criteria for when it will allow limited evaluations, and 3) CMS should establish policies for publicly releasing evaluation data. Some of these recommendations are driven by the limited data available for evaluation, lack of comparison populations, and the inability of evaluators to actually capture change in measures key to demonstrating waiver impacts such as costs and services provided. Our evaluation team has undertaken considerable effort to incorporate the findings of this report, develop a strong comparison strategy, and define and capture data on all the key elements of WV's waiver application.

West Virginia University is committed to conducting a scientifically rigorous evaluation of the waiver. Of particular importance is isolating the effects of the demonstration from those of other programs and services that are taking place throughout the state during the same time period. To achieve this, the evaluation team has incorporated the use of appropriate comparison groups into its analytic plan.

Our evaluation design consists of four main components, each of which are described in detail under the Analytic Methods section, below. The primary design of the evaluation is a *difference-in-differences approach*, using a comparator state (State A), which did not implement an 1115 Waiver over the course of the study period, as a control group. The difference-in-differences technique is an accepted way to mimic an experimental research design, in the absence of the ability to implement a true experimental design.

2. Target and Comparison Populations

One potential limitation to our difference-in-differences analysis is the possibility that there are policies being implemented in State A over our study period that – if not also implemented in WV at the same time (or vice versa) – might bias our estimates. To determine whether this is likely, we conducted a comprehensive, comparative policy landscape scan for WV and State A. In particular, we used State A's internet database to search archives of the general legislative sessions for opioid-related policies. We identified policies that would influence our evaluation outcomes, but which were not also enacted in WV. We focused on policies enacted from the 2015 legislative session onward, because we began our baseline data collection in 2015. We sent State A's policies to members of WV's Board of Pharmacy, Bureau for Behavioral Health and other key stakeholders (including legal counsel) within the Department of Health and Human Resources to determine whether and when similar policies were implemented in WV. We then assessed whether the policies could potentially introduce bias into our results; if so, we assessed the likely direction of the bias (i.e., toward or away from the null).

Upon review, we concluded that there was only one policy implemented in State A during the study period that was not concomitantly implemented in WV. To protect the identity of our comparator state, we focus here on the population that would be particularly impacted by this policy, and do not describe in detail the policies themselves. Because only one key subpopulation (not the entire state) is going to be influenced by the policy, we are able to empirically test for their effect by rerunning our analyses excluding these populations.

The key population of interest is *women of reproductive age and, by extension, babies born to women of reproductive age.* State A passed a specific policy to provide additional information to women of reproductive age and their children who were at risk for NAS or whose children were born with NAS. This subpopulation is particularly important, given the high rates of NAS in WV and the large role that Medicaid plays in health care delivery for pregnant women. Because State A is targeting a change in this population in particular, it could bias our results toward the null, suggesting that our waiver does not have an impact on this age group when it actually does. We do not expect this to be the case because the policy is informational only, but do want to take special precautions because of the importance of this subgroup. We will triangulate the impact of our waiver on this group using instate analyses that take advantage of a unique data source housed at WVU.

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The Birth Score Project (aka Project WATCH) is a state mandated surveillance tool that gathers data on several maternal and infant characteristics including health insurance coverage data. In October 2016, Project WATCH collaborated with The West Virginia Perinatal Partnership and the WV Department of Health and Human Resources to expand its surveillance tool to include real- time information on diagnosis of NAS at the time of infant discharge from the hospital. Because the Birth Score data include insurance status of all mothers (not just those in Medicaid), we are able to perform *another difference-in-differences analysis, using the privately insured population in WV as a control group* unaffected by Medicaid coverage expansion. Specifically, we will look at the impact of the waiver on the probability of a baby being born with NAS.

It should be noted that our policy scan also revealed that one State A policy provides a non-traditional care setting in which *school age children* can receive treatment and prevention services. WV does not have a similar program in place. Therefore, we might expect our results to be biased toward the null, suggesting that our waiver does not have an impact on this age group when it actually does. However, our WV state partners do not anticipate that the demonstration project will directly influence many children of school age, because the main overlap in populations affected by both high school and the waiver are 18-19 year olds who are still in school, which represents a very small fraction of the entire Medicaid population. For this reason, we will not be conducting additional analyses on this subpopulation. We will, however, run models that exclude this group, to see if our estimate change meaningfully.

In addition to the policy scan we undertook, we also compared pre-trends between WV and State A, to assess whether State A is an appropriate comparison group. The National Survey of Substance Abuse Treatment Services (N-SSATS) conducted by the Substance Abuse and

Mental Health Services Administration (SAMHSA) was used to assess the congruency between State A and West Virginia according to selected SUD specific pre-trends of interest. The N-SSATS collects data on alcohol and drug abuse and treatment facilities, both public and private, in all 50 states, the District of Columbia, and other US jurisdictions. Specific variables include location, organization, structure, services, and utilization. The N-SSATS also has questions that assess whether or not a facility provides services that are congruent with specific ASAM levels of care.

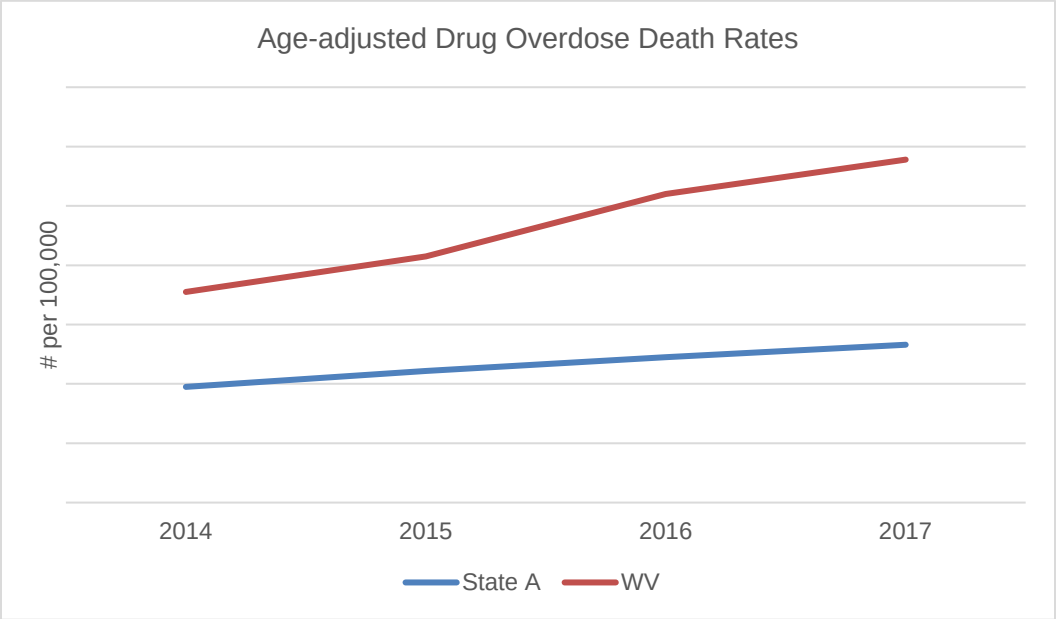
In assessing the congruency of State A with West Virginia, the N-SSATS was analyzed to denote similarities in SUD services provided by facilities that accept Medicaid payments. No statistically significant differences ($p > 0.05$) between State A and West Virginia were observed in the following SUD specific variables between 2014 and 2017:

Table 2. Measures Assessed to Determine Appropriateness of State A as a Comparison Group

Measure	N-SSATS Survey Question	Years
OTPALL	Are ALL of the substance abuse clients at this facility currently receiving methadone or buprenorphine?	2014-2016 *Question not asked in 2017
OPIOIDNAL	Relapse prevention w/ naltrexone	2015-2017 *Question introduced in 2015
OPIOIDDETOX	Detoxification services with methadone or burprenorphine	2015-2017 *Question introduced in 2015
OPIOIDWDRAW	Maintenance services with medically supervised withdrawal after pre-determined time	2015,2017 *Question introduced in 2015

All of the publicly available data sets considered do not allow stratification by primary payer, and thus precluded the ability to obtain estimates of overdose deaths among Medicaid recipients between State A and West Virginia. However, an examination of the CDC/NCHS, National Vital Statistics System, revealed that the age-adjusted rates of opioid overdose deaths were similar (and increasing) between State A and West Virginia between 2014 and 2017. We have not included a scale to protect the identity of State A.

Figure 3. Pretrends in Outcomes among State A and WV



An important condition of using State A's data is that the State's identity will remain anonymous in any CMS- or public-facing documents. Yet, at the same time, it is critical that CMS and readers of any public-facing documents be aware of any policies that might potentially bias our results. Therefore, we have worked with State A to draft prose and sample descriptive statistics tables that will describe the content of these policies without explicitly making clear which state is State A. These descriptions will provide readers with adequate context for our study, while still allowing State A to remain anonymous. The amount of detail disclosed above (regarding women of reproductive age and school age children) has been approved by both CMS and State A as satisfactory to meet these goals. Additionally, the level of detail in the following table has been approved by both entities (cells filled with XX will be filled in with actual data as the project progresses):

Table 3. Sample Summary Statistics for State A and WV

	West Virginia	State A	p-value
Population	1,787,126	4-9M	XX
Percent of population with Medicaid	27.9%	20-25%	XX
Sex			
Male	49.4%	48-49%	XX
Female	50.6%	51-52%	XX
Age			
0-9 years	XX		
10-19	XX	13.0%	XX
20-34 years	XX	20.0%	XX
35 to 44 years	XX	13.0%	XX
45 to 54 years	XX	13.0 %	XX
55 to 64 years	XX	15.0%	XX
65 to 74 years	XX	10.0%	XX
75 and over	XX	6.0%	XX
Race			
White	92.8%	75-85%	XX
Black	4.0%	10-20%	XX
Asian	0.8%	<10%	XX
Education			
Less than high school diploma	12.9%	<15%	XX
High school graduate (includes equivalency)	41.2%	30-35%	XX
Some college or associate's degree	25.7%	25-30%	XX
Bachelor's degree	12.2%	15-20%	XX
Graduate or professional degree	8.0%	10-15%	XX
Median Household Income	$43,469	$45-55,000	XX

** Note: To protect the anonymity of State A, we offer a range of values for each summary statistic. For the age variable, numbers are rounded to the nearest whole percentage. The P-values represent the statistical difference between the actual mean value (not a range) and WV's mean values.

3. Evaluation Period

The demonstration project began implementation in January 2018 and is scheduled to run through 2022. These years will represent the post-treatment period for the evaluation. In most cases, the pre-treatment period will begin in 2015, so that the results are not impacted by the Medicaid expansion that occurred in WV between 2013 and 2014. One exception is the NAS analyses. Because the NAS Birth Score data were not collected prior to 2017, our pre-demonstration period will begin then. The evaluation team does not expect lag between the beginning of implementation and the approval of a final evaluation design to be a major challenge as the bulk of our analysis relies on administrative claims data and other sources that are already being collected.

4. Data sources

The primary data source for this evaluation will be administrative Medicaid claims data, which are readily available to the evaluation team. Data access is facilitated by an existing Memorandum of

Understanding (MOU) between the WVU School of Public Health (SPH) and the WV DHHR. Pursuant to this MOU, WVU School of Public Health has employees embedded within the Medicaid agency who perform data analytics, program evaluation, and other policy research as directed by Medicaid leadership. In exchange, WVU SPH has access to de-identified Medicaid claims data that are stored on a Virtual Private Network (VPN) operated by WVU SPH. The WVU SPH embedded analysts regularly pull extracts of Medicaid claims data from the BMS Data Warehouse in order to update the claims data stored on the WVU SPH VPN. Data access, analyses, and evaluation efforts are discussed at monthly BMS-hosted data stewardship committee meetings. The limited data set currently includes all eligibility, authorization, pharmaceutical, facility, and professional claims, as well as provider-level reference data from January 2009 to December 2018. Medicaid providers in WV have up to one year following the date of service to submit claims to BMS, which leads to some lag in claims data availability. However, our previous experience using these data suggests that the lag is limited to approximately 6 months following the date of service.

This evaluation is interested in assessing the impact of the waiver on both all-cause and drug-related mortality among the WV Medicaid population. However, neither dates, nor cause of death, are routinely collected in Medicaid claims data. Hence, we will analyze these outcomes using mortality data that have been previously linked to WV Medicaid claims data. The Health Statistics Center within WV DHHR maintains a mortality database that includes death certificate data for all decedents in WV. These data include both date of death, as well as underlying and contributing cause of death codes. These data were recently incorporated into the BMS Data Warehouse and were linked to existing Medicaid enrollment data through an initiative organized by the CMS Innovation Accelerator Program. The data linkage was performed by the BMS Data Warehouse vendor—IBM / Truven—and is based on a probabilistic match on decedents' social security numbers, date of birth, and gender. These data are available to the WVU SPH evaluation team via the same aforementioned MOU between WVU SPH and WV DHHR.

While claims data provide a solid foundation for analysis, the evaluation team recognizes that effectively analyzing several important Waiver-related outcomes – especially those related to provider supply – will require additional data. Therefore, the evaluation team also plans to use data from publicly available data sets. The CMS Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set) and Core Set of Behavioral Health Measures for Medicaid and CHIP (Behavioral Health Core Set) contain behavioral health measures voluntarily reported by state Medicaid agencies. These datasets will be used to track visit follow-up after emergency department SUD related visits as well as opioid polysubstance use. The National Survey of Substance Abuse Treatment Services (N-SSATS), conducted via Substance Abuse and Mental Health Services Administration (SAMHSA) will be used to measure the number of residential facilities offering services that meet ASAM criteria. N-SSATS was specifically chosen as a data source due to the ability to limit analyses to facilities accepting Medicaid payments. The SAMSHA Treatment Episode Data Set (TEDS) will be used to assess the impact of the waiver on substance abuse treatment programs admissions and admission to facilities planning to administer medication assisted treatment. TEDS is a national data system that captures publicly funded (i.e., Medicaid) admissions to substance abuse treatment facilities. Similar to N-SSATS, it is possible

to focus the analyses to SUD encounters by Medicaid recipients to more directly assess the impact of the waiver on the intended population of interest. In contrast, several other nationally available data sets were considered but ultimately not included in the evaluation plan due to an inability to focus analyses on the Medicaid population. These include: the SAMSHA National Survey on Drug Use and Health (NSDUH), the SAMSHA Uniform Reporting System, the CDC Web-based Injury Statistics Query and Reporting System (WISQARS), and the CDC Wide-ranging ONline Data for Epidemiologic Research (WONDER).

Another important limitation in claims data is the availability of information on neonatal abstinence syndrome (NAS), which is historically problematic to diagnose given the subjective nature of symptom assessment coupled with a variety of available assessment tools. There are at least six commonly accepted tools that vary in content and length (7 to 21 items), relative strengths and weaknesses, and psychometric properties. Consequently, wide variability in both case assessment and case definition exists. This variability has likely contributed to an underreporting of NAS counts in commonly used data sources, including claims. To overcome these limitations and increase data reliability and validity, the state of West Virginia recently added NAS diagnosis to the Birth Score form that is completed on every infant born in West Virginia by state mandate. Routine training is offered for all providers assigning the score and quality checks are periodically implemented. The evaluation team will work with the WV Birth Score Program at WVU to obtain and analyze NAS data on WV Medicaid recipients to assess the impact of the Waiver on NAS Morbidity.

By nature, certain aspects of the evaluation exercise may require the collection of additional data that are outside of the predominantly standardized protocol (e.g., Medicaid claims). For example, qualitative data will be collected to assess outcomes that are unobtainable from other sources, such as those mentioned above. The details for qualitative data collection are outlined below, in our qualitative analysis section.

5. Analytic Methods

Difference-in-differences Design

Because a simple pre-post analysis of WV data would be subject to bias from non-waiver changes also occurring in the state, the evaluation team instead will compare the pre-post changes in WV outcomes to the pre-post changes in State A's outcomes, over the same time frame. This approach mitigates the effects of extraneous (non-waiver) factors and selection bias[4]. We follow the preferred difference-in-differences model outlined in the SUD Evaluation Guidance:

[4] For additional information the difference-in-differences technique, see the following: https://www.mailman.columbia.edu/research/population-health-methods/difference-difference-estimation

Outcome = β0 + β1*TIME + β2*POST + β3*(TIME*POST) + Bi* CONTROLS + ε

where:

TIME is a count variable that starts with the first month of pre-demonstration period data and ends with the last month of post-demonstration period data.

POST is the indicator variable that equals 1 if the month occurred on or after demonstration start date.

CONTROLS are covariates, such as age, gender, race, dual Medicare-Medicaid enrollment, and month.

Cost Analysis

Though costs will be analyzed within the same difference-in-differences framework described in the previous section, there are intricacies to analyzing costs that require additional explanation. Our plan for analyzing costs has been heavily informed by the SUD Evaluation Design guidance (Appendix C) provided by CMS (as part of the draft SMI/SED and SUD guidance).

WV's Medicaid services are delivered almost entirely through capitation agreements with MCOs. In some states, Medicaid encounter data do not include amounts that MCOs pay to providers for services rendered. We are fortunate in that BMS requires all MCOs to report actual amounts paid to providers for each encounter. We will use these net MCO payments, in addition to FFS payments (where appropriate) to calculate costs. Per CMS recommendations, we will be conducting a granular cost analysis using the following equation:

Total costs = inpatient + non-ED outpatient + ED outpatient + prescription + long-term care

This approach identifies cost drivers for the target population by splitting out costs associated with different types of care using claims data. As suggested by CMS, we will separate ED-related outpatient costs from other outpatient costs, given that ED services are particularly high-cost, and represent an important opportunity for cost savings that could be achieved with better access to SUD services.

We will not require minimum enrollment durations for beneficiaries to be included in the analysis. Beneficiaries will be included in the analysis during the first month in which a relevant SUD diagnosis or treatment claim was observed, and for up to 11 additional months that did not include a relevant diagnosis or treatment claim. Once an individual has period of 1 year with no relevant diagnosis or treatment claims, that beneficiary will be excluded from further analyses, unless and until they have a subsequent relevant diagnosis and/or treatment claim. This will ensure our analysis represents the costs of serving individuals in the target population with active treatment needs. All cost outcome measures will be expressed in terms of the recommended dollars per member per month.

Because some person-months will have $0 healthcare spending, and other months could have very large values, we will conduct two-part regression models. In particular, we will conduct a model that accounts for whether they are any costs in the person-month (logit model) and then

another model that accounts for the level of costs conditional on having non-zero costs (generalized linear model [GLM]). We will run separate models for each of the outcomes described in the equation above, including total costs. We will control for covariates including age, race, gender, dual eligibility status, and physical or behavior health comorbidities.

In addition to the analyses described above, we will calculate and trend average monthly spending, using the following template. We will also plot the means compiled in the tables below to show trends visually and verify that month-to-month variation is within expectations and does not indicate an underlying data error. If needed, we will conduct quarterly spending analyses to smooth out monthly variation in costs.

Table 4. Template for reporting unadjusted means of Medicaid cost estimates for individuals participating in the 1115 demonstration, by type of cost, period, and treatment/comparison group

		Pre-Demonstration		Post-Demonstration	
	Type of cost	Month 1	Month 2[a]	Month 1	Month 2 [a]
Treatment group costs					
Total costs	Total costs				
Type or source of care cost drivers	Outpatient costs – non-ED Outpatient costs – ED Inpatient costs Pharmacy costs Long-term care costs				
Comparison group costs					
Total costs	Total costs Total federal costs				
Type or source of care cost drivers	Outpatient costs – non-ED Outpatient costs – ED Inpatient costs Pharmacy costs Long-term care costs				

[a] Includes two pre-demonstration and post-demonstration months for illustrative purposes only. We will include at least one year of pre-demonstration and all post-demonstration data.

Table 5. Template for reporting adjusted cost outcomes: D-in-D regression results (present marginal effects and standard errors)

	Total costs	Total federal costs	Outpatient costs – non-ED	Outpatient costs – ED	Inpatient costs	Pharmacy costs	Long- term care costs
Logit							
Intervention group							
Demonstration period							
Treatment group * demonstration period							
Covariates							
Constant							
GLM							
Treatment group							
Demonstration period							
Treatment group * demonstration period							
Covariates							
Constant							

Within-state Analysis

We will undertake another methodological strategy to triangulate the results observed from the previous approaches. In particular, we will conduct a within-state analysis using an interrupted time-series design. This approach does not use State A as a comparison group, and therefore will be useful in cases where our difference-in-differences approach may yield biased results (as described above), or in cases where we can't use State A comparison claims data (e.g., for supply-related questions).

Our model will estimate different linear effects in the pre-demonstration and post-demonstration periods. We will report marginal effects and standard errors.

$$Costs = \beta 0 + \beta 1*TIME + \beta 2*POST + \beta 3*(TIME*POST) + Bi* CONTROLS + \varepsilon$$

where:

TIME is a count variable that starts with the first quarter of pre-demonstration period data and ends with the last quarter of post-demonstration period data.

POST is the indicator variable that equals 1 if the month occurred on or after demonstration start date.

CONTROLS are covariates, such as age, gender, race, dual Medicare-Medicaid enrollment, and month.

If the average marginal effect of the interaction term (β3*TIME*POST) is positive, then the outcomes in the post-demonstration period are statistically significantly higher than the outcomes in the pre-demonstration period, and vice versa. Importantly, ITS models without a comparison group cannot determine whether any observed changes are directly attributable to the demonstration itself, which is why we will interpret these results in conjunction with our causal findings from the difference-in-differences approach.

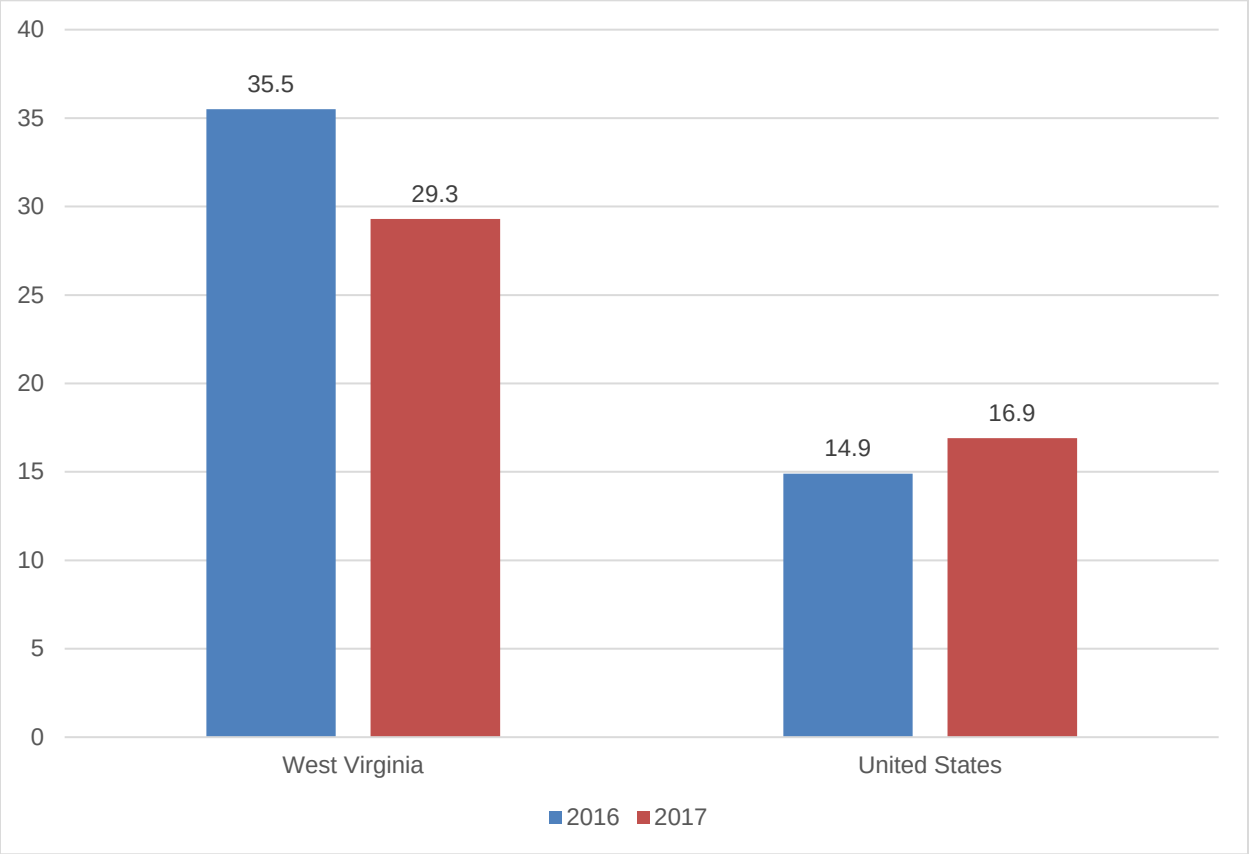
Benchmarking and State Trends Comparison

At CMS' request, we will also be benchmarking and comparing state trends in SUD outcomes to national standards. We will descriptively examine how much our outcomes of interest have changed during the demonstration, relative to national trends. In particular, we will use the following data metrics and sources.

The IET-AD measure from the Adult Core Set will be used to measure the impact of the waiver on outpatient visits for SUD treatment. This measure captures the percentage of adults with a new episode of alcohol or other drug dependence who initiated treatment within 14 days as well as the percentage who had two or more follow-up visits within 30 days. West Virginia's rate will be plotted against the median of all states reporting data starting with federal fiscal year (FFY) 2016. FFY 2016 covered a reporting time period of January 1, 2015 through November 5, 2015, and was the first year West Virginia reported the IET-AD measure. The following additional measures added to the Adult Core Set in FFY 2018 will also be used in the evaluation: Concurrent

Use of Opioids and Benzodiazepines (COB-AD), Follow-Up After Emergency Department Visit for Alcohol and Other Drug Abuse or Dependence (FUA-AD).The treatment episode database (TEDS-A) will be used to measure admissions for substance use treatment. This analysis will be limited to adult Medicaid recipients using the AGE and primary source of payment (PRIMPAY) variables (see Figure 4).

Figure 4. Sample Benchmarking Graph, Percentage of Admissions to Substance Use Treatment Facilities by Adults (18+) with Medicaid as a Primary Payer



Additional analyses will explore the primary substance leading to the admission (i.e., heroin).

The following data sources were also considered as additional non-Medicaid claims data sources, but were excluded from the evaluation plan after it was determined that there is no mechanism for limiting analyses to Medicaid recipients: CDC WONDER, CDC WISQARS, and NSDUH.It is possible to obtain cost and hospitalization estimates for Medicaid recipients using the Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases. However, such information is already available in the Medicaid claims data. West Virginia does not currently participate in the State Emergency Department Databases.

Qualitative Analysis

The final component of our analysis is qualitative and intended to yield information that is not otherwise attainable from administrative data sources. Due to significant concerns over nonresponse bias from employing traditional survey research methods, communication among providers and provider knowledge will be assessed via focus groups.

A purposive sample of providers will be guided by two broad, general questions per current phenomenological research recommendations. These two broad general questions are: "What have you experienced in terms of the phenomenon (i.e., communication among providers and provider knowledge)"; and, "What contexts or situations have typically influenced or affected your experiences of the phenomenon"? Per current recommendations, interviews with groups of 3 to 4 providers with a maximum sample size of 25 will be conducted annually over the three-year period between 2020 and 2022. Providers will be purposefully selected each year from the list of Medicaid substance use disorder providers maintained by the state. A maximum variation approach will be employed with a goal of annually selecting providers that represent all 4 geographic regions of the state (Ohio River Valley, Allegheny Plateau, Allegheny Highlands, Potomac Section). .

In line with traditional data collection and translational protocols, interviews will be audio recorded and transcribed by an external professional transcriber. A twofold coding process will be employed using the NVIVO® software subjected to line-by-line coding with a goal of identifying a parsimonious set of themes. Consensus with a second researcher will be sought per current qualitative research recommendations. The evaluation team has extensive experience in the application of both primary and secondary survey data collection and data analyses, as well as the collection, coding and translation of qualitative data, for example in previous evaluations for the state.

D. Methodological Limitations

Despite the strengths of our methodological approach, there are some important limitations that should provide context for our results. We describe them in detail here, and when possible, offer solutions to minimize their impact.

There are two critical components of the waiver for which we may not have pre-demonstration data: newly added coverage of methadone bundles and residential services. Both of these treatments were previously available to patients outside of a Medicaid reimbursement mechanism. Methadone may have been available to some recipients who could afford treatment, on an out-of-pocket cash-pay basis. We will attempt to overcome this limitation by adjusting for the number of Medicaid beneficiaries who may have been paying for methadone treatment out-of-pocket at Opioid Treatment Programs (OTPs). Methadone administration was not a covered Medicaid benefit until the waiver was implemented in January 2018. However, OTPs were still able to enroll as Medicaid providers prior to this date and were able receive reimbursement for some services (e.g. patient evaluation, counseling, and drug screening). Presumably, individuals who received these services from OTPs, in the absence of claims for other types of MAT, were

likely purchasing methadone out of pocket from these facilities. We will identify the number of beneficiaries in each month of the pre-demonstration period who received services from OTPs and did not have claims for other types of MAT and will assume that these individuals were purchasing methadone out-of-pocket during this time.
Residential room and board was available to some Medicaid recipients via a braided funding mechanism whereby BMS paid for medical services included as residential treatment, and the Bureau for Behavioral Health paid for room and board through grant funding. We will attempt to overcome this limitation by estimating the number of beneficiaries who were receiving residential services prior to waiver implementation. We will identify individuals in the pre-demonstration period who had claims spanning multiple days from comprehensive behavioral health centers that participated in the braided funding initiative with the Bureau for Behavioral Health. In all likelihood, individuals who had claims from these facilities for behavioral health counseling (CPT code H0004) for at least 10 consecutive days were in fact receiving residential treatment services at these facilities.

Second, one of the main concerns with any policy evaluation is that other in-state polices may be occurring over the study period that could bias our results. In partnership with WV DHHR, we have conducted an extensive WV policy analysis to determine whether there are other policies we need to be concerned with. Though this process, we became aware of several different programs employing Peer Recovery Support Specialist programs, in addition to the one created as a part of the demonstration project. To help understand the extent to which these other programs might influence our results, we took an extensive look at them, and summarize our findings below.

From 2017 through 2019, multiple federal and state funding streams have supported the hiring of peer recovery support specialists (PRSS) and the provision of associated services in WV. These have included funds specifically earmarked for PRSS, and funds for other initiatives for which PRSS might be hired, including the support of medication-assisted treatment (MAT) and quick response teams (QRT).

The funding sources for awards specifically supporting peer recovery support services included the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), and the federal Office of National Drug Control Policy (ONDCP) (see Table XX below).

Table 6. Federal and State Funding Streams Supporting Hire of PRSS in WV, 2017-2019.

Source	Title of Funding Stream	Abbr.	Time Frame
CDC	Public Health Crisis Response	PHCR	12/2018-11/2019
CDC	(Source of Mosaic Funding for Mon Health Medical Center)	MOS	?
ONDCP	Combatting Opioid Overdose through Community-Level Intervention	CLI	12/2017-12/2018
SAMHSA	State Targeted Response to the Opioid Crisis	STR	9/2017-8/2019
SAMHSA	State Opioid Response Grants	SOR	9/2018-8/2020

Through the awards focused on peer recovery support services, a variety of organizations have hired PRSS, including Comprehensive Behavioral Health Centers (CBHCs), Licensed Behavioral Health Centers (LBHCs), substance use disorder treatment programs, recovery programs, harm reduction programs, health departments, academic institutions, community justice programs, local government agencies, hospitals, and others (see Table 7 below).

Table 7. Organizations Awarded Federal Funding that Focused on Peer Recovery Support Services and Specialists in West Virginia, 2017-2019

Organization	Grant	Counties Served	Funds	# of PRSS
Beckley Comprehensive Treatment Center	SOR	Raleigh and surrounding counties	Unk	Unk
Boone Memorial Hospital	SOR	Boone	Unk	Unk
Charleston Comprehensive Treatment Center	SOR	Kanawha and surrounding counties	Unk	Unk
Drug Free Moms & Babies	STR	Greenbrier	$40,000	1
FMRS Health System	STR	Fayette, Monroe, Raleigh, Summers	$120,000	3
Greenbrier Day Report Center	STR	Greenbrier	$40,000	1
Harrison County Commision	STR	Harrison	$40,000	1
Hampshire County Pathways	STR	Hampshire	$80,000	2
Huntington Comprehensive Treatment Center	SOR	Cabell and surrounding counties	Unk	Unk

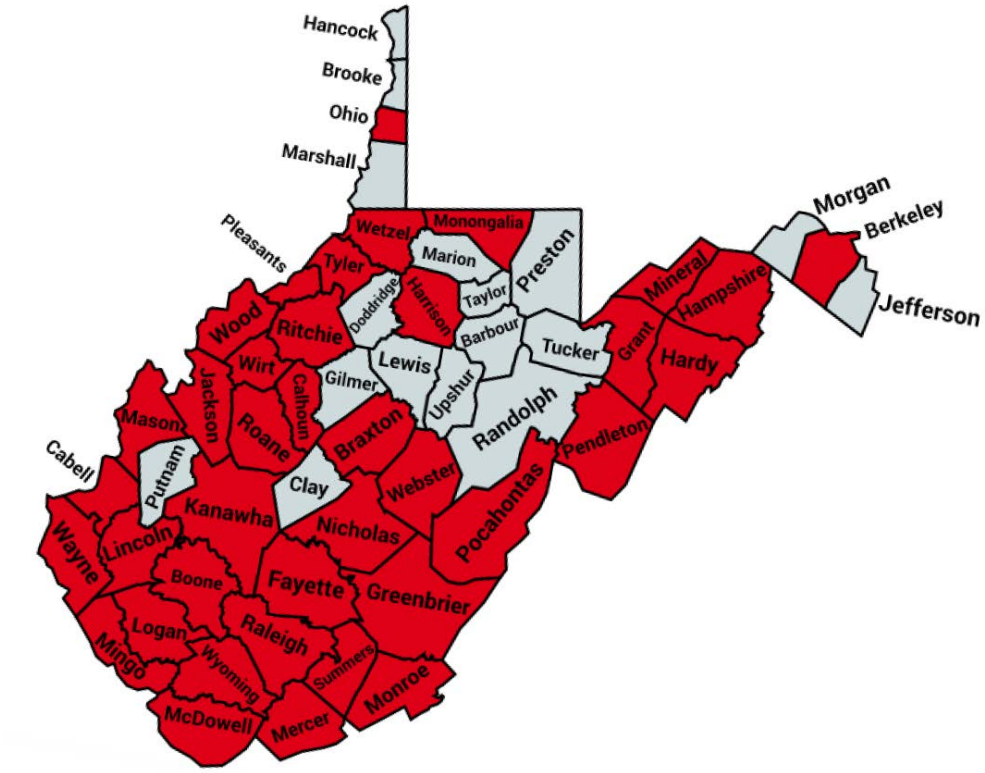
Organization	Grant	Counties Served	Funds	# of PRSS
Living Free Ohio Valley	STR	Ohio	$120,000	3
Marshall University	SOR	Cabell	Unk	Unk
Marshall University	SOR	Cabell,Lincoln, Logan, Mason, Mercer, Mingo, McDowell, Wyoming	Unk	Unk
Marshall University	PHCR	Fayette and Mason	$80,000	2
Milan Puskar Health Right	STR	Monongalia	$40,000	1
Morgantown Sober Living	STR	Monongalia	$160,000	4
Mosaic Group	?	Monongalia	?	?
Potomac Highlands Guild	STR	Grant, Hampshire, Hardy, Mineral, Pendleton	$40,000	1
Potomac Highlands Guild	SOR	Grant, Hampshire, Hardy, Mineral, Pendleton	Unk	Unk
Prestera	STR	Cabell, Lincoln, Mason, Wayne	$240,000	6
Recovery Point	STR	Cabell, Kanawha	$480,000	12
Seneca Health Care	STR	Greenbrier, Nicholas, Pocahontas, Webster	$240,000	6
Southern Highlands	SOR	McDowell, Mercer, Wyoming	Unk	Unk
Synergy Health	STR	Kanawha	$120,000	3
Synergy Health	SOR	Kanawha	Unk	Unk
The Lifehouse	STR	Cabell	$40,000	1
Tug River Health Association	STR	McDowell	$40,000	1
Westbrook Health	SOR	Calhoun, Jackson, Pleasants, Ritchie, Roane, Tyler, Wirt, Wood	Unk	Unk
Westcare Foundation	SOR	Braxton	Unk	Unk
West Virginia Sober Living	ONDCP	Monongalia	$58,344	2.25
West Virginia Sober Living	STR	Monongalia	$160,000	4

Organization	Grant	Counties Served	Funds	# of PRSS
West Virginia Sober Living/Ascension	SOR	Monongalia	Unk	Unk
West Virginia University School of Public Health	PHCR	Harrison and Wood	$80,000	2
Wheeling Comprehensive Treatment Center	SOR	Ohio and surrounding counties	Unk	Unk
Youth Advocate Programs	STR	Braxton, Berkeley, Jackson, Ohio, Wetzel, Wood	$40,000	1

In addition to the recent proliferation of peer recovery activities enabled by aforementioned federal and state funding streams, several other factors represent challenges to the effort to evaluate the implementation and impact of the peer recovery component of the demonstration project. First, recovery support services are provided in some settings in WV by specialists who do not have lived experience with substance use disorder (i.e., are non-peer, rather than peer specialists). Non-peer recovery support specialists are not eligible to bill for services under the demonstration project. Secondly, those recovery support specialists who have lived experience with SUD and were hired under the funding streams described were not always required to be trained and certified upon hire, although in some cases they were required to participate in a training and certification process that included specialized training related to opioid use disorder (OUD) during the funded project. Additionally, some of the passthrough grants did not limit eligibility to CBHCs or LBHCs to enable billing Medicaid for services. However, these Waiver announcements specified that organizations were expected to work toward sustainability, including through becoming eligible to bill for peer recovery support services via the Medicaid Waiver or other payers. These factors suggest that a substantial number of individuals funded and hired in WV to provide recovery support services, may not be eligible to bill Medicaid due to absence of lived experience, education/certification credentials, and employer eligibility.

Isolating the impact of the Demonstration Project's PRSS program alone represents a significant hurdle to overcome. We will attempt to do so by conducting a separate within-state analysis. Figure 5 below shows the counties that have PRSS funding from non-demonstration sources in red. The gray counties represent those that have PRSSs only through the demonstration project. We will compare outcomes among those in the gray counties alone who claim demonstration-funded PRSS services to those who do not use PRSS services.

Figure 5. Distribution of Non-Demonstration PRSS Programs, by County



E. Attachments

A. Independent Evaluator

About the West Virginia University School of Public Health: The WVU School of Public Health (SPH) is the first of its kind in WV. The school is built upon the strong foundation of the CEPH-accredited Department of Community Medicine and its affiliates. A central mission of the School is to identify and assess sustainable, cost-effective prevention and intervention strategies to address major public health concerns of West Virginians and other rural, underserved populations, with a strong focus on understanding and addressing health disparities. Five academic departments have formed in the WVU SPH, including Biostatistics, Epidemiology, Health Policy, Management & Leadership, Occupational & Environmental Health Sciences, and Social & Behavioral Science. The school employs a total of 54 full and part-time faculty, who perform nationally recognized work in multiple disciplines, including epidemiology, environmental health, community-based interventions, health services, and clinical research. There are currently over 74 Undergraduate, 68 MS/MPH students and 30 PhD students enrolled in the school, with enrollment projected to increase substantially in the next three years with the continuing development of new educational and training programs.

The school includes several active centers, including the Injury Control Research Center, the Office of Health Services Research, the Health Research Center, Public Health Training Center and the West Virginia Prevention Research Center. Fostering a dynamic interdisciplinary research enterprise, the new school has also established strong research and teaching partnerships with multiple state, regional and federal agencies, local, regional, and national organizations, and other entities, and encourages strong engagement in and with the community.

An environment exists for collaboration and interaction among the faculty, with their repertoire of interdisciplinary grants, contracts, and research interests that cross departmental, school, and institutional boundaries. The School also has a working relationship with the West Virginia University Department of Statistics, and with colleagues at the National Institute for Occupational Safety and Health (NIOSH), where there are additional collaborative faculty with great statistical expertise.

To receive more information or a copy of the evaluation design or reports, please contact:

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CV Attached as Appendix I

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CV Attached as Appendix II

B. No Conflict of Interest: Conflict of Interest Statement is attached as Appendix III

C. Evaluation Budget: The evaluation budget for year 1 is attached as Appendix IV

D. Timeline and Major Milestones

Table 8. Timeline and Major Milestones

Milestone	Date
Revised evaluation plan submitted to CMS	9/2019
Ongoing analysis	1/1/2020 – 12/31/2022
Evaluation team to receive data from State A	1/31/2020
Complete first round of provider interviews and focus groups	1/1/2020 – 6/30/2020
First interim report submitted to BMS, covering 1/1/2015 – 6/1/2020	12/31/2020
Complete second round of provider interviews and focus groups	1/1/2021 – 6/30/2021
Second interim report submitted to BMS, covering 1/1/2015 – 6/1/2021	12/31/2021
Complete final round of provider interviews and focus groups	1/1/2022 – 6/30/2022
Final report submitted to BMS and CMS	7/30/2023
Contribute to state waiver monitoring report	Quarterly from 12/1/2018 – 12/31/2020
Bi-weekly meetings with key stakeholders from BMS	1/1/2018 – 12/31/2022