CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: **11-W-00307/3**

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

AWARDEE: **West Virginia Department of Health and Human Services**

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by West Virginia for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period of this demonstration, be regarded as expenditures under the state's title XIX plan.

The following expenditure authorities may only be implemented consistent with the approved Special Terms and Conditions (STCs) and shall enable West Virginia to operate its section 1115 demonstration.

The expenditure authorities listed below promote the objectives of title XIX in the following ways:

- Improves health outcomes for Medicaid and other low-income populations in the state by covering treatment not otherwise covered by the state plan, and by making covered treatments available to previously excluded patients in institutions of mental disease (IMDs).

1. **Residential Treatment for Individuals with Substance Use Disorder (SUD).** Expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for SUD who are short-term residents in facilities that meet the definition of an institution for mental disease (IMD).

2. **Methadone Treatment.** Expenditures for services that could be covered under the Medicaid state plan; however, the state has elected to cover the services through expenditure authority instead.

3. **Peer Recovery Support Services**. Expenditures for services that could be covered under the Medicaid state plan; however, the state has elected to cover the services through expenditure authority instead.

4. **Expenditures Related to Administrative Simplification and Delivery Systems**. Expenditures under contracts with managed care entities that do not meet the requirements in 1903(m)(2)(A) and 1932(a) of the Act in so far as they incorporate 42 CFR 438.52(a) to the

extent necessary to allow the state to operate only one managed care plan in urban areas for enrollees in the Children with Serious Emotional Disorder Section 1915(c) Waiver (CSEDW).

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: **11-W-00307/3**

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

AWARDEE: **West Virginia Department of Health and Human Services**

I. PREFACE

The following are the amended Special Terms and Conditions (STCs) for West Virginia's Substance Use Disorders (SUD) section 1115(a) Medicaid demonstration (hereinafter referred to as "demonstration"). The parties to this agreement are the West Virginia Department of Health and Human Services ("state") and the Centers for Medicare & Medicaid Services (CMS). The STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS during the life of the demonstration. The STCs were approved on October 6, 2017, for the period of January 1, 2018 through December 31, 2022.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Substance Use Disorder Demonstration
V. General Reporting Requirements
VI. Evaluation of the Demonstration
VII. General Financial Requirements
VIII. Monitoring Budget Neutrality for the Demonstration
IX. Schedule of the State Deliverables during the Demonstration

Additional attachments have been included to provide supplementary information and guidance for specific STCs.

Attachment A: Developing the Evaluation Design
Attachment B: Preparing the Interim and Summative Evaluation Reports
Attachment C: SUD Monitoring Plan Protocol
Attachment D: SUD Evaluation Design

II. PROGRAM DESCRIPTION AND OBJECTIVES

The Substance Use Disorder (SUD) demonstration is a demonstration program to test a new

paradigm for the delivery of SUD services for all Medicaid enrollees. The SUD program demonstrates how comprehensive and high quality substance use disorder care can improve the health of Medicaid recipients while decreasing other health care system (such as emergency department and inpatient hospital) costs. Critical elements of the SUD demonstration include providing a continuum of care modeled after the American Society of Addiction Medicine Criteria (ASAM Criteria) or another comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for SUD treatment services, introducing policy and program guidance to ensure providers meet the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for standards of care, integrating SUD treatment services into a comprehensive managed care delivery system for those recipients receiving managed care under 1915(b) waiver authority; implementing utilization controls to improve care and ensure efficient use of resources; and implementing strategies to improve the quality of care through evidence-based best practices. This approach is expected to provide West Virginia Medicaid recipients with access to the care needed to achieve sustainable recovery.

Under this demonstration West Virginia expects to achieve the following to promote the objectives of title XIX:

- 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 another 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.

This demonstration also will provide expenditure authority that will operate next to the state's concurrent 1915(c) waiver CSEDW. Effectively, the state will automatically enroll CSEDW beneficiaries on a mandatory basis into a single MCO and not provide for a 90 day period of disenrollment. This allows the specialized plan to provide specialized and coordinated care to its members in a seamless and cost-effective way.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.

2. **Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the

Medicaid program expressed in law, regulation, and policy statement, not expressly identified as not applicable in the expenditure authority documents (of which these terms and conditions are part), must apply to the demonstration.

3. **Changes in Medicaid Law, Regulation, and Policy**. The state must, within the time frames specified in law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or policy statement, affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is expressly identified as not applicable.

4. Impact on Demonstration of Changes in Federal Law, Regulation, and Policy Statements. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration, as necessary, to comply with such change. The modified budget neutrality agreement will be effective upon the implementation of the change.

    A. If mandated changes in the federal law require state legislation, the changes must take effect on the day such state legislation becomes effective, or on the day such legislation was required to be in effect under the federal law.

5. **State Plan Amendments.** The state shall not be required to submit title XIX state plan amendments for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid state plan is affected by a change to the demonstration, a conforming amendment to the state plan will be required, except as otherwise noted in these STCs.

6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, enrollee rights, delivery systems, cost sharing, evaluation design, sources of non-federal share of funding and budget neutrality must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Social Security Act (the Act). The state must not implement changes to these elements without prior approval by CMS. Amendments to the demonstration are not retroactive and FFP will not be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than one hundred twenty (120) days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non- compliance with these STCs, including but not limited to failure by the state to

submit required reports and other deliverables in a timely fashion according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:

A. An explanation of the public process used by the state, consistent with the requirements of STC 14, to reach a decision regarding the requested amendment;

B. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include total computable "with waiver" and "without waiver" expenditure estimates as well as the current federal share of the "with waiver" and "without waiver" estimates. The data analysis shall contain both summary and detailed level expenditure data through the current approval period using the most recent actual expenditures that illustrates the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;

C. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation; and

D. If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.

8. **Extension of the Demonstration.** No later than twelve (12) months prior to the expiration date of the demonstration, the governor or chief executive officer of the state must submit to CMS notification that it expects to cover individuals under the Medicaid state plan or through some other type of coverage, a demonstration extension request, or a phase-out plan consistent with the requirements of STC 9.

   As part of the demonstration extension request, the state must provide documentation of compliance with the transparency requirements at 42 CFR 431.412(c) and the public notice and tribal consultation requirements outlined in STC 14.

9. **Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.

   A. Notification of Suspension or Termination: The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit its notification letter and a draft phase-out plan to CMS no less than five (5) months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft plan to CMS, the state must publish on its website the draft plan for a thirty (30) day public comment period. In addition, if applicable, the state must conduct tribal consultation in accordance with its approved tribal consultation state plan

amendment. Once the thirty (30) day public comment period has ended, the state must provide a summary of each public comment received, the state's response to the comment and how the state incorporated the received comment into a revised phase- out plan.

B. The state must obtain CMS approval of the phase-out plan prior to the implementation of the phase-out activities. Implementation of transition and phase-out activities must be no sooner than fourteen (14) days after CMS approval of the plan.

C. Phase-out Plan Requirements: The state must include, at a minimum, in its plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility for the affected beneficiaries, and ensure ongoing coverage for eligible individuals, as well as any community outreach activities.

D. Phase-out Procedures: The state must comply with all notice requirements found in 42 CFR 431.206, 431.210 and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration participants as outlined in 42 CFR 431.220 and 431.221. If a demonstration participant requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category as discussed in October 1, 2010, state Health Official Letter #10- 008.

E. Federal Financial Participation (FFP): If the project is terminated or any relevant waivers suspended by the state, FFP shall be limited to normal closeout costs associated with terminating the demonstration including services and administrative costs of disenrolling participants.

10. **CMS Right to Terminate or Suspend.** CMS may suspend or terminate, subject to adequate public notice, the demonstration in whole or in part at any time before the date of expiration, whenever it determines, following a hearing, that the state has materially failed to comply with the terms of the project. CMS will promptly notify the state in writing of the determination and the reasons for the suspension or termination, together with the effective date.

11. **Finding of Non-Compliance.** The state does not relinquish its rights to challenge the CMS finding that the state materially failed to comply.

12. **Withdrawal of Waiver Authority.** CMS reserves the right to withdraw waivers or

expenditure authorities at any time it determines that continuing the waivers or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services and administrative costs of disenrolling participants.

13. **Adequacy of Infrastructure.** The state must ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.

14. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the public notice procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

    If applicable, the state must also comply with the tribal consultation requirements as set forth in section 1902(a)(73) of the Act and implemented in regulation at 42 CFR 431.408(b), and the tribal consultation requirements contained in the state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment or extension, are proposed by the state.

15. **Federal Financial Participation (FFP).** No federal matching for expenditures for this demonstration will take effect until the effective date identified in the demonstration approval letter or as expressly stated within these STCs.

IV. SUBSTANCE USE DISORDER (SUD) DEMONSTRATION

16. **Program Description and Objectives.** The SUD demonstration is a demonstration program to test a new paradigm for the delivery of SUD services for all Medicaid enrollees, both those served via the managed care and fee-for-service delivery systems. No Medicaid state plan beneficiaries are excluded from the SUD demonstration. There are two (2) implementation dates of the SUD demonstration— January 1, 2018 for initial implementation, including coverage for methadone treatment services; and July 1, 2018 for full implementation, including residential treatment services, peer recovery

support services, and withdrawal management services. Note: room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

17. **SUD Demonstration Benefits.** The comprehensive SUD demonstration benefit package provides access to a full continuum of care for SUD treatment. Standard SUD services approved through the state plan benefit as well as SUD services approved through this demonstration will be available to all West Virginia Medicaid recipients who meet medical necessity criteria for services. The following service categories outlined in Table One (1) are included in the SUD demonstration benefit package for West Virginia Medicaid enrollees with the appropriate Medicaid authority designated:

Table One: SUD Demonstration Benefits (with Expenditure Authority)

ASAM Level of Care*	SUD Demonstration Benefit	Medicaid Authority	Costs Not Otherwise Matchable
N/A	Targeted Case Management	State plan	Services provided to short-term residents
N/A	Naloxone Administration Services	State plan	Services provided to short-term residents
0.5	Screening, Brief Intervention and Referral to Treatment	State plan	
1	Peer Recovery Support Services	Section 1115 demonstration	Services provided to short-term residents
1	Outpatient Services	State plan	
2.1	Intensive Outpatient Services	State plan	
2.5	Partial Hospitalization Services	State plan	
3.1	Clinically Managed Low Intensity Residential Services	Section 1115 demonstration	Services provided to short-term residents
3.3	Clinically Managed Population-Specific High Intensity Residential Services	Section 1115 demonstration	Services provided to short-term residents
3.5	Clinically Managed High Intensity Residential Services	Section 1115 demonstration	Services provided to short-term residents
3.7	Medically Monitored Intensive Inpatient Services	State plan and section 1115 demonstration	Services provided to short-term residents
4	Medically Managed Intensive Inpatient Services	State plan	

*If not using ASAM Criteria, the level of care should be at the same level of the ASAM criteria.

1-WM	Ambulatory Withdrawal Management Services	State plan	
2-WM	Ambulatory Withdrawal Management Services	State plan	
3.2-WM	Clinically Managed Residential Withdrawal Management Services	Section 1115 demonstration	Services provided to short-term residents
3.7-WM	Medically Monitored Inpatient Withdrawal Management Services	State plan	Services provided to short-term residents
OTP	Opioid Treatment Program Services	Section 1115 demonstration	Services provided to short-term residents
OBOT	Office Based Opioid Treatment	State plan	Services provided to short-term residents

*If not using ASAM Criteria, the level of care should be at the same level of the ASAM criteria.

The state attests that the services indicated in Table One (1), above, as being covered under Medicaid state plan authority are currently covered in the West Virginia Medicaid state plan. The following service definitions and provider qualifications are described for those SUD demonstration services, which are covered under this section 1115 demonstration.

Peer Recovery Support Services

Peer recovery support services are designed and delivered by individuals in recovery from substance use disorder (peer recovery coach) to provide counseling support to help prevent relapse and promote recovery. Services can be provided by appropriately trained staff when working under the supervision of a competent behavioral health professional (as defined by the State). A peer recovery coach must be 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. The peer must demonstrate the ability to support the recovery of others from substance use disorders. Similar to other provider types, ongoing continuing educational requirements for peer support providers must be in place.

Residential Treatment Services

Treatment services delivered to residents of an institutional care setting, including facilities that meet the definition of an institution for mental diseases (IMD), are provided to West

Virginia Medicaid recipients with an SUD diagnosis when determined to be medically necessary by the MCO utilization staff and in accordance with an individualized service plan. MCO utilization staff, physicians or medical directors will perform independent assessments to determine level of care and length of stay recommendations based upon the ASAM Criteria multidimensional assessment criteria or another comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines assessment criteria.

a. Residential treatment services are provided in a West Virginia Bureau of Medical Services (BMS)-certified facility that has been enrolled as a Medicaid provider and assessed by BMS as delivering care consistent with ASAM Levels 3.1, 3.3, 3.5, and/or 3.7 or the equivalent level of care of the state's chosen other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines, and, for participation in the managed care delivery system, has been credentialed and enrolled by an MCO as a network provider. Each residential treatment provider will be certified as meeting the provider and service specifications described in the BMS policy manual consistent with the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for the requisite level or sublevel of care prior to participating in the West Virginia Medicaid program under this section 1115 demonstration. The MCOs will provide credentialing for ASAM Levels 3.1, 3.3, 3.5 and/or 3.7 or credentialing for the levels of care of the other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines contingent on the providers receiving certification from the state.

b. Residential treatment services can be provided in settings of any size.

c. The state's average length of stay for individuals admitted into all BMS-certified facilities at all levels of care is thirty (30) days.

d. The implementation date for residential treatment services is July 1, 2018.

e. Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

Covered services include:

a. Clinically-directed therapeutic treatment to facilitate recovery skills, relapse prevention, and emotional coping strategies.

b. Addiction pharmacotherapy and drug screening;

c. Motivational enhancement and engagement strategies;

d. Counseling and clinical monitoring;

e. Withdrawal management and related treatment designed to alleviate acute emotional, behavioral, cognitive, or biomedical distress resulting from, or occurring with, an individual's use of alcohol and other drugs;

f. Regular monitoring of the individual's medication adherence;

g. Recovery support services;

h. Counseling services involving the beneficiary's family and significant others to advance the beneficiary's treatment goals, when (1) the counseling with the family member and significant others is for the direct benefit of the beneficiary, (2) the counseling is not aimed at addressing treatment needs of the beneficiary's family or significant others, and 3) the beneficiary is present except when it is clinically appropriate for the beneficiary to be absent in order to advance the beneficiary's treatment goals; and,

i. Education on benefits of medication assisted treatment and referral to treatment as necessary.

Opioid Treatment Program Services (methadone treatment services)
Physician-supervised daily or several times weekly opioid agonist medication and counseling services provided to maintain multidimensional stability for those with severe opioid use disorder in BMS-licensed methadone clinics in accordance with an individualized service plan determined by a licensed physician or licensed prescriber and approved and authorized according to state requirements.

Covered services include:

a. Linkage to psychological, medical, and psychiatric consultation.

b. Access to emergency medical and psychiatric care through connections with more intensive levels of care.

c. Access to evaluation and ongoing primary care.

d. Ability to conduct or arrange for appropriate laboratory and toxicology tests including urine drug screenings.

e. Availability of licensed physicians to evaluate and monitor use of methadone, buprenorphine products or naltrexone products and of pharmacists and nurses to dispense and administer these medications.

f. Individualized, person-centered assessment and treatment.

g. Assessing, ordering, administering, reassessing, and regulating medication and dose levels appropriate to the individual; supervising withdrawal management from opioid analgesics, including methadone, buprenorphine products or naltrexone

products; overseeing and facilitating access to appropriate treatment for opioid use disorder.

h. Medication for other physical and mental health illness is provided, as needed, either on-site or through collaboration with other providers. Cognitive, behavioral, and other substance use disorder-focused therapies, reflecting a variety of treatment approaches, provided to the individual on an individual, group, and/ or family basis.

i. Optional substance use care coordination provided, including integrating behavioral health into primary care and specialty medical settings through interdisciplinary care planning and monitoring individual progress and tracking individual outcomes; supporting conversations between buprenorphine-waivered practitioners and behavioral health professionals to develop and monitor individualized service plans; linking individuals with community resources to facilitate referrals and respond to social service needs; tracking and supporting individuals when they obtain medical, behavioral health, or social services outside the practice.

j. Referral for screening for infectious diseases such as HIV, hepatitis B and C, and tuberculosis at treatment initiation and then at least annually or more often based on risk factors.

18. **Incorporation of Industry Standards of Care.** Through revisions of its policy manual and contract requirements for managed care organizations (MCOs), BMS will establish standards of care for SUD demonstration services that incorporate industry standard benchmarks from the ASAM Criteria or another comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for patient assessment and placement, service and staffing specifications.

    a. Residential treatment services are provided in a BMS-certified facility that has been enrolled as a Medicaid provider and assessed by BMS as delivering care consistent with ASAM Levels 3.1, 3.3, 3.5, and/or 3.7 or another comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines, and, for participation in the managed care delivery system, has been credentialed and enrolled by an MCO as a network provider. Each residential treatment provider will be certified as meeting the provider and service specifications described in the BMS policy manual consistent with the ASAM Criteria or another comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for the requisite level or sublevel of care prior to participating in the West Virginia Medicaid program under this section 1115 demonstration.

    b. The MCOs will be responsible for credentialing all SUD demonstration service providers consistent with the key benchmarks from ASAM Criteria or from another

comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines as set forth in the BMS policy manual and revised MCO contracts.

c. All MCOs and SUD providers participating under this demonstration will incorporate the national patient assessment and placement guidelines as established in the ASAM Criteria or another comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines, into current assessment and level of care determination processes. The multidimensional assessment framework will be implemented as a standard component of the bio-psychosocial assessment and level of care determination process by January 1, 2018.

   Between January 1, 2018 and December 1, 2018, providers will receive training and education on the ASAM or the other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines level of care criteria and the application of the ASAM Criteria or the other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines in the assessment process. MCOs will be required to provide evidence of initial and ongoing training of providers during site reviews conducted by the state. The state will review a sample of the provider network to corroborate the findings regarding training provided by the MCOs. If discrepancies are found, the state will review additional providers to ensure compliance and issue corrective action against the MCO. As part of a quality monitoring strategy, the state will review personnel and clinical records of a sample of the provider network to determine appropriate application and fidelity to the established assessment process.

19. **SUD Monitoring Plan Protocol.** The state must submit an SUD Monitoring Plan Protocol within 150 calendar days after approval of this demonstration. The SUD Monitoring Plan protocol must be developed in cooperation with CMS and is subject to CMS approval. The approved SUD Monitoring Plan Protocol will be incorporated here as Attachment H. At a minimum, the SUD Monitoring Plan Protocol will describe the data collection, reporting and analytic methodologies for performance measures and data points identified by the state and CMS for inclusion. The SUD Monitoring Plan Protocol will specify the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Subject Area V of the demonstration. In addition, for each performance measure, the SUD Monitoring Plan Protocol will identify a baseline, a target to be achieved by the end of the demonstration and an annual goal for closing the gap between baseline and target expressed as percentage points. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.

V. GENERAL REPORTING REQUIREMENTS

20. **Deferral for Failure to Submit Timely Demonstration Deliverables**. CMS will issue deferrals in the amount of $5,000,000 (federal share) per deliverable when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or found to not be consistent with the requirements approved by CMS. Specifically:

    A. Thirty (30) days after the deliverable was due, CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non- compliant submission of required deliverables.

    B. For each deliverable, the state may submit a written request for an extension to submit the required deliverable. Extension requests that extend beyond the current calendar quarter must include a Corrective Action Plan (CAP).

        i. CMS may decline the extension request;

        ii. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided; and

        iii. If the state's request for an extension includes a CAP, CMS may agree to or further negotiate the CAP as an interim step before applying the deferral.

    C. The deferral would be issued against the next quarterly expenditure report following the written deferral notification.

    D. When the state submits the overdue deliverables(s) that are accepted by CMS, the deferral(s) will be released.

    E. As the purpose of a section 1115 demonstration is to test new methods of operation or services, and timely and complete submission of required deliverables is necessary for effective testing, a state's failure to submit all required deliverables may preclude a state from renewing a demonstration or obtaining a new demonstration.

    F. CMS will consider with the state an alternative set of operational steps for implementing the intended deferral to align the process with the state's existing deferral process, for example, which quarter the deferral applies to and how the deferral is released.

21. **Submission of Post-Approval Deliverables.** The state must submit all deliverables using the process stipulated by CMS and within the timeframes outlined within these

STCs.

22. **Compliance with Federal Systems Innovation.** As federal systems continue to evolve and incorporate additional 1115 waiver reporting and analytics functions, the state will work with CMS to:

    A. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;

    B. Ensure all 1115, Transformed Medicaid Statistical Information System (T-MSIS), and other data elements that have been agreed to are provided; and

    C. Submit deliverables through the appropriate system as directed by CMS.

23. **Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state shall cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration.

    This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state shall include in its contracts with entities that collect, produce or maintain data and files for the demonstration, that they shall make such data available for the federal evaluation as is required by the state under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 20.

24. **Cooperation with Federal Learning Collaboration Efforts.** The state will cooperate with improvement and learning collaboration efforts by CMS.

25. **Quarterly and Annual Operational Reports.** The state must submit three (3) Quarterly Reports and one (1) compiled Annual Report each demonstration year (DY). The information for the fourth quarterly report should be reported as distinct information within the Annual Report. The Quarterly Reports are due no later than sixty (60 days) following the end of each demonstration quarter. The compiled Annual Report is due no later than ninety (90) days following the end of the DY.

    A. The Quarterly and Annual Reports will include all required elements and should not direct readers to links outside the report. (Additional links not referenced in the document may be listed in a Reference/Bibliography section).

B. The Quarterly and Annual Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

1. Operational Updates - The reports shall provide sufficient information to document key operational and other challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held.
2. Performance Metrics – Any required monitoring and performance metrics must be included in writing in the Quarterly and Annual Reports. Information in the reports will follow the framework provided by CMS and be provided in a structured manner that supports federal tracking and analysis.
3. Budget Neutrality and Financial Reporting Requirements – The state must provide an updated budget neutrality workbook that includes established baseline and member months data with every Quarterly and Annual Report that meets all the reporting requirements for monitoring budget neutrality set forth in section VII. General Financial Requirements of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly expenditures associated with the populations affected by this demonstration on the Form CMS-64.

   Evaluation Activities and Interim Findings. The state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed. The state shall specify, for CMS approval, a set of performance and outcome metrics, including their specifications, reporting cycles, level of reporting (e.g., the state, health plan and provider level, and segmentation by population) to support rapid cycle assessments in trends for monitoring and evaluation of the demonstration.

26. **Additional Demonstration Annual Operational Report Requirements.** The Annual Report shall meet the requirements in 42 C.F.R. 431.428, which address both the content of the report and the publication of the draft and final reports on the State's public website. In addition to the fourth quarter information and the aggregated components of the Quarterly Reports, the Annual Report must, at a minimum, include the requirements outlined below:

A. Items included in the Quarterly Reports must be summarized to reflect the operation/activities throughout the DY;

B. Total annual expenditures for the demonstration population for each DY, with administrative costs reported separately;

C. Total contributions, withdrawals, balances, and credits; and

D. Yearly enrollment reports for demonstration enrollees for each DY (enrollees include all individuals enrolled in the demonstration) that include the member months, as required to evaluate compliance with the budget neutrality agreement.

27. **Close Out Operational Report**. Within one hundred twenty (120) days prior to the expiration of the demonstration, the state must submit a draft Close Out Report to CMS for comments.

    A. The draft Close Out Report must comply with the most current Guidance from CMS.

    B. The state will present to and participate in a discussion with CMS on the Close-Out Report.

    C. The state must take into consideration CMS' comments for incorporation into the final Close-Out Report.

    D. The Final Close-Out Report is due to CMS no later than thirty (30) days after receipt of CMS' comments.

    E. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 20.

28. **State Data Collection.** The state must collect data and information necessary to oversee service utilization and rate setting by provider/plan, comply with the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) and the Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set), collectively referred to as the CMS Child and Adult Core Measure Sets for Medicaid and CHIP, and comply with other existing federal measure sets.

    A. The state will use this information in ongoing monitoring of individual well-being, provider/plan performance, and continuous quality improvement efforts, in addition to complying with CMS reporting requirements.

    B. The state must maintain data dictionary and file layouts of the data collected.

    C. The raw and edited data will be made available to CMS within thirty (30) days of a written request.

29. **Monitoring Calls**. CMS will convene periodic conference calls with the state.

    A. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration.

    B. CMS will provide updates on any amendments or concept papers under review, as well as federal policies and issues that may affect any aspect of the demonstration.

    C. The state and CMS will jointly develop the agenda for the calls.

    D. Areas to be addressed during the monitoring call include, but are not limited to:

        1. Transition and implementation activities;
        2. Stakeholder concerns;
        3. Operations and performance;
        4. Enrollment;
        5. Cost sharing;
        6. Quality of care;
        7. Beneficiary access;
        8. Benefit package and wrap around benefits;
        9. Audits;
        10. Lawsuits;
        11. Financial reporting and budget neutrality issues;
        12. Progress on evaluation activities and contracts;
        13. Related legislative developments in the state; and
        14. Any demonstration changes or amendments the state is considering.

30. **Post Award Forum.** Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state shall afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least thirty (30) days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state must also post the most recent annual report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Quarterly Report associated with the quarter in which the forum was held, as well as in its compiled Annual Report.

VI. EVALUATION OF THE DEMONSTRATION

31. **Independent Evaluator.** At the beginning of the demonstration period, the state must arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The independent party must sign an agreement to conduct the demonstration evaluation in accord with the CMS-approved, Draft Evaluation Design, which will meet the requirements described in 42 C.F.R. 431.424 and the guidance provided in Attachment B: "Developing the Evaluation Design." For scientific integrity, every effort should be made to follow the approved methodology. State evaluation must follow the approved methodology; however, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

32. **Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A of these STCs. The state must submit, for CMS comment and approval, a Draft Evaluation Design with implementation timeline, for the demonstration to CMS no later than one hundred eighty (180) days after the effective date of these STCs. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state may choose to use the expertise of the independent party in the development of the Draft Evaluation Design.

33. **Evaluation Design Approval and Updates.** The state must submit a revised Draft Evaluation Design within sixty (60) days after receipt of CMS' comments. Upon CMS approval of the Draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the Quarterly Reports and Annual Reports.

34. **Evaluation Questions and Hypotheses.** Consistent with attachments A and B of these STCs the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. CMS recommends hypotheses include an assessment of the objectives of SUD section 1115 demonstrations, to include (but is not limited to): initiation and compliance with treatment, appropriate utilization of health services (emergency department and inpatient hospital settings), and a reduction in key outcomes such as deaths due to overdose.

    Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health

Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

35. **Evaluation Budget.** A budget for the evaluation shall be provided with the Draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluation such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design, if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.

36. **Evaluation Requirements.** The demonstration evaluation will meet the prevailing standards of scientific evaluation and academic rigor, as appropriate and feasible for each aspect of the evaluation, including standards for the evaluation design, conduct, and interpretation and reporting of findings. In addition, the evaluation design plan will include a description of how the effects of the demonstration will be isolated from those other changes occurring in the state at the same time through the use of comparison or control groups, regarding significant aspects of the demonstration.

    A. The demonstration evaluation will use the best available data; use controls and adjustments for and reporting of the limitations of data and their effects on results; and discuss the generalizability of results.

    B. The state shall arrange with an independent entity to conduct the evaluation. The evaluation design shall discuss the state's process for arranging with an independent entity to conduct the evaluation, including a description of the qualifications the entity must possess, how the state will ensure no conflict of interest, and a budget for evaluation activities.

37. **State Presentations for CMS**. CMS reserves the right to request that the state present and participate in a discussion with CMS on the final Evaluation Design, the interim evaluation, and/or the summative evaluation.

38. **State Must Separately Evaluate Components of the Demonstration.** The outcomes from each evaluation component must be integrated into one programmatic summary that describes whether the state met the demonstration goal, with recommendations for future efforts regarding all components.

39. **Draft Interim Evaluation Reports.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent renewal or

extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Report should be posted to the state's website with the application for public comment. Also refer to Attachment B for additional information on the Interim Evaluation Report.

A. The interim evaluation report will discuss evaluation progress and present findings to date as per the approved evaluation design.
B. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
C. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions, hypotheses and how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
D. The state must submit the final Interim Evaluation Report sixty (60) days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.
E. The Interim Evaluation Report must comply with Attachment B of these STCs.

40. **Summative Evaluation Report.** The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within eighteen (18) months of the end of this approval period. The draft Summative Evaluation Report must include the information in the approved Evaluation Design. Refer to Attachment B for additional information on the evaluation report.

    A. Unless otherwise agreed upon in writing by CMS, the state shall submit the final Summative Evaluation Report within sixty (60) days of receiving comments from CMS on the draft.
    B. The final Summative Evaluation Report must be posted to the state's Medicaid website within thirty (30) days of approval by CMS.

41. **Public Access**. The state shall post the final documents (e.g., Quarterly and Annual Reports, Final Operational Report, approved Evaluation Design, Final Interim Evaluation Report(s), Final Summative Evaluation Report(s), and the Final Evaluation Report) on the state's Medicaid website within thirty (30) days of approval by CMS.

42. **Additional Publications and Presentations.** For a period of twenty-four (24) months following CMS approval of the final reports, CMS will be notified prior to presentation of other reports and related publications (including, for example, journal articles), by the

state, contractor, or any other third party (an entity which is not the state or contractor) over which the state Medicaid agency has control. Prior to release of these reports, articles and other publications, CMS will be provided a copy including any associated press materials. CMS will be given thirty (30) days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews.

XII. GENERAL FINANCIAL REQUIREMENTS

43. **Quarterly Expenditure Reports.** The state must complete quarterly expenditure reports through the Medicaid and Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in section 2500 of the State Medicaid Manual, for services provided through this demonstration and that are subject to budget neutrality. CMS shall provide FFP for allowable demonstration expenditures only as long as they do not exceed the pre-defined limits on the costs incurred as specified in section VIII (Monitoring Budget Neutrality).

44. **Reporting Expenditures Subject to the Title XIX Budget Neutrality Expenditure Limit.** The following describes the reporting of expenditures subject to the budget neutrality limit:

    a. **Tracking Expenditures.** In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in section 2500 of the state Medicaid Manual. All demonstration expenditures claimed under the authority of title XIX of the Act and subject to the budget neutrality expenditure limit must be reported each quarter on separate Forms CMS-64.9 Waiver and/or CMS-64.9P Waiver, identified by the demonstration project number (11-W-00307/3) assigned by CMS, including the project number extension, which indicates the DY in which services were rendered.

    b. **Cost Settlements.** For monitoring purposes, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (form CMS-64.9P Waiver) for the summary sheet line 10B, in lieu of lines 9 or 10C. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual.

    c. **Pharmacy Rebates.** The state may propose a methodology for assigning a portion of pharmacy rebates to the demonstration services, in a way that reasonably reflects the actual rebate-eligible pharmacy utilization of those populations, and which reasonably identifies pharmacy rebate amounts with DYs. Use of the methodology is subject to the approval in advance by the CMS Regional Office, and changes to the methodology must be approved in advance by the Regional Office. A portion of pharmacy rebates assigned to the demonstration using the approved methodology will be reported on the appropriate Forms CMS-64.9 Waiver for the demonstration and not on any other CMS-64.9 form to avoid double-counting. Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.

d. **Use of Waiver Forms.** For each DY, separate Forms CMS-64.9 Waiver and/or CMS-64.9P Waiver shall be submitted reporting expenditures for individuals enrolled in the demonstration, subject to the budget neutrality limit (Section VIII of these (STCs). The state must complete separate waiver forms for the following eligibility group/waiver names:

   i. EG 1 – "SUD IMD" – This EG corresponds to Expenditure Authority #1 (Residential Treatment for Individuals with SUD) which includes all medical assistance expenditures including residential treatment costs with dates of service in a month when the beneficiary was a patient in an IMD.

   ii. EG 2 – "Methadone and Peer Support" – This EG corresponds to Expenditure Authorities #2 (Methadone Treatment) and #3 (Peer Recovery Support Services) which includes the PMPM cost of methadone and peer recovery support services.

45. **Title XIX Administrative Costs.** Administrative costs will not be included in the budget neutrality agreement, but the state must separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on Forms CMS-64.10 Waiver and/or CMS-64.10P Waiver. Administrative costs that are directly attributable to the demonstration must be reported under waiver name "SUD Admin."

46. **Claiming Period**. All claims for expenditures subject to the budget neutrality expenditure limit (including any cost settlements) must be made within two (2) years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be made within two (2) years after the conclusion or termination of the demonstration. During the latter two (2) year period, the state must continue to identify separately net expenditures related to dates of service during the operation of the section 1115 demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.

47. **Reporting Member Months**. The following describes the reporting of member months for the demonstration:

    a. For the purpose of calculating the budget neutrality expenditure limit, the state must provide to CMS, as part of the quarterly and annual reports as required under STC 25, the actual number of eligible member months for all demonstration expenditures. The state must submit a statement accompanying the quarterly and annual reports, certifying the accuracy of this information.

    b. The term "eligible member months" refers to the number of months in which persons

enrolled in the demonstration are eligible to receive services. For example, for EG 1 "IMD"/ Expenditure Authority #1 Residential Treatment for Individuals with SUD, member months are months of Medicaid eligibility during which the individual is an inpatient in an IMD under the terms of the demonstration for any day during the month. For EG 2 "Methadone and Peer Support," member months are all Medicaid eligible member months for Medicaid populations eligible for the SUD demonstration that are not EG 1 "IMD" member months.

48. **Standard Medicaid Funding Process.** The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable Medicaid expenditures on the quarterly Form CMS-37. In addition, the estimate of matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each FFY on the Form CMS-37 (narrative section) for both the Medical Assistance Payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within thirty (30) days after the end of each quarter, the state must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter just ended. CMS shall reconcile expenditures reported on the Form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

49. **Extent of Federal Financial Participation for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS shall provide FFP at the applicable federal matching rates for the demonstration as a whole as outlined below, subject to the budget neutrality limits described in section VIII.

    a. Administrative costs, including those associated with the administration of the demonstration; and

    b. Net expenditures and prior period adjustments, made under approved Expenditure Authorities granted through section 1115(a)(2) of the Act, with dates of service during the operation of the demonstration and consistent with the applicable STC requirements.

50. **Sources of Non-Federal Share.** The state must certify that matching non-federal share of funds for the demonstration are state/local monies. The state further assures that such funds shall not be used as the match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval

    a. CMS may review at any time the sources of the non-federal share of funding for the demonstration. The state agrees that all funding sources deemed unacceptable

by CMS shall be addressed within the time frames set by CMS.

b. Any amendments that impact the financial status of the program shall require the state to provide information to CMS regarding all sources of the non-federal share of funding.

51. **State Certification of Funding Conditions**. The state must certify that the following conditions for non-federal share of demonstration expenditures are met:

a. Units of government, including governmentally operated health care providers, may certify that state or local tax dollars have been expended as the non-federal share of funds under the demonstration.

b. To the extent the state utilizes certified public expenditures (CPEs) as the funding mechanism for title XIX (or under section 1115 authority) payments, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.

c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for payments under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such tax revenue (state or local) used to satisfy demonstration expenditures. The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.

d. The state may use intergovernmental transfers to the extent that such funds are derived from state or local tax revenues and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments. Under all circumstances, health care providers must retain one hundred (100) percent of the claimed expenditure. Moreover, no pre-arranged agreements (contractual or otherwise) exist between health care providers and state and/or local government to return and/or redirect any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, (including health care provider-related taxes), fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

52. **Program Integrity.** The state must have processes in place to ensure that there is no duplication of federal funding for any aspect of the demonstration.

VIII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

53. **Limit on Title XIX Funding.** The state must be subject to a limit on the amount of federal title XIX funding that the state may receive on approved demonstration service expenditures incurred during the period of approval of the demonstration. The limit is determined by using a per capita cost method, and budget neutrality expenditure caps are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. The data supplied by the state to CMS to set the annual caps is subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit. CMS' assessment of the state's compliance with these annual limits will be done using the Schedule C report from the CMS-64.

54. **Risk.** The state must be at risk for the per capita cost (as determined by the method described below) for demonstration eligibles under this budget neutrality agreement, but not for the number of demonstration eligibles. Because CMS provides FFP for all demonstration eligibles, West Virginia must not be at risk for changing economic conditions that impact enrollment levels. However, by placing West Virginia at risk for the per capita costs for current eligibles, CMS assures that the federal demonstration expenditures do not exceed the level of expenditures had there been no demonstration.

55. **Budget Neutrality Expenditure Limit.** The budget neutrality test includes an allowance for hypothetical services. The expected costs of the hypothetical services are reflected in the "without waiver" budget neutrality expenditure limit. The state must not accrue budget neutrality "savings" from the hypothetical services.

	Trend	**DY 1**	**DY 2**	**DY 3**	**DY 4**	**DY 5**
SUD IMD PMPM	5.4%	$2,807.11	$2,958.69	$3,118.46	$3,286.86	$3,464.35

Methadone and Peer Supports PMPM Note: The DY 1 PMPM includes six (6) rather than twelve (12 months of peer supports; and, as a result, the PMPM for this EG is lower in DY 1.	5.4%	$1.85	$3.32	$3.50	$3.69	$3.89

Composite Federal Share Ratio. The federal share of the budget neutrality expenditure limit is calculated by multiplying the limit times the Composite Federal Share. The Composite Federal Share is the ratio calculated by dividing the sum total of federal financial participation (FFP) received by the state on actual demonstration expenditures during the approval period, as reported through the Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) and summarized on Schedule C with consolidation of additional allowable demonstration offsets such as, but not limited to, premium collections and pharmacy rebates, by total computable demonstration expenditures for the same period as reported on the same forms. For the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed-upon method.

56. **Future Adjustments to the Budget Neutrality Expenditure Limit.** CMS reserves the right to adjust the budget neutrality expenditure limit to be consistent with enforcement of impermissible provider payments, health care related taxes, new federal statutes, or policy interpretations implemented through letters, memoranda, or regulations with respect to the provision of services covered under the demonstration.

57. **Enforcement of Budget Neutrality.** CMS will enforce budget neutrality over the life of this demonstration rather than on an annual basis. However, if the state's expenditures exceed the calculated cumulative budget neutrality expenditure cap by the percentage identified below for any of the demonstration years, the state must submit a corrective action plan to CMS for approval.

Demo Year	Cumulative Target Definition	Percentage
DY 1	DY 1 budget limit amount plus:	1.0 percent
DY 2	DYs 1 through 2 combined budget limit amount plus:	1.0 percent
DY 3	DYs 1 through 3 combined budget limit amount plus:	1.0 percent
DY 4	DYs 1 through 4 combined budget limit amount plus:	0.5 percent
DY 5	DYs 1 through 5 combined budget limit amount plus:	0 percent

IX. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

Date – Specific	Deliverable	STC Reference
150 days after approval March 4, 2018	Submit SUD Monitoring Plan Protocol	STC 19
180 days after approval April 3, 2018	Submit draft Evaluation Design	STC 32
60 days after CMS comments received	Submit revised Evaluation Design	STC 33
09/01/2022	Submit Draft Close Out Report	STC 27
Annual	By March 31 - Draft Annual Report	STC 25
Annual	Within 30 days of receipt of CMS comments – Final Annual Report	STC 25, 26
Quarterly	Quarterly Progress Reports	STC 25

Attachment A: Developing the Evaluation Design

Introduction

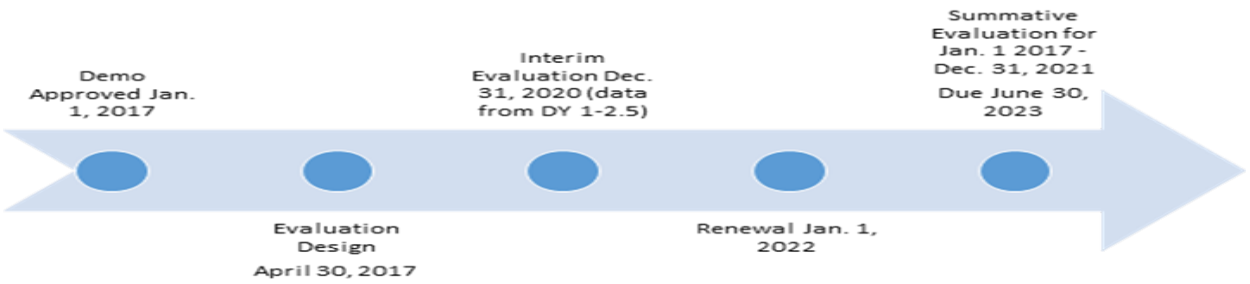
For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform both Congress and CMS about Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Designs

All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals**.**

The format for the Evaluation Design is as follows:
General Background Information;
Evaluation Questions and Hypotheses;
Methodology;
Methodological Limitations;
Attachments.

Submission Timelines
There is a specified timeline for the state's submission of Evaluation Design and Reports. (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within thirty (30) days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of All Evaluation Designs
The Evaluation Design sets the stage for the Interim and Summative Evaluation Reports. It is important that the Evaluation Design explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology (and limitations) for the evaluation. A copy of the state's Driver Diagram (described in more detail in paragraph B2 below) should be included with an explanation of the depicted information.

A. General Background Information – In this section, the state should include basic information about the demonstration, such as:

1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).

2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;

4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

5) Describe the population groups impacted by the demonstration.

B. Evaluation Questions and Hypotheses – In this section, the state should:

1. Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.

2. Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf

3. Identify the state's hypotheses about the outcomes of the demonstration:

4. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;

5. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

C. Methodology– In this section, the state is to describe in detail the proposed research methodology. The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

This section provides the evidence that the demonstration evaluation will use the best available data; reports on, controls for, and makes appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what will be measured and how. Specifically, this section establishes:

1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?

2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.

3) *Evaluation Period* – Describe the time periods for which data will be included.

4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and

submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:

a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
b. Qualitative analysis methods may be used, and must be described in detail.
c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

   If primary data (data collected specifically for the evaluation) – The methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection. (Copies of any proposed surveys must be reviewed with CMS for approval before implementation).

6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:

   a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.
   b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
   c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
   d. The application of sensitivity analyses, as appropriate, should be considered.

7) *Other Additions* – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

Table A. Example Design Table for the Evaluation of the Demonstration

Research Question	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
Hypothesis 1				
Research question 1a	-Measure 1 -Measure 2 -Measure 3	-Sample e.g. All attributed Medicaid beneficiaries -Beneficiaries with diabetes diagnosis	-Medicaid fee-for-service and encounter claims records	-Interrupted time series
Research question 1b	-Measure 1 -Measure 2 -Measure 3 -Measure 4	-sample, e.g., PPS patients who meet survey selection requirements (used services within the last 6 months)	-Patient survey	Descriptive statistics
Hypothesis 2				
Research question 2a	-Measure 1 -Measure 2	-Sample, e.g., PPS administrators	-Key informants	Qualitative analysis of interview material

D. Methodological Limitations – This section provides detailed information on the limitations of the evaluation. This could include the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize the limitations. Additionally, this section should include any information about features of the demonstration that effectively present methodological constraints that the state would like CMS to take into consideration in its review. For example:

1) When the state demonstration is:
    a. Long-standing, non-complex, unchanged, or
    b. Has previously been rigorously evaluated and found to be successful, or
    c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)

2) When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
    a. Operating smoothly without administrative changes; and
    b. No or minimal appeals and grievances; and
    c. No state issues with CMS-64 reporting or budget neutrality; and
    d. No Corrective Action Plans (CAP) for the demonstration.

E. Attachments

A. Independent Evaluator. The process the state will use for obtaining an independent entity to conduct the analysis and write the Evaluation Report, including a description of the qualifications the entity must possess. As soon as known, this section should be updated to include:
    a. Information about the organization conducting the evaluation;

b. Contact information for the organization, including how to obtain a copy of the evaluation;
c. The name and contact information of the Principal Investigator; and
d. Curriculum Vitae of the Principal Investigator.

B. No Conflict of Interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. This includes "No Conflict of Interest" signed conformation statements.

C. Evaluation Budget. A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.

D. Timeline and Major Milestones. Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

Attachment B: Preparing the Interim and Summative Evaluation Reports

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provide important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. As these valid analyses multiply (by a single state or by multiple states with similar demonstrations) and the data sources improve, the reliability of evaluation findings will be able to shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

Intent of this Guidance

The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Guidance is intended to assist states with organizing the required information in a standardized format and understanding the criteria that CMS will use in reviewing the submitted Interim and Summative Evaluation Reports.

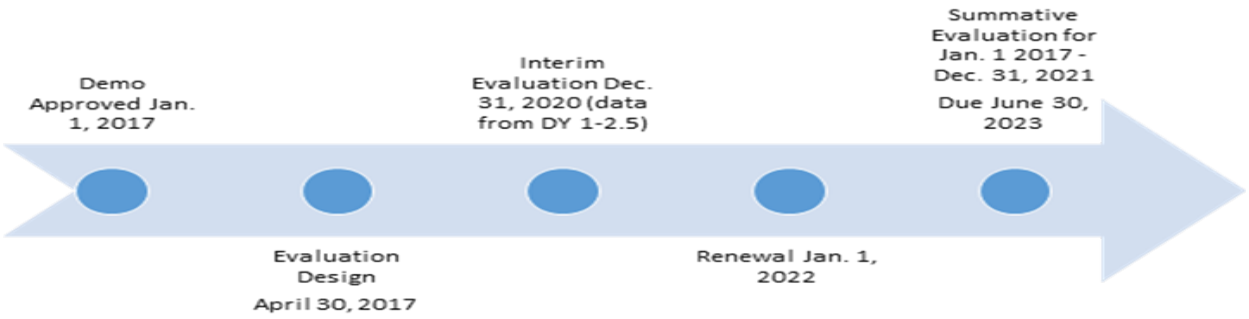
The format for the Interim and Summative Evaluation reports is as follows:

A. Executive Summary;
B. General Background Information;
C. Evaluation Questions and Hypotheses;
D. Methodology;
E. Methodological Limitations;
F. Results;

G. Conclusions;
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
I. Lessons Learned and Recommendations; and
J. Attachment(s).

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish to the state's website the evaluation design within thirty (30) days of CMS approval, and publish reports within thirty (30) days of submission to CMS , pursuant to 42 CFR 431.424. CMS will also publish a copy to Medicaid.gov.



Required Core Components of Interim and Summative Evaluation Reports

The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. A copy of the state's Driver Diagram (described in the Evaluation Design guidance) must be included with an explanation of the depicted information. The Evaluation Report should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. Therefore, the state's submission must include:

A. Executive Summary – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.

B. General Background Information about the Demonstration – In this section, the state should include basic information about the demonstration, such as:

1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
5) Describe the population groups impacted by the demonstration.

C. Evaluation Questions and Hypotheses – In this section, the state should:
1) Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
2) Identify the state's hypotheses about the outcomes of the demonstration;
   a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
   b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
   c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

D. Methodology – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design. The evaluation design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An interim report should provide any available data to date, including both quantitative and qualitative assessments. The Evaluation Design should assure there is appropriate data development and collection in a timely manner to support developing an interim evaluation.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to

explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1. *Evaluation Design* – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?
2. *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.
3. *Evaluation Period* – Describe the time periods for which data will be collected
4. *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?
5. *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data.
6. *Analytic methods* – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
7. *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.

A. Methodological Limitations

This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.

B. Results – In this section, the state presents and uses the quantitative and qualitative data to show to whether and to what degree the evaluation questions and hypotheses of the demonstration were achieved. The findings should visually depict the demonstration results (tables, charts, graphs). This section should include information on the statistical tests conducted.

C. Conclusions – In this section, the state will present the conclusions about the evaluation results.

1) In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?

2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:
   a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

D. Interpretations, Policy Implications and Interactions with Other State Initiatives – In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long range planning. This should include interrelations of the demonstration with other aspects of the state's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretation of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

E. Lessons Learned and Recommendations – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

1. What lessons were learned as a result of the demonstration?
2. What would you recommend to other states which may be interested in implementing a similar approach?

F. Attachment

Evaluation Design: Provide the CMS-approved Evaluation Design

Attachment C: SUD Monitoring Plan Protocol

July 5th, 2018

***Note:** This template is being finalized for review and approval by OMB. It is structured for easy and consistent use by states and will facilitate cross-state assessment and the identification of trends, challenges and best practices to support learning collaboration and policy / operations enhancements as may be needed. Until such time, its use is optional, although it conveys the nature and extent of monitoring information that CMS is seeking on SUD demonstrations, and the state's comments on its structure and ease of use are helpful in finalizing it. The SUD STCs require the state's compliance with Federal Systems Updates. As federal systems continue to evolve and incorporate additional 1115 waiver reporting and analytics functions, the state is required to work with CMS to:*

a. *Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;*
b. *Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and*
c. *Submit deliverables to the appropriate system as directed by CMS.*

When this template is OMB approved, then the state will be required to use it.

1. Transmittal Title Page for the State's SUD Demonstration or SUD Components of Broader Demonstration

The state should complete this Transmittal Title Page as part of its SUD Monitoring Protocol. This form should be submitted as the title page of all Monitoring Reports. The content of this transmittal table should stay consistent over time.

State	West Virginia
Demonstration Name	West Virginia Continuum of Care for Medicaid Enrollees with Substance Use Disorders (Project Number: 11 – W – 00307/3)
Approval Date	October 6, 2017
Approval Period	January 1, 2018 through December 31, 2022
SUD (or if broader demonstration, then SUD Related) Demonstration Goals and Objectives	Under this demonstration, the State expects to achieve the following to promote the objectives of Title XIX: • 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 American Society of Addiction Medicine (ASAM®) Criteria • Decrease medically inappropriate and avoidable utilization of high-cost emergency department (ED) and hospital services by enrollees with SUD • Improve care coordination and care transitions for Medicaid enrollees with SUD.

2. Proposed Modifications to SUD Narrative Information on Implementation, by Reporting Topic

Summary of proposed modification	Related metric (if any)	Justification for modification
1. Assessment of Need and Qualification for SUD Services		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
2. Access to Critical Levels of Care for OUD and other SUDs (Milestone 1)		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
3. Use of Evidence-based, SUD-specific Patient Placement Criteria (Milestone 2)		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
4. Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities (Milestone 3)		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
5. Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment for OUD (Milestone 4)		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		

☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).
6. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD (Milestone 5)
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).
7. Improved Care Coordination and Transitions between Levels of Care (Milestone 6)
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).
8. SUD Health Information Technology (Health IT)
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).
9. Other SUD-Related Metrics
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).
10. Budget Neutrality
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).

11. SUD-Related Demonstration Operations and Policy
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).
12. SUD Demonstration Evaluation Update
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).
13. Other Demonstration Reporting
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).
14. Notable State Achievements and/or Innovations
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).

3. Acknowledgement of Budget Neutrality Reporting-

☒ The state has reviewed the Budget Neutrality workbook provided by the project officer and understands the expectations for quarterly and annual monitoring reports. The state will provide the requested budget neutrality information (no modifications).

4. SUD Demonstration Monitoring Reporting Schedule

Report name:	DY1 Q1 report	DY1 Q2 report	DY1 Q3 report	DY1 Q4 (annual) report	DY2 Q1 report
Report due date:	Due 60 days after quarter ends	Due 60 days after quarter ends	Due 60 days after quarter ends	Due 90 days after quarter ends	Due 60 days after quarter ends
Measurement Periods, by type of metric/information					
Narrative information	DY1 Q1	DY1 Q2	DY1 Q3	DY1 Q4	DY2 Q1
Grievances and appeals metrics	DY1 Q1	DY1 Q2	DY1 Q3	DY1 Q4	DY2 Q1
Claims-based or state-identified monthly and quarterly metrics	NA	DY1 Q1	DY1 Q2	DY1 Q3	DY1 Q4
Annual CMS-constructed or state-identified metrics (calculated for demonstration year)	NA	NA	NA	NA	DY1
Annual metrics that are established quality measures (calculated for calendar year)	NA	NA	NA	DY1 (Q1-Q4): if state's DY ends 1/30 – 12/30	DY1 (Q1-Q4): if state's DY ends 12/31 – 1/29

Medicaid Section 1115 SUD Demonstration Monitoring Protocol

State: West Virginia
Demonstration Name: West Virginia Creating a Continuum of Care for Medicaid Enrollees with Substance Use Disorders
Submitted on: 5/30/2019 Revised

State will report (Y/N)	Reporting priority	#	CMS Metric name	CMS Metric description	Data source	Measurement period	Reporting frequency	Baseline Reporting Period (MM/DD/YYYY--MM/DD/YYYY)	Annual goal	Overall demonstration target	Attest that planned reporting matches the CMS-provided specification (Y/N)	Explanation of any deviations from CMS specifications	Demonstration Year and Quarter in which reporting will begin (DY1Q3)	Explanation of any plans to phase in reporting over time
Assessment of need and qualification for SUD treatment services														
Y	Recommended	1	Assessed for SUD Treatment Needs Using a Standardized Screening Tool	Number of beneficiaries screened for SUD treatment needs using a standardized screening tool during the measurement period	Medical record review or claims	Month	Quarterly	1/1/2018 - 12/31/2018	20%	Increase	N	The Criminal Justice subpopulation cannot be identified at this time.	DY3Q1	N/A
Y	Recommended	2	Medicaid Beneficiaries with Newly Initiated SUD Treatment/Diagnosis	Number of beneficiaries with a SUD diagnosis and a SUD-related service during the measurement period but not in the three months before the measurement period	Claims	Month	Quarterly	1/1/2018 - 12/31/2018	5%	Increase	N	The Criminal Justice subpopulation cannot be identified at this time.	DY3Q1	N/A
Y	Required	3	Medicaid Beneficiaries with SUD Diagnosis (monthly)	Number of beneficiaries with a SUD diagnosis and a SUD-related service during the measurement period and/or in the 11 months before the measurement period	Claims	Month	Quarterly	1/1/2018 - 12/31/2018	1%	Decrease	N	The Criminal Justice subpopulation cannot be identified at this time.	DY3Q1	N/A
Y	Required	4	Medicaid Beneficiaries with SUD Diagnosis (annually)	Number of beneficiaries with a SUD diagnosis and a SUD-related service during the measurement period and/or in the 12 months before the measurement period	Claims	Year	Annually	1/1/2018 - 12/31/2018	1%	Decrease	Y	The cause of delay for this metric is that this is a annual metric, and the December data will not be loaded into the system until February of the following year. The State will have some of the data available, but not all data will be loaded in the system. This will delay all fourth quarter reports.	DY3Q1	There will be a delay of Q4, which will be reported in Q2 of the following demonstration year
Y	Required	5	Medicaid Beneficiaries Treated in an IMD for SUD	Number of beneficiaries with a claim for residential treatment for SUD in an IMD during the reporting year	Claims	Year	Annually	1/1/2018 - 12/31/2018	5%	Increase	Y	The cause of delay for this metric is that this is a annual metric, and the December data will not be loaded into the system until February of the following year. The State will have some of the data available, but not all data will be loaded in the system. This will delay all fourth quarter reports.	DY3Q1	There will be a delay of Q4, which will be reported in Q2 of the following demonstration year
Milestone 1: Access to critical levels of care for OUD and other SUDs														
Y	Required	6	Any SUD Treatment	Number of beneficiaries enrolled in the measurement period receiving any SUD treatment service, facility claim, or pharmacy claim during the measurement period	Claims	Month	Quarterly	1/1/2018 - 12/31/2018	5%	Increase	N	The Criminal Justice subpopulation cannot be identified at this time.	DY3Q1	N/A
Y	Required	7	Early Intervention	Number of beneficiaries who used early intervention services (such as procedure codes associated with SBIRT) during the measurement period	Claims	Month	Quarterly	1/1/2018 - 12/31/2018	5%	Increase	N	The Criminal Justice subpopulation cannot be identified at this time. WV utilizes the follow codes for SBIRT services: H0031, 90791, 90792 Services billed with these state-specific codes include a screening for SUD. SBIRT is part of the documentation requirement for the noted codes, and is performed once yearly for ages 10 and up.	DY3Q1	N/A
Y	Required	8	Outpatient Services	Number of beneficiaries who used outpatient services for SUD (such as outpatient recovery or motivational enhancement therapies, step down care, and monitoring for stable patients) during the measurement period	Claims	Month	Quarterly	1/1/2018 - 12/31/2018	5%	Increase	N	The Criminal Justice subpopulation cannot be identified at this time.	DY3Q1	N/A
Y	Required	9	Intensive Outpatient and Partial Hospitalization Services	Number of unique beneficiaries who used intensive outpatient and/or partial hospitalization services for SUD (such as specialized outpatient SUD therapy or other clinical services) during the measurement period	Claims	Month	Quarterly	1/1/2018 - 12/31/2018 (Previously July 1 - June 30)	7%	Increase	N	The State is unable to currently run intensive outpatient claims in system. The State cannot identify intensive outpatient services in the system, and at this time there is no plan to change the system because it would require opening up the State Plan. The Criminal Justice subpopulation cannot be identified at this time.	DY3Q1	N/A
Y	Required	10	Residential and Inpatient Services	Number of beneficiaries who use residential and/or inpatient services for SUD during the measurement period	Claims	Month	Quarterly	1/1/2018 - 12/31/2018 (Previously July 1 - June 30)	10%	Increase	N	The Criminal Justice subpopulation cannot be identified at this time.	DY3Q1	N/A

State will report (Y/N)	Reporting priority	#	CMS Metric name	CMS Metric description	Data source	Measurement period	Reporting frequency	Baseline Reporting Period (MM/DD/YYYY–MM/DD/YYYY)	Annual goal	Overall demonstration target	Attest that planned reporting matches the CMS-provided specification (Y/N)	Explanation of any deviations from CMS specifications	Demonstration Year and Quarter in which reporting will begin (DY1Q3)	Explanation of any plans to phase in reporting over time
Y	Required	11	Withdrawal Management	Number of beneficiaries who use withdrawal management services (such as outpatient, inpatient, or residential) during the measurement period	Claims	Month	Quarterly	1/1/2018 - 12/31/2018	2% - 5%	Increase	N	The Criminal Justice subpopulation cannot be identified at this time.	DY3Q1	Will report in DY3
Y	Required	12	Medication Assisted Treatment	Number of beneficiaries who have a claim for MAT for SUD during the measurement period	Claims	Month	Quarterly	1/1/2018 - 12/31/2018	5%	Increase	N	The Criminal Justice subpopulation cannot be identified at this time.	DY3Q1	N/A
Y	Required	36	Average Length of Stay in IMDs	The average length of stay for beneficiaries discharged from IMD residential treatment for SUD	Claims; State-specific IMD database	Year	Annually	1/1/2018 - 12/31/2018	2%	Decrease	N	Data source will only be claims for West Virginia The State only pays for in-state IMD stays. The cause of delay for this metric is that this is a annual metric, and the December data will not be loaded into the system until February of the following year. The State will have some of the data available, but not all data will be loaded in the system. This will delay all fourth quarter reports.	DY3Q1	There will be a delay of Q4, which will be reported in Q2 of the following demonstration year
Milestone 2: Use of evidence-based, SUD-specific patient placement criteria														
Y	State Identified	S.1	State-Defined: The State will follow nationally-recognized evidence based guidelines for use of evidence-based, SUD-specific patient placement criteria	The State will follow The American Society of Addiction Medicine (ASAM) Criteria for SUD-specific patient placement critiera for Levels of Care 2.1 and higher.	N/A	N/A	N/A	N/A	N/A	N/A			N/A	N/A
Milestone 3: Use of nationally recognized SUD-specific program standards to set provider qualifications for residential treatment facilities														
Y	State Identified	S.2	State-Defined: The State will follow nationally-recognized evidence based practice guidelines for the use of recognized SUD-specific program standards to set provider qualifications for residential treatment facilities	The State will follow The American Society of Addiction Medicine (ASAM) Criteria for SUD-specific patient placement critiera for Levels of Care 2.1 and higher.	N/A	N/A	N/A	N/A	N/A	N/A			N/A	N/A
Milestone 4: Sufficient provider capacity at critical levels of care including for medication assisted treatment for OUD														
Y	Required	13	SUD Provider Availability	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period	Provider enrollment database; Claims	Year	Annually	1/1/2018 - 12/31/2018	Increase	1%	Y	The State can conduct a count of all physicians, PAs, APRNs, psychologists, LICSWs, PLCs, day report centers, CACs, and LBHCs	DY3Q1	N/A
Y	Required	14	SUD Provider Availability - MAT	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period and who meet the standards to provide buprenorphine or methadone as part of MAT	Provider enrollment database; Claims; SAMHSA datasets	Year	Annually	1/1/2018 - 12/31/2018	Increase	8%	Y	The State will provide a list of the SAMHSA approved MAT providers West Virginia State Code has established a moratorium on enrolling both in-state and out-of-state OTPs. Therefore, the number of OTPs is unlikely to change. The State will report all OTPs and enrolled buprenorphine providers but does not track individual physicians within the OTPs.	DY3Q1	N/A
Milestone 5: Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD														

State will report (Y/N)	Reporting priority	#	CMS Metric name	CMS Metric description	Data source	Measurement period	Reporting frequency	Baseline Reporting Period (MM/DD/YYYY–MM/DD/YYYY)	Annual goal	Overall demonstration target	Attest that planned reporting matches the CMS-provided specification (Y/N)	Explanation of any deviations from CMS specifications	Demonstration Year and Quarter in which reporting will begin (DY1Q3)	Explanation of any plans to phase in reporting over time
Y	Required	15	Initiation and Engagement of Alcohol and Other Drug (AOD) Dependence Treatment (IET) [NCQA; NQF #0004; Medicaid Adult Core Set]	1. Initiation of AOD Treatment—percentage of beneficiaries who initiated treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or MAT within 14 days of the diagnosis 2.Engagement of AOD Treatment—percentage of beneficiaries who initiated treatment and who had two or more additional AOD services or MAT within 34 days of the initiation visit	Claims	Year	Annually	1/1/2018 - 12/31/2018	5%	Increase	N	1. For the Initiation and Engagement numerators, HEDIS specifies that multiple visits that occur on the same day may be counted if the visits are with different providers. We cannot determine whether the providers are different, so we begin the check for visits on the day after the index episode or initiation event date, and only count engagement events on separate dates of service. T**he State confirms the use of claims to calculate the metrics. The State also confirms the ability to count multiple claims on the same date of service; however, the State cannot determine the different provider types for multiple claims on the same day due to how the measure is built in the reporting system.** 2. HEDIS specifies that Access/Availability of Care measures should utilize suspended, pending, and denied claims as well as paid claims. Only paid claims are utilized in our rule measure calculations. **Denied claims are not counted in the reporting system. This deviation exists across all quality measures and cannot be feasibly changed.** The cause of delay for this metric is that this is a annual metric, and the December data will not be loaded into the system until February of the following year. The State will have some of the data available, but not all data will be loaded in the	DY3Q1	There will be a delay of Q4, which will be reported in Q2 of the following demonstration year
Y	Required	18	Use of Opioids at High Dosage in Persons Without Cancer [PQA, NQF #2940; Medicaid Adult Core Set]	Rate per 1,000 beneficiaries age 18 and older included in the denominator without cancer who received prescriptions for opioids with a daily dosage greater than 120 morphine milligram equivalents for 90 consecutive days or longer. Patients in hospice are also excluded.	Claims	Year	Annually	1/1/2018 - 12/31/2018	1%	Decrease	Y	N/A	DY2Q3	TBD
N	Recommended	19	Use of Opioids from Multiple Providers in Persons Without Cancer [PQA; NQF #2950]	Rate per 1,000 beneficiaries included in the denominator without cancer who received prescriptions for opioids from four or more prescribers and four or more pharmacies.	Claims	Year	Annually	N/A	N/A	N/A	N/A	N/A	N/A	N/A
N	Recommended	20	Use of Opioids at High Dosage from Multiple Providers in Persons Without Cancer [PQA, NQF #2951]	Rate per 1,000 beneficiaries included in the denominator without cancer who received prescriptions for opioids greater than 120mg morphine equivalent dose (MED) for 90 consecutive days or longer, and from four or more prescribers and four or more pharmacies.	Claims	Year	Annually	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Y	Required	21	Concurrent Use of Opioids and Benzodiazepines [PQA]	Percentage of beneficiaries age 18 and older with concurrent use of prescription opioids and benzodiazepines. Patients with a cancer diagnosis or in hospice are excluded.	Claims	Year	Annually	1/1/2018 - 12/31/2018	1%	Decrease	Y	N/A	DY3Q1	TBD
Y	Required	22	Continuity of Pharmacotherapy for Opioid Use Disorder [RAND; NQF #3175]	Percentage of adults in the denominator with pharmacotherapy for OUD who have at least 180 days of continuous treatment	Claims	Year	Annually	1/1/2018 - 12/31/2018	1%	Increase	Y	N/A	DY3Q1	TBD
Milestone 6: Improved care coordination and transitions between levels of care														
N	Recommended	16	SUB-3 Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge [Joint Commission; NQF #1664]	SUB-3 rate: Patients who are identified with alcohol or drug use disorder who receive or refuse at discharge a prescription for FDA-approved medications for alcohol or drug use disorder, OR who receive or refuse a referral for addictions treatment. SUB-3a rate: Patients who are identified with alcohol or drug disorder who receive a prescription for FDA-approved medications for alcohol or drug use disorder OR a referral for addictions treatment.	Medical record review or claims	Year	Annually	N/A	N/A	N/A	N/A	N/A	N/A	N/A

State will report (Y/N)	Reporting priority	#	CMS Metric name	CMS Metric description	Data source	Measurement period	Reporting frequency	Baseline Reporting Period (MM/DD/YYYY--MM/DD/YYYY)	Annual goal	Overall demonstration target	Attest that planned reporting matches the CMS-provided specification (Y/N)	Explanation of any deviations from CMS specifications	Demonstration Year and Quarter in which reporting will begin (DY1Q3)	Explanation of any plans to phase in reporting over time
Y	Required	17	Follow-up after Discharge from the Emergency Department for Mental Health or Alcohol or Other Drug Dependence§ [NCQA; NQF #2605; Medicaid Adult Core Set]	Percentage of ED visits for beneficiaries who have a principal diagnosis of mental illness or AOD abuse or dependence and who had a follow-up visit for mental illness or AOD. Four rates are reported: **Percentage 1.** Percentage of ED visits for mental illness for which the beneficiary received follow-up within 7 days of the ED visit (8 total days). **Percentage 2.** Percentage of ED visits for mental illness for which the beneficiary received follow-up within 30 days of the ED visit (31 total days) **Percentage 3.** Percentage of ED visits for which the beneficiary received a follow-up visit for mental illness or AOD within 30 days of the ED visit (31 total days) **Percentage 4.** Percentage of ED visits for which the beneficiary received a follow-up visit for mental illness or AOD within 7 days of the ED visit (8 total days)	Claims	Year	Annually	1/1/2018 - 12/31/2018	5%	Increase	Y	Age restriction of 21-64 Upon further review, the age restriction is 18 -64 years of age	N/A	TBD
SUD health information technology (SUD health IT) (Insert at least one selected metric per key health IT question 1-3. See instructions document for further guidance.)														
Y	Required	S.3	Total number of PDMP users, number of checks	How information technology being used to slow down the rate of growth of individuals identified with SUD via PDMP checking by provider types (prescribers, dispensers)	PDMP	Year	Annually	1/1/2018 - 12/31/2018	2%	Increase	N/A	N/A	DY3Q1	TBD
Y	Required	S.4	Total number of telehealth/telemedicine visits with an SUD diagnosis	How information technology being used to treat effectively individuals identified with SUD via telehealth	Claims	Year	Annually	1/1/2018 - 12/31/2018	5%	Increase	N/A	N/A	DY3Q1	TBD
Y	Required	S.5	Total number of patients per 1,000 beneficiaries receiving concurrent MAT and therapy services	How information technology being used to effectively monitor "recovery" supports and services for individuals identified with SUD via tracking Medication-assisted treatment (MAT) (use of medications with counseling and behavioral therapies to treat substance use disorders and prevent opioid overdose	Claims	Year	Annually	1/1/2018 - 12/31/2018	5%	Increase	N/A	N/A	DY3Q1	TBD
Other SUD-related metrics														
Y	Required	23	Emergency Department Utilization for SUD per 1,000 Medicaid Beneficiaries	Total number of ED visits for SUD per 1,000 beneficiaries in the measurement period	Claims	Month	Quarterly	1/1/2018 - 12/31/2018	5%	Decrease	Y	N/A	DY3Q1	TBD
Y	Required	24	Inpatient Stays for SUD per 1,000 Medicaid Beneficiaries	Total number of inpatient stays per 1,000 beneficiaries in the measurement period	Claims	Month	Quarterly	1/1/2018 - 12/31/2018	10%	Decrease	Y	N/A	DY3Q1	TBD
Y	Required	25	Readmissions Among Beneficiaries with SUD	The number of acute inpatient stays among beneficiaries with SUD during the measurement period followed by an acute readmission within 30 days.	Claims	Year	Annually	1/1/2018 - 12/31/2018	5%	Decrease	N	1. The criteria specify that the enrollee should be age 18 years and older as of the date of discharge. We cannot determine age based on the discharge date, so we include enrollees age 18 years and older anytime during the reporting period. 2. The exclusion criteria have been simplified. We did not implement exclusion criteria for admissions in which there was a planned readmission within 30 days for kidney transplants or other organ transplants for the autologous pancreatic cells or for a potentially planned procedure without a principal acute diagnosis. We did include exclusion criteria for admissions in which the admission date was the same as the discharge date, for admissions for pregnancy or perinatal conditions, for stays in which the enrollee died, and for admissions in	DY3Q1	TBD
Y	Required	26	Overdose Deaths (count)	Number of overdose deaths during the measurement period among Medicaid beneficiaries living in a geographic area covered by the demonstration. States are encouraged to report the cause of overdose death as specifically as possible (for example, prescription vs. illicit opioid).	State data on cause of death	Year	Annually	1/1/2018 - 12/31/2018	1%	Decrease	Y	N/A	DY3Q1	TBD
Y	Required	27	Overdose Deaths (rate)	Rate of overdose deaths during the measurement period among adult Medicaid beneficiaries living in a geographic area covered by the demonstration. States are encouraged to report the cause of overdose death as specifically as possible (for example, prescription vs. illicit opioid).	State data on cause of death	Year	Annually	1/1/2018 - 12/31/2018	1%	Decrease	Y	N/A	DY3Q1	TBD
Y	Recommended	28	SUD Spending	Total Medicaid SUD spending during the measurement period.	Claims	Year	Annually	1/1/2018 - 12/31/2018	5%	Increase	Y	N/A	DY3Q1	TBD
Y	Recommended	29	SUD Spending Within IMDs	Total Medicaid SUD spending on residential treatment within IMDs during the measurement period	Claims	Year	Annually	1/1/2018 - 12/31/2018	5%	Decrease	Y	N/A	DY3Q1	TBD

State will report (Y/N)	Reporting priority	#	CMS Metric name	CMS Metric description	Data source	Measurement period	Reporting frequency	Baseline Reporting Period (MM/DD/YYYY--MM/DD/YYYY)	Annual goal	Overall demonstration target	Attest that planned reporting matches the CMS-provided specification (Y/N)	Explanation of any deviations from CMS specifications	Demonstration Year and Quarter in which reporting will begin (DY1Q3)	Explanation of any plans to phase in reporting over time
Y	Recommended	30	Per Capita SUD Spending	Per capita SUD spending during the measurement period	Claims	Year	Annually	1/1/2018 - 12/31/2018	5%	Increase	Y	N/A	DY3Q1	TBD
Y	Recommended	31	Per Capita SUD Spending Within IMDs	Per capita SUD spending within IMDs during the measurement period	Claims	Year	Annually	1/1/2018 - 12/31/2018	5%	Increase	Y	N/A	DY3Q1	TBD
Y	Required	32	Access to Preventive/ Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD	The percentage of Medicaid beneficiaries with SUD who had an ambulatory or preventive care visit during the measurement period.	Claims	Year	Annually	1/1/2018 - 12/31/2018	5%	Increase	Y	N/A	DY3Q1	TBD
N	Recommended	33	Grievances Related to SUD Treatment Services	Number of grievances filed during the measurement period that are related to SUD treatment services	Administrative records	Quarter	Quarterly	N/A	N/A	N/A	N/A	N/A	N/A	N/A
N	Recommended	34	Appeals Related to SUD Treatment Services	Number of appeals filed during the measurement period that are related to SUD treatment services	Administrative records	Quarter	Quarterly	N/A	N/A	N/A	N/A	N/A	N/A	N/A
N	Recommended	35	Critical Incidents Related to SUD Treatment Services	Number of critical incidents filed during the measurement period that are related to SUD treatment services	Administrative records	Quarter	Quarterly	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Evaluation Design

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

4/8/2020

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:

[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.

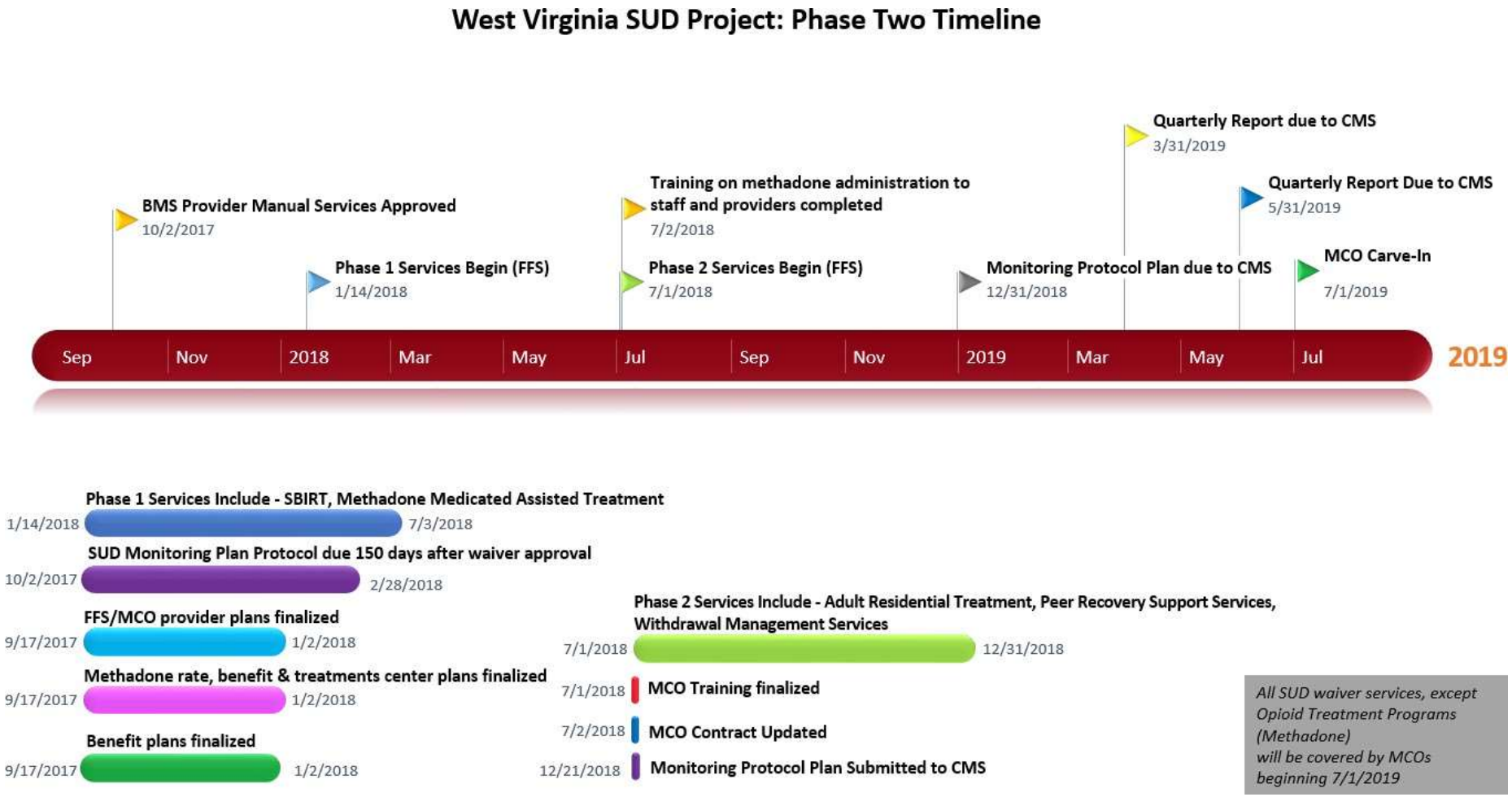
1. **Peer Recovery Support Services (PRSS):** These services are designed and delivered by individuals in recovery from SUD (peer recovery coaches), who provide counseling support to help prevent relapse and promote recovery. Services are provided by appropriately trained staff employed by Licensed Behavioral 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

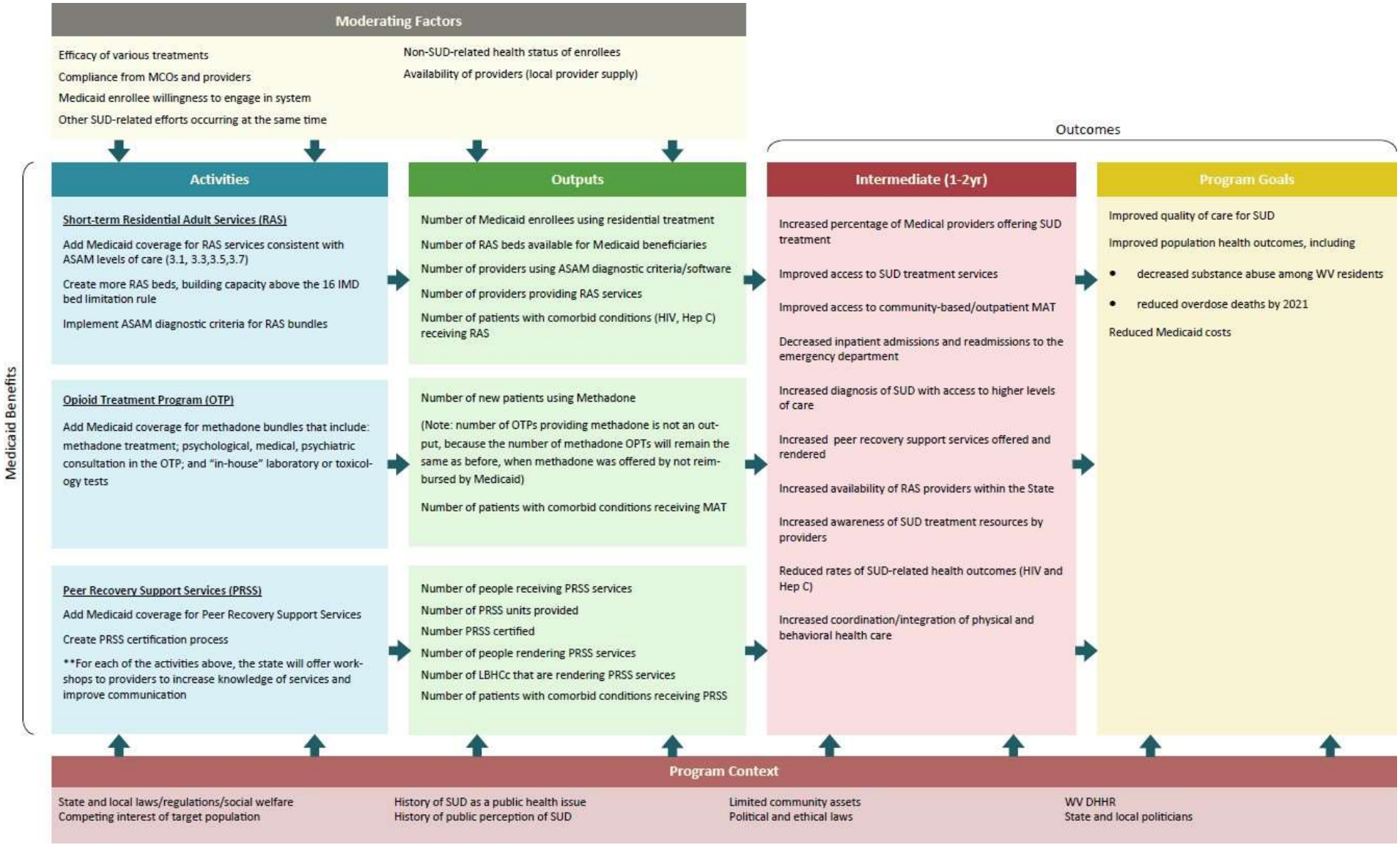
This demonstration is intended to impact West Virginia residents with SUD who are enrolled in Medicaid. In particular, the policy will target those who need services meeting ASAM levels of care 3.1-3.7, and those who were previously unable to afford methadone or PRSS services.

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). 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: Count 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: Count 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 with SUD, enrolled for any amount of time during the measurement period	Medicaid claims	Difference-in-differences

	Continuity of pharmacotherapy for OUD	NQF #3175	Number of participants who have at least 180 days of continuous pharmacotherapy with a medication prescribed for OUD without a gap of more than seven days	Individuals who had a diagnosis of OUD and at least one claim for an OUD medication	Claims data	Difference-in-differences
	Percentage of beneficiaries with an SUD diagnosis (including beneficiaries with an OUD diagnosis) who used SUD services per month	None	Number of enrollees who receive a service during the measurement period by service type	Number of enrollees	Claims data	Descriptive statistics, Difference-in-differences
	Time to treatment	NBHQF Goal 1	Sum of (date of clinical assessment- date of 1st contact)	Number of clinical assessments	Claims data	Descriptive statistics, difference-in-differences
	Rate of continuation of treatment	NBHQF Goal 1	Sum of (date of first treatment service-date of clinical assessment)	Number of enrollees receiving treatment	Claims data	Descriptive statistics, difference-in-differences
	Length of engagement in treatment	NBHQF Goal 1	Number of clients completing 4th treatment session within 30 days	Number of enrollees receiving treatment	Claims data	Descriptive statistics, 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. 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)	All Medicaid beneficiaries with SUD, enrolled for at least one month (30 consecutive days) during the measurement period. Number of beneficiaries/1000	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) [Note: this is to measure SUD morbidity, not treatment rates.]	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 [We are looking at the whole Medicaid population as a denominator, because transmission is not limited to needles.]	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 [We are looking at the whole Medicaid population as a denominator, because transmission is not limited to needles.]	Medicaid claims	Difference-in-differences
	Access to preventive / ambulatory health services for adult Medicaid beneficiaries with SUD	NCQA	Number of beneficiaries with SUD who had an ambulatory or preventive care visit during the measurement period	Number of beneficiaries with an SUD diagnosis	Claims data	Descriptive statistics, difference-in-differences

	Plan All-cause readmissions	None	At least one acute unplanned readmission for any diagnosis within 30 days of the date of discharge from the index hospital stay, that is on or between the second day of the measurement year and the end of the measurement year	Medicaid beneficiaries age 18 and older with a discharge from an acute inpatient stay (index hospital stay) on or between January 1 and December 1 of the measurement year	Claims data	Descriptive statistics, 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	All Medicaid beneficiaries with SUD, 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
			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 including 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 with SUD, 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 during the measurement period Step 1. Identify all claims for ED visits during the measurement period. 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 with SUD, 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 with SUD	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.	All Medicaid beneficiaries with SUD, enrolled 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 with SUD, enrolled for any amount of time during the measurement period	Medicaid claims	Difference-in-differences
Intermediate Outcome	Emergency department visits for SUD-related diagnoses and specifically for OUD	None (from page B.8 from CMS SMI/SED and SUD evaluation design guidance, Appendix B)	The number of ED visits for SUD during the measurement period	Beneficiaries enrolled in Medicaid for at least one month (30 consecutive days) 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 (and specifically for OUD)	Mathematica Policy Research Technical Specifications for Monitoring Metrics	Number of beneficiaries with an inpatient admission for SUD (and specifically for OUD)	Total number of beneficiaries/1,000 member months		Difference-in-differences
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.

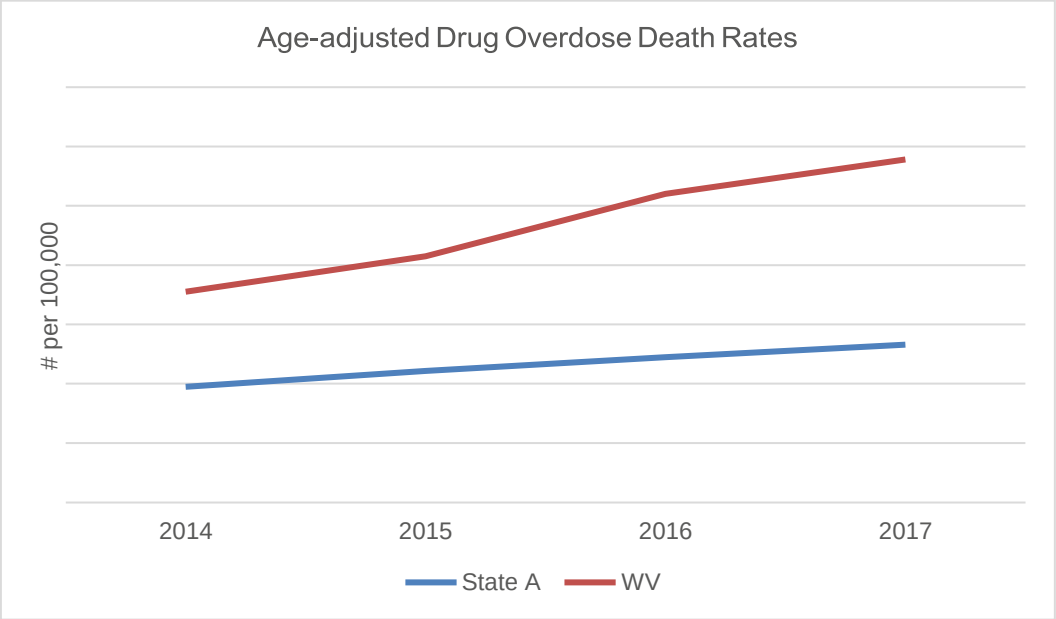
In assessing the congruency of State A with West Virginia, the N-SSATS was analyzed to denote similarities in SUD services provided by facilities that accept Medicaid payments. No statistically significant differences ($p > 0.05$) between State A and West Virginia were observed in the following SUD specific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

Basic Descriptive Analysis

Though the focus of our evaluation design approach is our difference-in-differences analysis using our comparison state, we appreciate that it will be helpful to CMS and BMS to have a set of descriptive analyses that will allow for “apples-to-apples” comparison to trends in other states. Therefore, for all of the measures possible (describe in Table 1), we will provide descriptive data, including frequencies/rates or percentages, at the monthly level. We will use tests of significance (such as t-tests, chi-square tests, etc.) comparing outcomes after the waiver to those before of the waiver.

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.

Our general difference-in-differences model is:

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

Where:

Y is the outcome.

TREATMENT is the indicator that equals 1 for a beneficiary in the treatment group, 0 if in the comparison group.

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

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

The coefficient B3 on this **interaction term** is the estimate of the treatment effect under the common trend assumption.

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). Table 4, modeled on Table C.1 in Appendix C of the SUD evaluation design guidance provides detail on the types of costs we will examine, and proposed data sources.

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. 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. 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.

We will follow the preferred difference-in-differences model outlined in the SUD Evaluation Guidance:

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

Where:

TREATMENT is the indicator that equals 1 for a beneficiary in the treatment group, 0 if in the comparison group.

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

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

We will interpret the outcomes from the model above in accordance with the SUD Evaluation Guidance: “The outputs generated from the D-in-D model demonstrate the trends in PMPM costs in the treatment and comparison groups over time from before and after the demonstration began, including whether the rate of change differs in each of the groups. If the average marginal effect of the interaction term (β3*TREATMENT*POST) is a positive dollar amount, then the demonstration is associated with a statistically significant increase in costs relative to the comparison group trend, whereas if the interaction term is a negative dollar amount, then the demonstration is associated with a statistically significant decrease in costs relative to the comparison group trend.”

However, we also note, that β_2 —the coefficient on the post period indicator— may also be of interest because it identifies changes in the level of costs immediately after the intervention began, and because it may also be more easily compared to results from other states. To ensure anyone interested receives this information, we will report full regression results in, for example, manuscripts appendices..

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 Tables 5 and 6 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. Cost Outcome Measures

Level of Analysis	Type of Costs	Description/Data Source
Total Costs	Total costs	Sum of IP, OP, Rx, Residential/IMD, LT costs, administrative costs
	Total federal costs	Total Medicaid costs * Federal medical assistance percentage (FMAP) for WV [NOTE: We will use the appropriate FMAP from Form CMS -64]
Costs related to diagnosis and treatment	SUD-IMD costs	IMD costs reported from claims with SUD diagnosis and/or procedure codes
	Other SUD costs	Costs with SUD diagnosis and/or procedure code from claims data
	Non-SUD costs	Costs without SUD diagnosis and/or procedure code from claims data
Source of treatment cost drivers for beneficiaries in the SUD population	Outpatient costs, non-ED	OP claims data file
	Outpatient costs, ED	OP claims data file
	Inpatient costs	IP claims data file
	Pharmacy costs	Drug claims data file
	Long-term care costs	Facility Header/Detail claims data files
	Residential/IMD costs	Facility Header/Detail claims data files

Table 5. 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				

[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 6. 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.

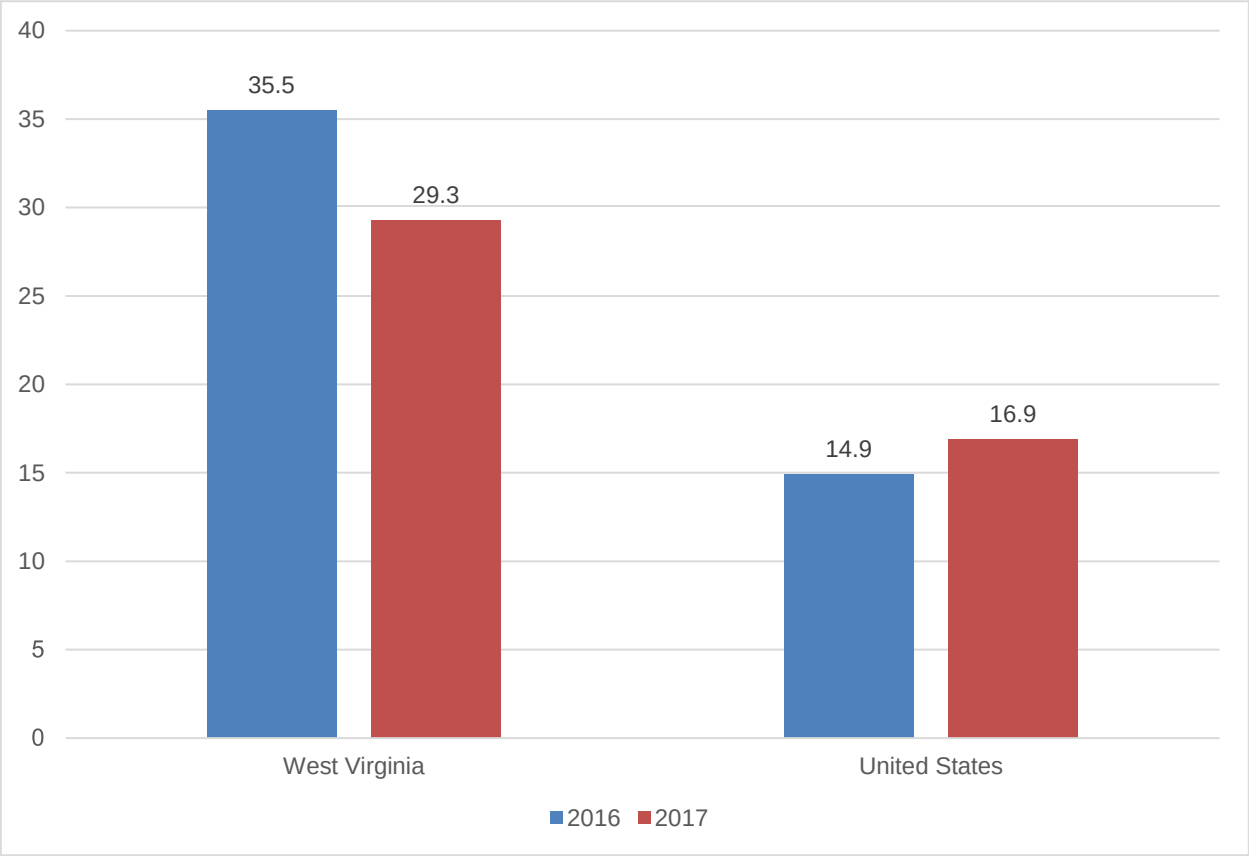
Benchmarking and State Trends Comparison

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

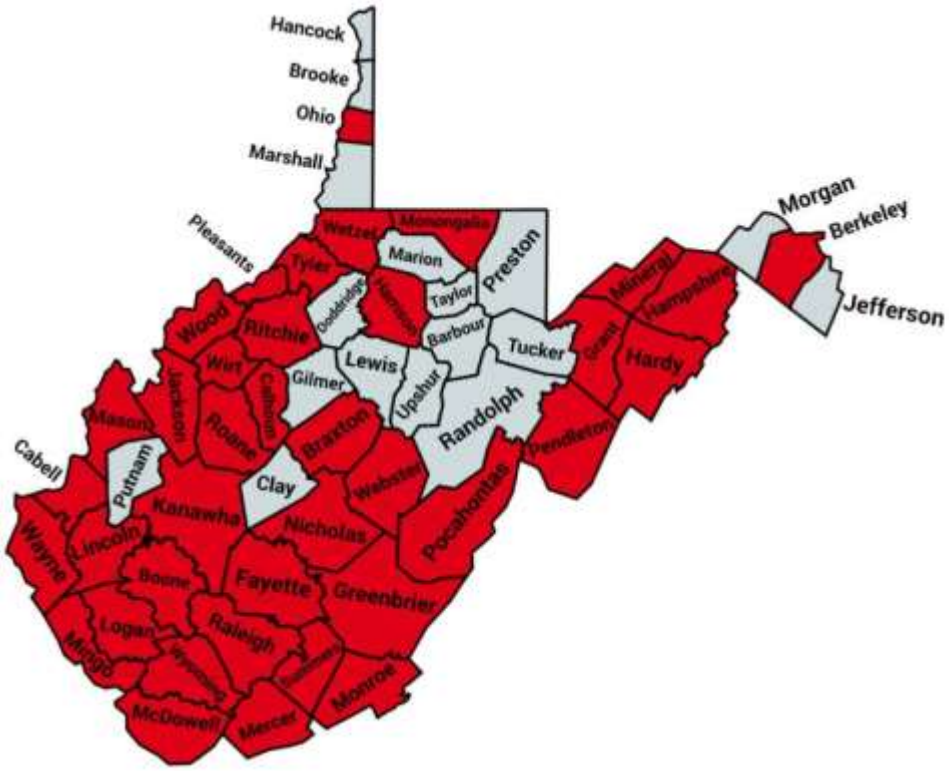
Organization	Grant	Counties Served	Funds	# of PRSS
Living Free Ohio Valley	STR	Ohio	$120,000	3
Marshall University	SOR	Cabell	Unk	Unk
Marshall University	SOR	Cabell,Lincoln, Logan, Mason, Mercer, Mingo, McDowell, Wyoming	Unk	Unk
Marshall University	PHCR	Fayette and Mason	$80,000	2
Milan Puskar Health 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

Appendix I: Thomas K. Bias - Curriculum Vitae (304)
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Professional Positions

2017-Present **Associate Professor**, Department of Health Policy, Management, and Leadership, West Virginia University School of Public Health

2016-Present **Director,** Health Research Center, West Virginia University School of Public Health

2013-2017 **Assistant Professor**, Department of Health Policy, Management, and Leadership, West Virginia University School of Public Health

2013-2016 **Interim Co-Director,** Health Research Center, West Virginia University School of Public Health.

2011-2013 **Research Instructor**, Department of Health Policy, Management, and Leadership, West Virginia University School of Public Health.

2011 **Research Associate**, Health Research Center, West Virginia University

2010-2011 **Research Specialist II,** Program Evaluation Unit, West Virginia Division of Rehabilitation Services, Department of Education and the Arts.

Education

PhD, West Virginia University, 2010.
Major: Political Science
Dissertation: *The Politics and Public Policy of Small City Downtown Redevelopment*

MA, West Virginia University, 2006.
Major: Political Science

BA, West Virginia University, 2004.
Major: Political Science

RESEARCH

Refereed Journal Articles

*=Student Collaborator

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Agarwal, P*., **Bias, T.**, Vasile, E., Moore L., Davis S.*, Davidoff, D. (2015). Exploring Health Insurance Status and Emergency Department Utilization. *Health Services Research and Managerial Epidemiology.* Published Online.

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Pilkerton, C*., Singh, S*., **Bias, T.**, and Frisbee, S. (2015). Changes in Cardiovascular Health in the United States, 2003-2011. *Journal of the American Heart Association.* 4(9).

Bias, T., Leyden K., and Zimmerman, J.* (2015). Exploring Policymaker Perceptions of Small City Downtowns in the United States. *Planning Practice and Research.* 30(5), 497-513.

Pilkerton, C.*, **Bias, T**. (2015). Evaluation of West Virginia's Health Lifestyles Act Physical Education Component Using YRBS. *Journal of Physical Activity and Health*. 12(5), 655-658.

Bias, T., Fitzgerald, M.P., Agarwal, P.*, and Vasile, E. (2015). Awareness and Interest in the West Virginia Health Insurance Marketplace. *Population Health Management.* 18(4), 307-313.

Bias, T., Fitzgerald, M. P., Gurley-Calvez, T. (2015). Strategies for Policy Evaluation of Health Insurance Marketplaces. *Journal of Public Health Management and Practice,* 21(1), 62-68.

Bias, T., Goldberg, A., Hannum, T. M.* (2011). Catholics and the death penalty: Religion as a filter for political beliefs. Interdisciplinary Journal of Research on Religion. *Interdisciplinary Journal of Research on Religion,* 7(10), Online.

Bua-lam, P., **Bias, T.** (2011). Economic Impacts of WVDRS on consumers with significant disabilities:realistic return-on- investment models for state-federal VR programs. *Journal of Rehabilitation,* 77(3), 25-30.

Bua-Lam, P., **Bias, T.** (2011). Estimating Worklife return on investment of WVDRS youth and older consumers with significant disabilities. *Rehabilitation Administration,* 35, 17-36.

Bias, T., Leyden, K. M., Abildso, C., Reger-Nash, B., Bauman, A. (2010). The importance of being parsimonious: reliability of a brief community walkability assessment instrument. *Health and Place,* 16(4), 755–758.

Maddock, J. E., Reger-Nash, B., Heinrich, K., Leyden, K. M., **Bias, T.** (2009). Priority of activity-friendly community issues among key decision makers in Hawaii. *Journal of Physical Activity and Health,* 6(3), 386–390.

Leyden, K. M., Reger-Nash, B., Bauman, A., **Bias, T.** (2008). Changing the Hearts and Minds of Policymakers: An exploratory study associated with the West Virginia Walks Campaign. *American Journal of Health Promotion,* 22, 204-207.

Bias, T., Brisbin, R. A., Leyden, K. M. (2007). Citizen evaluations of West Virginia government: stability and change 1992-2006. *West Virginia Public Affairs Reporter,* 23, 2-6.

Sponsored Research

Principal Investigator, “Exploring Factors Related to Patient Retention at Camden Clark Hospital”. Sponsored by Camden Clark Hospital. $5,000. (July 2017-December 2017)

Principal Investigator, “West Virginia United Health System Community Health Needs Assessments”. Sponsored by West Virginia United Health System. $330,000. (January 2017-December 2019).

Co-Investigator, “Impact of Rail Trails on Economic Development and Community Health,” Sponsored by the Rails-to-Trails Conservancy. $23,027. (August 2016 - February 2017).

Principal Investigator, “Garrett County Opioid Project Evaluation Technical Assistance,” Sponsored by the Garrett County Health Department. $25,000. (August 2016 - June 2018).

Principal Investigator, “St. Joseph’s Hospital Community Health Needs Assessment”. Sponsored by St. Joseph’s Hospital. $20,000. (January - October 2016).

Principal Investigator, “United Health Center Community Health Needs Assessment”. Sponsored by United Health Center. $17,000. (May - December 2016).

Principal Investigator, “Belington On-TRAC Technical Assistance”. Sponsored by the West Virginia Development Office, $1,000. (May 2016).

Principal Investigator, “Technical Assistance for On-TRAC Growing Healthy Communities Grantees”, Sponsored by the West Virginia Development Office, $24,000. (January 2016 - March 2016).

Co-Principal Investigator, “Ruby Memorial Hospital Community Health Needs Assessment”. Sponsored by Ruby Memorial Hospital, $20,000. (October 2015 - June 2016).

Principal Investigator, “Strategic Planning for the Garrett County Maryland Opioid Management Program”, Sponsored by the Garrett County Maryland Health Department, $12,500. (September 2015 - August 2016).

Principal Investigator, “Evaluation of the West Side LAUNCH Project”, Sponsored by the West Virginia Bureau for Public Health, $400,000. (October 2014 - September 2018).

Co-Principal Investigator, “Evaluation of the West Virginia Home Visitation Domestic Violence Screenings”, $387,000. (September 2014 - September 2016).

Co-Investigator, “Evaluation of the West Virginia Fatherhood Involvement Initiative”, $350,000. (March 2015 - February 2017). .

Principal Investigator, “Community Needs Assessment on Opioid Abuse and Misuse in Garrett County, Maryland,” Sponsored by the Garrett County Health Department, $11,500. (March 2015 - June 2015).

Principal Investigator, “Growing Healthy Communities Evaluation and Health Impact Assessment Training,” Sponsored by the Claude Worthington Benedum Foundation, $60,000. (January 2015 - December 2015).

Principal Investigator, "Health Impact Assessment in Fairmont, WV," Sponsored by Association of State and Territorial Health Officials/Centers for Disease Control and Prevention, $20,000. (January 2014 - June 2014).

Co-Investigator, “Prevention Drug Overdose - Prevention for States,” Sponsored by the US Centers for Disease Control and Prevention/WV Department of Health and Human Resources. $281,848 (September 2014 - February 2018).

Principal Investigator, later Co-Principal Investigator, "Evaluation of WV Perinatal Oral Health Project," Sponsored by Health Resources Services Administration/WV Bureau for Public Health, $200,000. (September 2013 - August 2017).

Principal Investigator, "Evaluation of the West Virginia Health Insurance Market Place (PI)," Sponsored by Health and Human Services/WV Offices of the Insurance Commission, $2,149,493. (March 2013 - March 2017).

Principal Investigator,"Team Nutrition," Sponsored by United States Department of Agriculture/WV Department of Education, $58,714. (October 1, 2011 - December 31, 2013).

Principal Investigator, "Evaluation of West Virginia’s Cardiovascular Prevention and Control Program Quality Improvement Efforts" Sponsored by the Centers for Disease Control and Prevention/WV Bureau for Public Health, $16,954. (June 2012 - June 2013).

Principal Investigator, "Evaluation of Implementation and Impact of Cardiovascular Health Program," Sponsored by the Centers for Disease Control and Prevention/WV Bureau for Public Health, $18,649. (June 30, 2012 - June 29, 2013).

Principal Investigator, "Evaluation of West Virginia’s Diabetes Prevention and Control Program Year 3," Sponsored by the Centers for Disease Control and Prevention/WV Bureau for Public Health, $68,989.00. (March 29, 2012 - March 28, 2013).

Principal Investigator, "Evaluation of West Virginia’s “Communities Putting Prevention to Work” Project (PI)," Sponsored by the Centers for Disease Control and Prevention/WV Bureau for Public Health, $256,866. (March 2011 - December 2012).

Principal Investigator, "Developing an Evaluation for the WV Health Benefit Exchange," Sponsored by Health and Human Services/WV Offices of the Insurance Commission, $86,290.00. (April 2012 - February 2013).

Co-Principal Investigator, "Evaluation of the State Health Access Program," Sponsored by Health Resources Services Administration/WV Bureau for Public Health, $146,369. (September 2011 - August 2013).

Co-Principal Investigator,"Evaluation of West Virginia's Community Transformation Grant Sponsored by the Centers for Disease Control and Prevention/WV Bureau for Public Health, $102,242. (September 2011 - August 2012).

Co-Principal Investigator, "Communities Putting Prevention to Work Enhanced Evaluation Supplement" Sponsored by the Centers for Disease Control and Prevention/WV Bureau for Public Health, $577,567. (March 2011 - July 2012).

Co-Investigator, "Zamzee Pilot Study 2.0 (research team)," Sponsored by HopeLab, $50,000. (August 2011 - June 2012).

Principal Investigator,"Evaluation of West Virginia's Diabetes Prevention and Control Program Year 2" Sponsored by the Centers for Disease Control and Prevention/WV Bureau for Public Health, $32,319. (March 2011 - March 2012).

Non-Peer Reviewed Reports and Manuscripts

Bias, T., Sarkees E. in collaboration with the WVU Prevention Research Center. (2017) Evaluation Report for the West Virginia Tobacco Quitline. Submitted to the West Virginia Bureau for Tobacco Prevention.

Bias, T., Abildso, C., Coffman, J., and Vasile, E. (2015) Growing Health Communities Project Evaluation Report. Submitted to the West Virginia Development Office and the Claude Worthington Benedum Foundation.

Bias, T., Fitzgerald, P., Galvez, T., et. al. (2015) Evaluation of the West Virginia Health Insurance Marketplace: Executive Summary. Report submitted to the West Virginia Offices of the Insurance Commissioner.

Bias T., Fitzgerald P, Galvez T., et. al. (2014) First year evaluation reports for on the West Virginia Health Insurance Marketplace. Report submitted to the West Virginia Offices of the Insurance Commissioner.

Bias, T., Abildso, G., Vasile, E., and Coffman, J. (2014) *Health Impact Assessment for Fairmont, West Virginia.* Report submitted to the Association of State and Territorial Health Officials.

Abildso, C., **Bias, T**., Moore, L., Coffman, J., Vasile, E., Frost, S., Moore, L. (2013). *WV Connect: Evaluation of a Pilot Project to Expand Coverage and Access to Care for Working Uninsured West Virginia Residents*. Report submitted to the WV Bureau for Public Health.

Abildso, C., Moore, L., **Bias, T.**, et. al. (2013) *WV Connect: Evaluation of a Pilot Project to Expand Coverage and Access to Care for Working Uninsured West Virginia Residents.*. Report submitted ot the West Virginia Department of Health and Human Resources.

Bias, T., Moore, L. (2013) *Full-Scale Systems Change Evaluation Report of the West Virginia Cardiovascular Health Program*. . Report Sent Submitted to the WV Cardiovascular Health Program.

Bias, T., Moore, L. (2013) *Comprehensive Three Year Evaluation Report*. Report Sent Submitted to the WV Diabetes Prevention and Control Program.

Bias, T., Coffman, J. E., Moore, L. C. (2012) *Report on Evaluation of Team Nutrition Year 1*. Report Submitted to the West Virginia Department of Education Office of Child Nutrition..

Bradlyn, A. S., Harris, C. V., Moore, L. C., Frost, S., Blake, K. K., Coffman, J., Matthews-Ewald, M., Penwell, L., **Bias, T**. (2012) *West Virginia Standards for School Nutrition Year Two Evaluation Executive Summary*. Report submitted to the West Virginia Department of Education.

Bias, T., Moore L. (2012) *Evaluation of the Diabetes Prevention and Control Program Quality Improvement Efforts.*. Report Submitted to the WV Diabetes Prevention and Control Program.

Bias, T., Bua-Lam, P. (2011) *Estimating Worklife Return on Investment of Youth with Significant Disabilities after Receipt of Services from the West Virginia Division of Rehabilitation Services*. Report submitted to the United States Rehabilitation Services Administration.

Bias, T. (2008). *Robert Michels*. Entry in the International Encyclopedia of the Social Sciences.

Bias, T. (2008). *Parking a luxury, not a necessity on campus*. The Daily Athenaeum.Bias, T., e. *Change the Future Evaluation Report*. Submitted to the West Virginia Bureau for Public Health.

Presentations

Bias, T. Rural Health Interest Group at the West Virginia University School of Medicine. “How the Changing Map of Health Insurance in the United States Could Impact Appalachia”. Morgantown, WV (November 2017.)

Feng, X, Tan, X, Zheng, T., Riley, B., **Bias, T.,** Becker, J., and Sambamoorthi, U. Poster Presentation at the International Society of Pharmacoeconomics and Outcomes Research

Mid-Year Conference. “Polypharmacy among West Virginia Medicaid beneficiaries: prevalence, utilization, cost, and potential geographical disparities” London, UK. (April 2017.)

Duval, R., **Bias, T.,** Echeverria R., King, D., Matyasovsky, M., Mentzer, T. Podium presentation at the American Political Science Association Annual Meeting. “Analyzing Policies for their Long-term Disequilibrating Impacts on the Intergenerational Distribution of Wealth and Health.” Philadelphia, PA. (September, 2016).

Duval, R., **Bias, T.,** Echeverria R., King, D., Matyasovsky, M., Mentzer, T. Poster presentation at AcademyHealth Annual Research Meeting. “Analyzing Policies for their Long-term Disequilibrating Impacts on the Intergenerational Distribution of Wealth and Health.” Boston, MA. (June 2016).

Alwhaibi, M., Sambamoorthi, U., Madhavan, S., Kelly, K., Bias, T., and Walkup, J. International Society of Pharmacoeconomics and Outcomes Research Conference. “Newly Diagnosed Depression after Cancer Diagnosis among Elderly with Breast, Colorectal, and Prostate Cancer.” Washington, D.C. (May 2016).

Agarwal, P., **Bias, T.**, Sambmoorthi, U. International Society of Pharmacoeconomics and Outcomes Research Conference. “Health Care Expenditures Associated with Persistent Emergency Department Use: A Multi-State Analysis of Medicaid Beneficiaries”. Washington, D.C. (May 2016).

Miller, M., **Bias, T.,** Wright, J., and Tieman, K. National Main Street Conference. “Best Practices, Measurement, and Sustainability in Growing Healthy Communities”. Classroom Session. Milwaukee, WI (May 2016).

Bias, T. Rural Health Interest Group at the West Virginia University School of Medicine. “Barriers and Facilitators for Practitioners: Medicaid Expansion in West Virginia.” Morgantown, WV (March 2016).

Eller, W. and **Bias, T.** Ambiguity and Crisis Symposium sponsored by the Journal of Policy and Politics and North Carolina State University. “Magic Bullets or Snake Oil? The Role of Policy Entrepreneurs in Policy Process Theory”. Raleigh, NC (February 2016).

Abildso, C., Gurka, K., **Bias T.** Active Living Research Conference. “Using Data to Impact Policy: The Road to Complete Streets Policy in West Virginia”. Clearwater, FL (February 2016).

Bias, T., Abildso, C., Vasile, E., Coffman, J. Active Living Research Conference. “Bridging the Divide between Policymakers and Public Health Researchers using Health Impact Assessment”. Clearwater, FL. (February 2016.)

Bias, T. West Virginia Statewide Health Impact Assessment Symposium. “Case Study: Health Impact Assessment in Fairmont, WV.” Charleston, WV. (September 2015).

Eller, W., **Bias T.,** International Conference on Public Policy. “Making Eight or Hitting Dirt: The Importance of Failed Entrepreneurs in Policy Systems Theory,” Milan, Italy. (July 2015).

Bias, T., International Society of Pharmacoeconomics and Outcomes Research Student Distinguished Speaker Series. “Health Insurance Exchange in West Virginia”, Morgantown, WV. (September 2014).

Bias, T., Abildso, C., Vasile, E., Coffman, J., Southeast Regional Health Impact Association Meeting, "Engaging West Virginia's Growing Healthy Communities Partners to Identify Opportunities for HIA," Davidson, NC. (August 2014).

Vasile, E. (Author & Presenter), **Bias, T.** (Author), Agarwal, P. (Author), Davis, S. M. (Author), Davidov, D. (Author), AcademyHealth Annual Research Meeting, "Emergency Department Utilization among the Insured in West Virginia," AcademyHealth, San Diego, CA. (June 2014).

Fitzgerald, M. P., **Bias, T.,** Vasile, E., Moore, L., Agarwal, P., American Council on Consumer Interests Annual Conference, "Examining Underlying Assumptions of ACA and Consumer Awareness of the Key Advantage of Using Health Insurance Marketplaces," Milwaulkee, WI. (April 2014)

Frisbee, S. (Presenter), Pilkerton, C. S. (Presenter), **Bias, T.** (Presenter), American Heart Association Epidemiology & Prevention / Nutrition, Physical Activity and Metabolism 2014 Scientific Sessions, "County cardiovascular health is associated with county-level health care resources," American Heart Association, San Francisco, California. (March 2014).

Frisbee, S. (Presenter), Pilkerton, C. S. (Presenter), **Bias, T**. (Presenter), American Heart Association Epidemiology & Prevention / Nutrition, Physical Activity and Metabolism 2014 Scientific Sessions, "County-level cardiovascular health in the United States," American Heart Association, San Francisco, California. (March 2014).

Bias, T., Fitzgerald, P., Gurley-Calvez, T., Moore, l., Vasile, E., 2013 American Public Health Association Meeting, "Evaluation of a West Virginia Health Insurance Exchange," Boston,MA. (November 2013).

Bias, T., Vasline, E., National Governor’s Association and Robert Wood Johnson Foundation’s “Monitoring and Evaluation Plans for Health Insurance Marketplaces” Webinar., "Evaluation of the Health Insurance Marketplace in West Virginia," Online. (September 2013).

Bias, T., Presentation for the West Virginia University Behavioral Medicine Grand Rounds, "The Affordable Care Act and Behavioral Medicine," Morgantown,WV. (September 2013).

Bias, T., Harris, C. V., Bradlyn, A. S., Moore, L. C., Frost, S., Coffman, J., Reeves, M., Brainard, B. S., 2012 American Public Health Association Meeting, "How Communities Putting Prevention to Work Fostered Policy Change in Rural West Virginia," San Francisco, CA. (October 2012).

Bias, T., the 5th Annual Rehabilitation Summit, "Estimating Worklife Return on Investment of Transitional Youth with Significant Disabilities.," San Antonio, TX. (September 2012).

Bias, T., How policy can influence obesity related issues in rural and low income areas: evidence from West Virginia Walks, "the graduate Behavioral and Biomedical Sciences T32 Trainees," Morgantown,WV. (February 2012).

Bias, T., Hannum, T. M., Midwestern Political Science Association Conference, "A historical look at religious support for the death penalty," Chicago,IL. (April 2010).

Bias, T., The Urban Affairs Association, "The politics and policy of small city downtown revitalization," Honolulu,HI. (March 2010).

Maddock, j. E., Reger-Nash, B., Leyden, K., **Bias, T**., 2nd International Congress on Physical Activity and Public Health, "Priority of active environment issues among key decision makers in Hawaii.." (April 2008).

Bias, T., Leyden, K. M., Reger-Nash, B., Maddock, J. E., Bauman, A., Robert Wood Johnson Foundation Active Living Conference Poster Presentation, "Changing attitudes of policymakers using public health interventions: survey instrument and test-retest reliability.," Washington,DC. (April 2008).

Leyden, K. M., Reger-Nash, B., Bauman, A., **Bias, T.**, West Virginia University Presidential Inauguration Research Day, "Changing the hearts & minds of policymakers: an exploratory study associated with the West Virginia Walks campaign," Morgantown,WV. (November 2007).

Bias, T., Spahiu, A., West Virginia Political Science Association, "Lobbying in West Virginia," Charleston WV. (April 2007).

Scotto, T., Lackey, G., **Bias, T.**, American Political Science Association Annual Meeting., "Religion and partisanship in the United States.," Philadelphia PA. (September 2006).

Bias, T., West Virginia Public Radio, "Citizen evaluations of West Virginia government: stability and change 1992-2006.." (May 2006).

Bias, T., Bribin, R. A., Leyden, K. M., West Virginia Political Science Association, "Citizen evaluations of West Virginia government: stability and change 1992-2006.","" Elkins, WV. (October 2005).

Recognition and Awards

Fitzgerald, P., **Bias, T**., and Gurley-Calvez, T. (2015). The Affordable Care Act and Consumer Well-Being: Knowns and Unknowns. *Journal of Consumer Affairs. Selected as one of the most relevant articles of the last fifty years as part of an anniversary issue.*

Agarwal, P., **Bias, T.**, Sambamoorthi, U. International Society of Pharmacoeconomics and Outcomes Research Conference. “Health Care Expenditures Associated with Persistent Emergency Department Use: A Multi-State Analysis of Medicaid Beneficiaries”. (2016). *Selected as the overall best podium presentation at the conference.*

Bias, T., Abildso, C., Coffman, J., and Vasile, E. (2015). Bridging the Divide between Policymakers and Public Health Researchers. *Selected as one of six winners of a contest for best papers connecting researchers and policymakers by the American Public Health Association and American Planning Association.*

Our research around Return-on-Investment for State Vocational Rehabilitation Programs has been nationally recognized by the Rehabilitation Services Administration as “best practices” and incorporated into guidance for state programs.

“*Graduate Student Research at West Virginia University Shapes Public Policy*”. (February 2011). *Recognition of dissertations that have a real impact on public policy.*

Nominated as Outstanding Teacher of the Year for the Eberly College of Arts and Sciences.

TEACHING

Teaching Experience

West Virginia University
HPML 624 *Policy Tools*
HPML 622 *Analytic Methods for Health Policy, Management, and Leadership* HPML 670 *Policy Analysis*
HPML 675 *Healthcare and INsurance Policy: Medicaid, Medicare, Affordable Care Act*
HPML 695 *Independent Study*
POLS 317 *Interest Groups and Democracy*
POLS 321 *West Virginia Government*

Directed Student Learning

Dissertation Committee
Chair: Parul Agurwal, PhD Candidate (2013 - 2015)
Committee Co-Chair: Courtney Pilkerton, MD/PhD Candidate (2013-2015)
Committee Member: Brooke Towner, PhD Candidate (2016-Present)
Committee Member: Monira Alwhaibi, PhD Candidate (2014-2016)

SERVICE

Department Service

Committee Chair, HPML Admissions Committee. (2013-Present).

Committee Chair, HPML Faculty Search Committee (2016)

Committee Chair, HPML Faculty Search Committee (2015)

Committee Member, HPML Faculty Search Committee. (2012-2013).

Committee Member, HPML Interim Chair Search Committee. (2013).

Facilitated Department of Health Policy, Management, and Leadership Department Student Orientation. (2012).

College Service

Committee Chair, School of Public Health Curriculum Committee (2016-

Present)Committee Member, Promotion and Tenure Committee (2017 -

Present) Committee Member, Bylaws Committee (2016-2017)

Committee Member, Dean's Research Advisory Council (2015 - 2016).

Committee Member, Dean's Faculty Advisory Committee (2014)

Poster Reviewer for MPH Student Practicum and Internship. (2012 - 2014).

Committee Member, SPH Practicum Committee. (2012 - 2014).

Committee Member, SPH Academic Affairs Committee. (2013).

Committee Member, School of Public Health Academics Standards Committee. (2012 - 2013).

Committee Chair, Junior Faculty Monthly Meetings. (2011 - 2013).

School of Public Health Information Technology Committee. (2011 - 2012).

University Service

Committee Member, Community Leadership Academy Planning Committee (2016-Present)

Committee Member, Vice-President's Faculty Advisory Committee (2014-2015)

Faculty Advisor, WVU Hockey Team. (2014-2015)

Professional Service

Reviewer: *American Journal of Public Health, Cities, Journal of Consumer Affairs, Journal of Public Health Management and Practice, Journal of Health and Place, Journal of Politics, Journal of Racial and Ethnic Disparities, International Journal of Environmental Research and Public Health.*

Participant, State-University Partnership Learning Networks. Coordinated by Academy Health. (2017-Present)

Committee Member, Oral Health State Plan Surveillance Team, Charleston, WV. (2014 - 2015).

Committee Member, Bureau for Public Health PHHS Block Grant Advisory Committee. (2014 - 2015).

Invited Participant in West Virginia Bureau for Public Health State Public Health System Performance Assessment. (2012).

Facilitator, West Virginia Local Government Leadership Academy Executive Session in Canaan Valley, Canaan Valley, WV. (2011).

Coordination of the West Virginia Local Government Leadership Academy, Charleston, WV. (2009 - 2010).

Co-Coordination of the Center for Advancement of Leadership Skills. (2009).

Co-Coordination of the West Virginia Local Government Leadership Academy. (2005 - 2009).

Assistant Editor, West Virginia Public Affairs Reporter, Institute for Public Affairs, West Virginia University. (2006-2010)

Public Service

Board Member, West Virginia Community Development HUB. (November 2013 - Present).
Board Chair, 2017-Present

Board Member, Morgantown Pedestrian Safety Board, Morgantown. (2007 - 2013).

West Virginia Communities Putting Prevention to Work Grant State Management Team. (2011 - 2012).

West Virginia Community Transformation Grant State Management Team. (2011 - 2012).

Chairperson, Morgantown Pedestrian Safety Board. (2007 - 2009).

Appendix II: CURRICULUM VITAE
LINDSAY ALLEN, PHD MA

Updated January 2018

CONTACT INFORMATION

West Virginia University
School of Public Health
Department of Health Policy, Management, & Leadership

Mobile: (312) 502-3561
Office: (304) 293-1247
Email: lindsay.allen@hsc.wvu.edu
Website: www.lindsaylallen.com
Twitter:@ _Lindsay_Allen

FIELDS OF INTEREST

Health economics, health services research, health care access and utilization

ACADEMIC POSITIONS

Assistant Professor, West Virginia University 2017-Present

EDUCATION

Ph.D. **Emory University** Health Economics and Health Services Research 2017

Dissertation Title: The Impact of Urgent Care Centers and Retail Centers on Health Care Access and Emergency Department Use

M.A. **University of Chicago** Health Administration and Policy 2010

B.A. **Johns Hopkins University** Cognitive Science: Neuroscience, Neuropsychology 2004

AWARDED GRANTS

West Virginia Medicaid Substance Use Disorder 1115 Waiver Evaluation
Role: Co-Principal Investigator
Amount: $260,000 (first year of funding)
Funding Agency: West Virginia Bureau for Medical Services
Duration: 2018-2022

West Virginia Digital Economy Initiative
Role: Principal Investigator
Amount: $297,700
Funding Agency: Cisco Fund
Duration: 2018-2020

The Impact of Urgent Care Centers and Retail Clinics on Healthcare Access and Emergency Department (Dissertation Award)
Role: Principal Investigator
Amount: $41,989
Funding Agency: Agency for Healthcare Research and Quality
Duration: 2016-2017

PUBLICATIONS

Peer-Reviewed Publications

Johnston K, **Allen L**, Melanson T, Pitts S. A "Patch" to the NYU Emergency Department Algorithm. *Health Services Research*. 2017; 52(4): 1264-1276.

Cummings JR, Ji X, Allen L, Lally C, Druss BG. Racial and ethnic differences in ADHD treatment quality among Medicaid-enrolled youth. *Pediatrics* 139 (6): e20162444.

Cummings J, **Allen L**, Clennon J, Ji X, Druss B. Geographic Access to Specialty Mental Health Care across High- and Low-income U.S. Communities. *JAMA Psychiatry.* 2017; 74(5): 276-484.

Cummings J, **Allen L**, Ko M, Bonney L, Hunter Jones J, Cooper H. Changes in Health Care Access and Utilization among Participants in a Public Housing Relocation Program in Atlanta, Georgia. *Health and Place.* 2016; 42:63-68.

Allen L, Cummings J. Emergent Department Use Among Hispanic Adults: The Role of Acculturation. *Medical Care*. 2016; 54(5):449-456.

Allen L, Thorpe K, Joski P. The Effect of Obesity and Chronic Conditions on Medicare Spending, 1987-2011. *Pharmacotfconomics.* 2015; 33(7):691-697.

Thorpe K, **Allen L**, Joski P. Out-Of-Pocket Prescription Costs Under A Median Silver Plan Are Twice As High As They Are In The Average Employer Plan. *Health Affairs.* 2015; 34(10):1695-1703.

Thorpe K, **Allen L,** Joski P. The Role of Chronic Disease, Obesity, and Improved Treatment and Detection in Accounting for the Rise in Health Care Spending Between 1987 and 2011. *Applied Health tfconomics and Health Policy.* 2015; 13(4):381-387.

Book Chapters

Burgess J, Hockenberry J**, Allen L**. Inefficiencies in Health Care Provision" in Emerging Trends in the Social and Behavioral Sciences (eds.) Robert Scott and Stephen Kosslyn, John Wiley and Sons, 2015.

PODIUM PRESENTATIONS

Allen L, Hockenberry J, Cummings J. *The Impact of Urgent Care Centers on tfmergency Department Use*. 2017 Southern Economics Association Annual Meeting, Tampa, FL

Allen L, Hockenberry J, Cummings J. *The Impact of Urgent Care Centers on tfmergency Department Use*. 2017 Department of Economics Seminar Series, West Virginia University, Morgantown, WV

Allen L, Hockenberry J, Cummings J. *The Impact of Urgent Care Centers on tfmergency Department Use*. 2016 Southeastern Health Economics Study Group, Virginia Commonwealth University, Richmond, VA.

Allen L, Cummings, J. *tfmergency Department Use Among Hispanic Adults: The Role of Acculturation.* 2015 AcademyHealth Annual Research Meeting, Minneapolis, MN.

Allen L, Cummings, J. *Demand for tfmergency Department Care by Hispanic Individuals.* 2015 Southern Economics Association Annual Meeting, New Orleans, LA.

OTHER PROFESSIONAL EXPERIENCE

Senior Health Care Analyst 2010-2012
ECRI Institute, Plymouth Meeting, PA

Pharmaceutical Sales Representative 2004-2008
AstraZeneca, Baltimore MD and Chicago, IL s

TEACHING

Undergraduate Level
Introduction to Heath Policy
Health Economics

Graduate Level
Health Economics
Theory-based Research Design

REFEREEING

Health Affairs, Medical Care, Southern Economic Journal

HONORS AND AWARDS

Livingston Fellowship Award, Rollins School of Public Health (2016, awarded annually to the top-performing PhD student in the department)

Emerging Leader Award, Emory University (2013, awarded annually to the first-year graduate or undergraduate student who best exemplifies leadership through campus and/or community involvement)

Laney Graduate School Fellowship, Emory University (2012-2015)

Erikson Fellowship in Hospital Administration, University of Chicago (2009)

Martha Burton Merit Scholarship, University of Chicago (2008-2010)

PROFESSIONAL MEMBERSHIPS

AcademyHealth, American Society of Health Economists, International Health Economics Association

Appendix III - Conflict of Interest Statement

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES
Commissioner's Office
350 Capitol Street, Room 251
Charleston, West Virginia 25301-3712
Telephone: (304) 558-1700 Fax: (304) 558-1451

Bill J. Crouch
Cabinet Secretary

Cynthia E. Beane
Commissioner

MEMORANDUM

Date: March 30, 2018

To: Julie Sharp, M.P.P., Technical Director, Division of State Demonstrations and Waivers, State Demonstrations Group, Center for Medicaid and CHIP Services, Centers for Medicare & Medicaid Services

From: Cynthia Beane, Commissioner

RE: Evaluation Design Draft - Section 1115 demonstration "Creating a Continuum of Care for Medicaid Enrollees with Substance Use Disorders"

The West Virginia Department of Health and Human Resources (DHHR), as part of West Virginia's (State) implementation of the five-year Section 1115 demonstration "Creating a Continuum of Care for Medicaid Enrollees with Substance Use Disorders" (SUD demonstration), has selected the West Virginia University School of Public Health to be the State's independent entity to conduct the evaluation design of the SUD demonstration.

As part of this selection of the West Virginia University School of Public Health, DHHR confirms there is no conflict of interest that will impact the evaluation of the SUD demonstration. To ensure there is no conflict of interest, DHHR will make every effort to not impact the approved methodology (as described in the requirements described in 42 C.F.R. 431.424 and the guidance provided in Attachment B: "Developing the Evaluation Design" of the Special Terms and Conditions of the SUD demonstration) agreed upon by the West Virginia University School of Public Health and Centers for Medicare & Medicaid Services (CMS).

If you need additional information or have any questions, please do not hesitate to contact me at (304) 558-1700.

Cynthia Beane, MSW, LCSW
Commissioner

Appendix IV - Budget

The attached spreadsheets display our internal budgets for Years 1-3. For Years 4-5, we anticipate having a similar annual budget, allowing for salary increases and additional conference travel to disseminate results.

Therefore, our estimated budget for the entire 5 year project is as follows:

Year	**Budget**
1	$267,313
2	$266,570
3	$292,376
4	$305,147
5	$313,918
Total	**$1,445,324**

Project Year 1 Budget

TASK 1 TASK 2 TASK 3 TASK 4 TASK 5 TASK 6 TASK 7 TASK 8

Task Name		Bias	Kristjansson	Baus	Allen	HRC	Davis/HPML	BMED	BMED	
Co-Investigator / Task Manager	Rate	Tom Bias	Alfgeir Kristjansson	Adam Baus	Lindsay Allen	Herb Linn	Steve Davis	Laura Lander	James Berry	Total
Benefits Eligigle Salaries		$ 43,719	$ 9,205	$ 4,332	$ 20,000	$ 54,007	$ 4,794	$ 967	$ 995	$ 138,019
Fringe Benefits	23.50%	$ 10,274	$ 2,163	$ 1,018	$ 4,700	$ 12,691	$ 1,127	$ 227	$ 234	$ 32,434
Nonbenefit Eligible Salaries		$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Fringe Benefits	8.00%	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Graduate Assistants		$ 12,500	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 12,500
Fringe Benefits	6.00%	$ 750	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 750
Student Workers		$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Fringe Benefits	2.00%	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
General (includes consultant)		$ 8,550	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 8,550
Subcontract		$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
WVUH/UHA Contract			$ -	$ -	$ -	$ -	$ -	$ 525	$ 5,653	$ 6,178
Travel		$ 3,315	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 3,315
Repairs/Alterations		$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Equipment<$5,000		$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Equipment>$5,000		$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
TDC		$ 79,108	$ 11,368	$ 5,350	$ 24,700	$ 66,698	$ 5,921	$ 1,719	$ 6,882	$ 201,746
F&A	32.50%	*$ 25,710*	*$ 3,695*	*$ 1,739*	*$ 8,028*	*$ 21,677*	*$ 1,924*	*$ 559*	*$ 2,237*	*$ 65,567*
Total for Task		**$ 104,818**	**$ 15,063**	**$ 7,089**	**$ 32,728**	**$ 88,375**	**$ 7,845**	**$ 2,278**	**$ 9,119**	$ 267,313
College / Department		HPML	Social & Behavioral Sciences	Social & Behavioral Sciences	HPML	SPH Health Research Center	HPML	Behavioral Medicine	Behavioral Medicine	
Office Award Manager		Kristin Summers	Kristin Summers	Kristin Summers	Kristin Summers	Kristin Summers	Kristin Summers	Tammy Feathers	Tammy Feathers	
DA Number		580000600	580000500	580000500	580000600	580000630	580000600	492210010	492210010	
DA Name		HPML	Social & Behavioral Sciences	Social & Behavioral Sciences	HPML	SPH Health Research Center	HPML	Behavioral Medicine	Behavioral Medicine	
Cost Sharing										
Last Name Line Item $ Amount DA No. Oracle Fund No. or Award No. Cost Sharing Total for Task										

DA - HSC Soph Health Affairs
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Project Year 2 Budget

Task Name		Bias	Kristjansson	Baus	Allen	Davis	Lander	Berry
Co-investigator / Task Manager	Rate	Tom Bias	Alfgeir Kristjansson	Adam Baus	Lindsay Allen	Steve Davis	Laura Lander	James Berry
Benefits Elibigle Salaries		$ 77,760	$ 12,974	$ 5,568	$ 25,094	$ 10,074	$ 1,095	$ 1,020
Fringe Benefits	24.00%	$ 18,662	$ 3,114	$ 1,336	$ 6,022	$ 2,418	$ 263	$ 245
Nonbenefit Eligible Salaries		$ -	$ -	$ -	$ -	$ -	$ -	$ -
Fringe Benefits	7.80%	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Graduate Assistants		$ -	$ -	$ -	$ -	$ -	$ -	$ -
Fringe Benefits	5.00%	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Student Workers		$ -	$ -	$ -	$ -	$ -	$ -	$ -
Fringe Benefits	1.50%	$ -	$ -	$ -	$ -	$ -	$ -	$ -
General		$ 2,500,	$ -	$ -	$ -	$ -	$ -	$ -
Subcontract		$ -	$ -	$ -	$ -	$ -	$ -	$ -
RC/WVUH/UHA Contract		$ 21,505	$ -	$ -	$ -	$ -	$ 1,095	$ 6,431
Travel		$ 4,009	$ -	$ -	$ -	$ -	$ -	$ -
Repairs/Alterations		$ -	$ -	$ -	$ -	$ -	$ -	$ -
Equipment<$5,000		$ -	$ -	$ -	$ -	$ -	$ -	$ -
Equipment>$5,000		$ -	$ -	$ -	$ -	$ -	$ -	$ -
F&A	*32.50%*	*$ 40,442*	*$ 5,229*	*$ 2,244*	*$ 10,118*	*$ 4,060*	*$ 797*	*$ 2,501*
Total for Task		**$ 164,878,**	**$ 21,317**	**$ 9,148**	**$ 41,228**	**$ 16,552**	**$ 3,250**	**$ 10,197**
College / Department								
Office Award Manager								
DA Number								
DA Name								
Cost Sharing								
Last Name Line Item $ Amount DA No. Oracle Fund No. or Award No. Cost Sharing Total for Task								

Project Year 3 Budget

Personnel					
	Year 3				
Name	base salary	percent time	salary request	fringe benefits	total request
Faculty and Benefit Eligible					
Tom Bias	$ 148,601.13	15%	$ 22,290.17	$ 5,461.09	$ 27,751.00
Alfgeir Kristjansson	$129,740.28	3%	$ 3,892.21	$ 953.59	$ 4,846.00
Nathan Pauly	$125,660.00	10%	$ 12,566.00	$ 3,078.67	$ 15,645.00
Lindsay Allen	$ 114,062.45	35%	$ 39,921.86	$ 9,780.85	$ 49,703.00
TBD Program Manager	$ 77,250.00	50%	$ 38,625.00	$ 9,463.13	$ 48,088.00
Steve Davis SPH salary	$122,964.49	20%	$ 24,592.90	$ 6,025.26	$ 30,618.00
Other Service Personnel					
	$ -	0%	$ -	$ -	$ -
	$ -	0%	$ -	$ -	$ -
	$ -	0%	$ -	$ -	$ -
Graduate Assisstants					
MPH Student (approx. 20 hours per week * 52 weeks per year *$17 per hou	$ 17,680.00	100%	$ 17,680.00	$ 1,237.60	$ 18,918.00
	$ -	0%	$ -	$ -	$ -
Totals Wages and Fringes			$ 159,568.13	$ 36,000.19	$ 195,569.00
UHA/Contractual Agreements	Base salary	Effort %	salary request	Fringe	Total Year 2
Herb Linn (Research Corp)	$ 86,714.01	20%	$ 17,342.80	$ 4,248.99	$ 21,591.79
			$ -	$ -	$ -
Subtotal Contractual Agreements			$ 17,342.80	$ 4,248.99	$ 21,592.00
General Expenses & Equipment Less than $5000					
Server Space	$ 500.00				$ 500.00
Software	$ 1,000.00				$ 1,000.00
Supplies and printing	$ 1,000.00				$ 1,000.00
	$ -				$ -
	$ -				$ -
	$ -				$ -
Subtotal General Expenses					$ 2,500.00
Travel					
day trips to Charleston, one per month	$ 1,000.00				$ 1,000.00
	$ -				$ -
	$ -				$ -
Subtotal Travel					$ 1,000.00
Total Direct Cost				Total Direct Cost	$ 220,661
Modified Total Direct Cost				Modified Total D(	$ 220,661
Direct costs minus consortium F&A			Direct costs minus consortium F&		$ 220,661.00
Indirect Cost (32.5%)				Indirect Cost	$ 71,715
Total Cost Year 1				Total Cost Year 2	$ 292,376

Project Years 4-5 Projected Budget

PERSONNEL (SENIOR AND OTHER PERSONNEL)					[03/01/2021-02/28/2022]			[03/01/2022-02/28/2023]					
Name	Role	Month	Effort	Inst Sal	YEAR 4 Req Sal	YEAR 4 Fringes	TOTAL YEAR 4	YEAR 5 Req Sal	YEAR 5 Fringes	YEAR 5 TOTAL	TOTAL SALAR	TOTAL FRINGE	TOTAL COSTS
Lindsay Allen	PI		35%	117,484	$41,119	$10,074	$51,193	$42,353	$10,376	$52,729	$83,472	$20,450	$103,922
Tom Bias	Co-Investigate		15%	150,087	$22,513	$5,516	$28,029	$23,188	$5,681	$28,869	$45,701	$11,197	$56,898
Alfgeir Kristjansson	Co-Investigate		3%	132,335	$3,970	$973	$4,943	$4,089	$1,002	$5,091	$8,059	$1,975	$10,034
Nathan Pauly	Co-Investigate		10%	129,430	$12,943	$3,171	$16,114	$13,331	$3,266	$16,597	$26,274	$6,437	$32,711
Steve Davis	Co-Investigate		20%	132,287	$26,457	$6,482	$32,939	$27,251	$6,676	$33,927	$53,708	$13,158	$66,866
TBD Program Manager	Co-Investigate		50%	79,568	$39,784	$9,747	$49,531	$40,978	$10,040	$51,018	$80,762	$19,787	$100,549
MPH Student	Graduate Asst		100%	18,210	$18,210	$1,275	$19,485	$18,756	$1,313	$20,069	$36,366	$2,588	$39,554
					$0	$0	$0	$0	$0	$0	$0	$0	$0
					$0	$0	$0	$0	$0	$0	$0	$0	$0
					$0	$0	$0	$0	$0	$0	$0	$0	$0
					$0	$0	$0	$0	$0	$0	$0	$0	$0
					$0	$0	$0	$0	$0	$0	$0	$0	$0
					$0	$0	$0	$0	$0	$0	$0	$0	$0
PERSONNEL SUB TOTAL					#####	$37,238	#####	#####	$38,354	#####	#####	$75,592	$410,534

	YEAR 1 TOTALS	YEAR 2 TOTALS	SUB TOTALS	TOTAL COSTS
EQUIPMENT				
None	$0	$0	$0	$0
	$0	$0	$0	$0
	$0	$0	$0	$0
EQUIPMENT SUB TOTAL	$0	$0	$0	$0
TRAVEL				
Domestic Travel	$1,000	$1,000	$2,000	$2,000
Foreign Travel	$0	$0	$0	$0
TRAVEL SUB TOTAL	$1,000	$1,000	$2,000	$2,000
PARTICIPANT/TRAINEE SUPPORT COSTS				
	$0	$0	$0	$0
PARTICIPANT/TRAINEE SUB TOTAL	$0	$0	$0	$0
MATERIALS AND SUPPLIES				
Molecular/Cell Biology Supplies	$0	$0	$0	$0
Cell Culture/Tissue Supplies, Assays, Enzymes	$0	$0	$0	$0
Chemicals, Reagents & Antibodies	$0	$0	$0	$0
Radioactive Isotopes, de-identified human tissue samples, etc...	$0	$0	$0	$0
Miscellaneous/general lab supplies (plastics, tubes, gloves....)	$0	$0	$0	$0
Other [list line item here]	$0	$0	$0	$0
MATERIALS & SUPPLIES SUB TOTAL	$0	$0	$0	$0
OTHER DIRECT COSTS/EXPENSES				
Publication, printing, advertising/recruitment, poster fees	$1,000	$1,000	$2,000	$2,000
Server Space	$500	$500	$1,000	$1,000
ADP/Computer Services (Software)	$1,000	$1,000	$2,000	$2,000
Subawards/Consortium	$0	$0	$0	$0
Core Facility User Fees: [List cores here]	$0	$0	$0	$0
Alterations and Renovations	$0	$0	$0	$0
Purchase of Lab Animals [List specific type here]	$0	$0	$0	$0
Daily animal housing/per diem	$0	$0	$0	$0
UHA Contractual Services	$0	$0	$0	$0
Other DC [Herb Linn-Research Corp]	$21,592	$22,240	$43,832	$43,832
OTHER DIRECT COSTS SUB TOTAL	$24,092	$24,740	$48,832	$48,832
R&R SUB TOTAL DIRECT COSTS	$227,326	$234,040	$461,366	$461,366
MODIFIED TOTAL DIRECT COST BASE	$227,326	$234,040	$461,366	$461,366
INDIRECT COSTS TOTAL	$73,881	$76,063	$149,944	$149,944
TOTAL DIRECT + INDIRECT COSTS	$301,207	$310,103	$611,310	$611,310