CENTERS FOR MEDICARE & MEDICAID SERVICES

WAIVER AUTHORITY

NUMBER: 11-W-00307/3

TITLE: Evolving West Virginia Medicaid's Behavioral Health Continuum of Care

Section 1115(a) Demonstration

AWARDEE: West Virginia Department of Human Services, Bureau for Medical Services

Under the authority of section 1115(a)(1) of the Social Security Act ("the Act"), the following waiver is granted to enable West Virginia (referred to herein as the state or the State) to operate the Evolving West Virginia Medicaid's Behavioral Health Continuum of Care demonstration (formerly called the West Virginia Creating a Continuum of Care for Medicaid Enrollees with Substance Use Disorders [SUD] demonstration). This waiver is effective beginning January 1, 2025 and is limited to the extent necessary to achieve the objectives below. This waiver may only be implemented consistent with the approved Special Terms and Conditions (STCs) set forth in the accompanying document.

As discussed in the Centers for Medicare & Medicaid Services' (CMS) approval letter, the Secretary of Health and Human Services has determined that the Evolving West Virginia Medicaid's Behavioral Health Continuum of Care demonstration, including the granting of the waiver described below, is likely to assist in promoting the objectives of title XIX of the Act.

Except as provided below with respect to expenditure authority, all requirements of the Medicaid program expressed in law, regulation and policy statement, not expressly waived in this list, shall apply to the demonstration project for the period beginning January 1, 2025 through December 31, 2029.

Coverage of Certain Screening, Diagnostic, Section 1902(a)(84)(D) and Targeted Case Management Services for Eligible Juveniles in the 30 Days Prior to Release

To enable the state not to provide coverage of the screening, diagnostic, and targeted case management services identified in section 1902(a)(84)(D) of the Act for eligible juveniles described in section 1902(nn)(2) of the Act as a state plan benefit in the 30 days prior to the release of such eligible juveniles from a public institution, to the extent and for the period that the state instead provides such coverage to such eligible juveniles under the approved expenditure authorities under this demonstration. The state will provide coverage to eligible juveniles described in section 1902(nn)(2) in alignment with section 1902(a)(84)(D) of the Act at a level equal to or greater than would be required under the state plan.

CENTERS FOR MEDICARE & MEDICAID SERVICES

EXPENDITURE AUTHORITIES

NUMBER: 11-W-00307/3

TITLE: Evolving West Virginia Medicaid's Behavioral Health Continuum of Care

Section 1115(a) Demonstration

AWARDEE: West Virginia Department of Human Services, Bureau for Medical 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 from January 1, 2025 through December 31, 2029, unless otherwise specified, 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 the above-identified section 1115(a) demonstration.

- 1. Residential and Inpatient Treatment for Individuals with Substance Use Disorder (SUD). Expenditures for Medicaid state plan services furnished to otherwise eligible individuals who are primarily receiving treatment and/or withdrawal management services for SUD who are short-term residents in facilities that meet the definition of an institution for mental disease (IMD).
- 2. **Peer Recovery Support Specialist (PRSS) 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.
- 3. 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).
- 4. **Expenditures for Pre-Release Services.** Expenditures for pre-release services, as described in these STCs, provided to qualifying Medicaid individuals for up to 90 days immediately prior to the expected date of release from a correctional facility that is participating in the reentry demonstration initiative.
- 5. Expenditures for Pre-Release Administrative Costs. Capped expenditures for payments for allowable administrative costs, supports, transitional non-service expenditures, infrastructure and interventions, as is detailed in STC 8.12, which may not be recognized as medical assistance under section 1905(a) and may not otherwise qualify for federal matching funds under section 1903, to the extent such activities are authorized as part of the reentry demonstration initiative.

- 6. **Health-Related Social Needs (HRSN) Services.** Expenditures for allowable HRSN services not otherwise covered that are furnished to individuals who meet the qualifying criteria as described in Section 9. This expenditure authority is contingent upon compliance with Section 9, as well as all other applicable STCs.
- 7. **Expenditures Related to Quick Response Teams (QRTs).** Expenditures for QRT services, as described in Section 10, provided to qualifying beneficiaries by providers that elect and are approved by the West Virginia Bureau of Medical Services (BMS) to pilot the QRT benefit.
- 8. **Expenditures Related to Recovery-Related Support Services**. Expenditures for recovery-related support services, as described in Section 11, provided to qualifying beneficiaries.

<u>Medicaid Requirements Not Applicable to the Medicaid Expenditure Authority for Pre-Release Services:</u>

Statewideness Section 1902(a)(1)

To enable the state to provide pre-release services, as authorized under this demonstration, to qualifying individuals on a geographically limited basis, in accordance with the Reentry Demonstration Initiative Implementation Plan.

Amount, Duration, and Scope of Services and Comparability

Section 1902(a)(10)(B)

To enable the state to provide only a limited set of pre-release services, as specified in these STCs, to qualifying individuals that is different than the services available to all other individuals outside of correctional facility settings in the same eligibility groups authorized under the state plan or demonstration authority.

Freedom of Choice

Section 1902(a)(23)(A)

To enable the state to require qualifying individuals to receive pre-release services, as authorized under this demonstration, through only certain providers.

Title XIX Requirements Not Applicable to the HRSN Expenditure Authority:

Comparability; Amount, Duration, and Scope; Provision of Medical Assistance

Section 1902(a)(10)(b) and Section 1902(a)(17)

To the extent necessary to allow the state to offer HRSN services and to vary the amount, duration, and scope of HRSN services covered for a subset of beneficiaries, depending on beneficiary needs as determined by the application of qualifying criteria, as specified in Section 9 of the STCs.

<u>Title XIX Requirements Not Applicable to the Quick Response Teams (QRT) Expenditure Authority:</u>

Freedom of Choice

Section 1902(a)(23)(A)

To enable the state to require qualifying individuals to receive services from QRTs, as authorized under this demonstration, through only certain providers.

<u>Title XIX Requirements Not Applicable to the Recovery-Related Support Services (RRSS)</u> Expenditure Authority:

Freedom of Choice

Section 1902(a)(23)(A)

To enable the state to require qualifying individuals to receive RRSS, as authorized under this demonstration, through only certain providers.

CENTERS FOR MEDICARE & MEDICAID SERVICES

SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00307/3

TITLE: Evolving West Virginia Medicaid's Behavioral Health Continuum of Care

Section 1115(a) Demonstration

AWARDEE: West Virginia Department of Human Services, Bureau of Medical Services

1. PREFACE

The following are the Special Terms and Conditions (STCs) for the "Evolving West Virginia Medicaid's Behavioral Health Continuum of Care" section 1115(a) Medicaid demonstration (hereinafter "demonstration"; formerly called the "West Virginia Continuum of Care for Medicaid Enrollees with Substance Use Disorders (SUD)" demonstration), to enable the West Virginia Department of Human Services, Bureau of Medical Services (BMS) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted West Virginia (hereinafter "state") waivers of requirements under section 1902(a) of the Social Security Act (Act), and expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on those waiver and expenditure authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS related to the demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted.

The STCs related to the programs for those populations affected by the demonstration are effective from January 1, 2025 through December 31, 2029, unless otherwise specified.

The STCs have been arranged into the following subject areas:

1	Preface
2	Program Description and Objectives
3	General Program Requirements
4	Eligibility and Enrollment
5	Substance Use Disorder (SUD) Program and Benefits
6	Peer Recovery Support Specialist (PRSS) Services
7	Mandatory MCO Enrollment for CSEDW Members
8	Reentry Demonstration Initiative
9	Health-Related Social Needs (HRSN) Services
10	Quick Response Teams (QRTs)
11	Recovery-Related Support Services (RRSS)
12	Cost Sharing
13	Delivery System
14	Monitoring and Reporting Requirements

15	General Financial Requirements
16	Monitoring Budget Neutrality
17	Evaluation of the Demonstration
18	Schedule of State Deliverables for the Demonstration Period

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 Implementation Plan [Reserved]			
Attachment D	Health IT Plan [Reserved]			
Attachment E	Monitoring Protocol [Reserved]			
Attachment F	Evaluation Design [Reserved]			
Attachment G	Reentry Demonstration Initiative Qualifying Conditions and Services			
Attachment H	Reentry Demonstration Initiative Implementation Plan [Reserved]			
Attachment I	Reentry Demonstration Initiative Reinvestment Plan [Reserved]			
Attachment J	Assessment of Beneficiary Eligibility and Needs and Provider			
	Qualifications for HRSN Services Protocol [Reserved]			
Attachment K	HRSN Services Matrix			
Attachment L	HRSN Implementation Plan [Reserved]			

2. PROGRAM DESCRIPTION AND OBJECTIVES

West Virginia's section 1115 Substance Use Disorder (SUD) demonstration, originally called the "West Virginia Continuum of Care for Medicaid Enrollees with Substance Use Disorders (SUD)" demonstration, was first approved on October 6, 2017, and implemented on January 1, 2018. The demonstration tests a new paradigm for the delivery of SUD services by expanding the SUD continuum of care beyond what was previously available to West Virginia Medicaid enrollees through the state plan in order to provide enrollees with access to the care needed to achieve sustainable recovery. Critical elements of the SUD demonstration include providing a continuum of care modeled after the American Society of Addiction Medicine (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 enrollees 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.

Under this extension, the state will continue two SUD programs from the first demonstration period: SUD services provided in an institution for mental disease (IMD) and peer recovery support specialist (PRSS) services. Another SUD program approved under the first

demonstration period was medication-assisted treatment (MAT), including methadone treatment. In 2018, methadone became a mandatory Medicaid benefit after Congress passed the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act. In October 2021, West Virginia was approved for a state plan amendment (SPA) to cover all forms of MAT under state plan authority instead of section 1115 authority; this SPA became effective on October 1, 2020. In the extension period, West Virginia will continue the authority that requires beneficiaries under the Children with Serious Emotional Disorder 1915(c) waiver (CSEDW) to be automatically enrolled on a mandatory basis into a single, specialized managed care organization (MCO).

As part of the extension, the state is receiving authority for these additional initiatives targeting West Virginia Medicaid enrollees with SUD: health-related social needs (HRSN) services, quick response teams (QRTs), and recovery-related support services (RRSS). CMS is also approving coverage of a targeted set of pre-release services for certain individuals for 90 days immediately prior to their expected date of release from a participating correctional facility. As part of this approval, CMS has authorized payments for allowable administrative costs related to implementation of these pre-release services. CMS is approving the state's request to change the name of its demonstration to, "Evolving West Virginia Medicaid's Behavioral Health Continuum of Care," to reflect the state's efforts to evolve its continuum of care by adding and expanding services in the demonstration to better support Medicaid enrollees with SUD.

During the extension approval period, West Virginia will continue to test whether the programs in the demonstration, described in these STCs, are likely to assist in promoting the objectives of Medicaid by achieving the following:

- Improved quality of care and population health outcomes for Medicaid enrollees with SUD;
- Increased 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.
- Decreased medically inappropriate and avoidable utilization of high-cost emergency department and hospital services by enrollees with SUD; and
- Improved care coordination and care transitions for Medicaid enrollees with SUD

3. GENERAL PROGRAM REQUIREMENTS

- 3.1. 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 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).
- 3.2. Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy. All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and policy statement, not expressly waived or identified as not

- applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.
- 3.3. Changes in Medicaid and CHIP Law, Regulation, and Policy. The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 3.7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

3.4. Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.

- a. 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, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 3.7 of this section) as a result of the change in FFP.
- b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.
- 3.5. **State Plan Amendments.** The state will not be required to submit title XIX or XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP state plans govern.
- 3.6. Changes Subject to the Amendment Process. Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements 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 Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the

demonstration that have not been approved through the amendment process set forth in STC 3.7 below, except as provided in STC 3.3.

- 3.7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar 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 the failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. 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 3.12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;
 - b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
 - c. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of 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;
 - d. An up-to-date CHIP allotment worksheet, if necessary;
 - e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.
- 3.8. **Extension of the Demonstration.** States that intend to request an extension of the demonstration must submit an application to CMS at least 12 months in advance from the Governor of the state in accordance with the requirements of 42 CFR 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit phase-out plan consistent with the requirements of STC 3.9.
- 3.9. **Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.
 - a. <u>Notification of Suspension or Termination.</u> 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 a

notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 3.12, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

- b. <u>Transition and Phase-out Plan Requirements.</u> The state must include, at a minimum, in its phase-out 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 redeterminations of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.
- c. <u>Transition and Phase-out Plan Approval.</u> The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.
- d. Transition and Phase-out Procedures. The state must redetermine eligibility for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category prior to making a determination of ineligibility as required under 42 CFR 435.916(d)(1). For individuals determined ineligible for Medicaid and CHIP, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e). The state must comply with all applicable advance notice requirements and fair hearing rights described at 42 CFR, 431, Subpart E. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230.
- e. Exemption from Public Notice Procedures 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
- f. <u>Enrollment Limitation during Demonstration Phase-Out.</u> If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not

- impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.
- g. <u>Federal Financial Participation (FFP)</u>. If the project is terminated or any relevant waivers are suspended by the state, FFP must be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.
- 3.10. Withdrawal of Waiver or Expenditure Authority. CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX and title XXI. 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's 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, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.
- 3.11. **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.
- 3.12. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR section 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.

The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 3.7 or extension, are proposed by the state.

- 3.13. **Federal Financial Participation (FFP).** No federal matching funds for expenditures for this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.
- 3.14. **Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all

delegated functions to operating agencies, MCOs, and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

3.15. Common Rule Exemption. The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(d)(5).

4. ELIGIBILITY AND ENROLLMENT

4.1. **Eligibility Groups Affected by the Demonstration.** Under the demonstration, there is no change to Medicaid eligibility and the standards and methodologies for eligibility remain set forth under the state plan.

5. SUBSTANCE USE DISORDER (SUD) PROGRAM AND BENEFITS

5.1. **SUD Program Benefits.** The demonstration benefit package for Medicaid beneficiaries will include SUD treatment services, including services provided in residential and inpatient treatment settings that qualify as an IMD, which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Medicaid beneficiaries who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance, including opioid use disorder (OUD)/SUD services, that would otherwise be matchable if the beneficiary were not residing in an IMD. The state will aim for a statewide average length of stay of 30 days or less in residential treatment settings, to be monitored pursuant to the SUD Monitoring Protocol as outlined in STC 14.5, to ensure short-term residential stays.

Under this demonstration, beneficiaries will have access to high quality, evidence-based OUD/SUD treatment services across a comprehensive continuum of care, ranging from residential and inpatient treatment to ongoing chronic care for these conditions in cost-effective community-based settings.

5.2. SUD Implementation Plan and Health Information Technology (HIT) Plan. Given that CMS's requirements for the SUD Implementation Plan have changed since the state's original submission, the state must submit a revised implementation plan to CMS no later than 90 days post approval of this demonstration extension. The revised implementation plan will be affixed to the STCs as Attachment C. Any future modifications to the approved Implementation Plan will require CMS approval. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral. The SUD Implementation Plan describes the strategic approach and a detailed project implementation plan, including timetables and

programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives of this SUD demonstration project:

- a. Access to Critical Levels of Care for OUD and other SUDs. Coverage of OUD/SUD treatment services across a comprehensive continuum of care including: outpatient; intensive outpatient; medication assisted treatment (medication as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state); intensive levels of care in residential and inpatient settings; and medically supervised withdrawal management, within 12-24 months of demonstration approval;
- b. Use of Evidence-based SUD-specific Patient Placement Criteria. Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of demonstration approval;
- c. *Patient Placement*. Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of demonstration approval;
- d. Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities. Currently, residential treatment services are required to be licensed by the West Virginia Office of Health Facility Licensure & Certification (OHFLAC) as a licensed behavioral health center or a hospital (as applicable for higher level of care programs), per state code. Providers also must have certification. The state must establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;
- e. Standards of Care. Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;
- f. Standards of Care. Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of demonstration approval;

- g. Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for SUD/OUD. An assessment of the availability of providers in the critical levels of care throughout the state, or in the regions of the state participating under this demonstration, including those that offer MAT within 12 months of demonstration approval;
- h. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and SUD/OUD. Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;
- i. Improved Care Coordination and Transitions between Levels of Care. Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of demonstration approval;
- j. *SUD Health IT Plan*. Implementation of a Substance Use Disorder Health Information Technology Plan which describes technology that will support the aims of the demonstration. Further information which describes milestones and metrics are detailed in STC 5.3 and Attachment C.
- 5.3. **SUD Health Information Technology Plan ("HIT Plan").** The SUD Health IT plan applies to all states where the Health IT functionalities are expected to impact beneficiaries within the demonstration. As outlined in SMDL #17-003, states must submit to CMS the applicable Health IT Plan(s), to be included as a section(s) of the associated Implementation Plan(s) (see STC 5.2) to develop infrastructure and capabilities consistent with the requirements outlined in each demonstration-type.

The Health IT Plan should describe how technology can support outcomes through care coordination; linkages to public health and prescription drug monitoring programs; establish data and reporting structure to monitor outcomes and support data driven interventions. Such technology should, per 42 CFR 433.112(b), use open interfaces and exposed application programming interfaces and ensure alignment with, and incorporation of, industry standards adopted by the Office of the National Coordinator for Health IT in accordance with 42 CFR part 170, subpart B.

- a. The state must include in its Monitoring Protocol (see STC 14.5) an approach to monitoring its SUD Health IT Plan which will include performance metrics to be approved in advance by CMS.
- b. The state must monitor progress, each demonstration year (DY), on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS within its Annual Report (see STC 14.6).

- c. As applicable, the state should advance the standards identified in the 'Interoperability Standards Advisory—Best Available Standards and Implementation Specifications' (ISA) in developing and implementing the state's SUD Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.
- d. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state should use the federally recognized standards.
- e. Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally recognized ISA standards.
- f. Components of the Health IT Plan include:
 - i. The Health IT Plan must describe the state's alignment with Section 5042 of the SUPPORT Act requiring Medicaid providers to query a Qualified Prescription Drug Monitoring Program (PDMP).¹
 - ii. The Health IT Plan must address how the state's Qualified PDMP will enhance ease of use for prescribers and other state and federal stakeholders.² States should favor procurement strategies that incorporate qualified PDMP data into electronic health records as discrete data without added interface costs to Medicaid providers, leveraging existing federal investments in RX Check for Interstate data sharing.
 - iii. The Health IT Plan will describe how technology will support substance use disorder prevention and treatment outcomes described by the demonstration.
 - iv. In developing the Health IT Plan, states should use the following resources:
 - 1. States may use federal resources available on Health IT.Gov (https://www.healthit.gov/topic/behavioral-health) including but not limited to "Behavioral Health and Physical Health Integration" and "Section 4: Opioid Epidemic and Health IT" (https://www.healthit.gov/playbook/health-information-exchange/).
 - 2. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT

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¹ Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance prescriptions in states. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the "opioid" epidemic and facilitate a nimble and targeted response.

² Ibid.

- Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.
- 3. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP interoperability, electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.
- 4. States should review the Office of the National Coordinator's Interoperability Standards Advisory (https://www.healthit.gov/isa/) for information on appropriate standards which may not be required per 45 CFR part 170, subpart B for enhanced funding, but still should be considered industry standards per 42 CFR 433.112(b)(12).
- 5.4. **Evaluation.** The SUD Evaluation will be subject to the same requirements as the overall demonstration evaluation, as described in Sections 14 (Monitoring and Reporting Requirements) and 17 (Evaluation of the Demonstration) of these STCs.
- 5.5. **Unallowable Expenditures Under the SUD Expenditure Authority.** In addition to the other unallowable costs and caveats already outlined in these STCs, the state may not receive FFP under any expenditure authority approved under this demonstration for any of the following:
 - a. Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

6. PEER RECOVERY SUPPORT SPECIALIST (PRSS) SERVICES

6.1. Peer recovery support specialists (PRSS) are individuals who are successful in their own recovery process from SUD who help others in similar situations by providing recovery support to help prevent relapse and promote recovery. Peer recovery support services are recommended by a licensed practitioner. Services can be provided by PRSS working under the supervision of a competent behavioral health professional (as defined by the state). A PRSS must be certified through a West Virginia Department of Human Services-approved training program that provides peer support providers with a basic set of competencies necessary to perform the peer support function. A PRSS must demonstrate the ability to support the recovery of others from substance use disorders and complete continuing educational requirements.

7. MANDATORY MCO ENROLLMENT FOR CSEDW MEMBERS

7.1. This demonstration provides expenditure authority that operates next to the state's concurrent 1915(c) Children with Serious Emotional Disorders waiver (CSEDW). Effectively, the state automatically enrolls CSEDW beneficiaries on a mandatory basis into a single managed care organization (MCO) and does 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.

- 7.2. The state's contract with the specialty plan/ MCO must require a transition of care protocol to ensure continuity of care for members. The Specialty Plan/ MCO must continue medically necessary services without any form of prior approval and without regard to whether such services are provided by in-network or out-of-network providers for at least 90 days. To ensure continuity of care, if the Specialty Plan/ MCO does not currently have a member's provider in its network, the Specialty Plan/MCO is required to offer a contract or a single case agreement for a minimum of 90 days to providers (including out of state placement providers) that have provided treatment to Specialty Plan members prior to enrollment. The Specialty Plan/ MCO is required to continue services for at least 90 days unless the member/family has opted to discontinue such services or selects a provider that is in-network.
- 7.3. **Assurance of Adequate Capacity and Services**. For the single MCO that furnishes services to CSEDW beneficiaries during the mandatory lock-in period, as authorized by this 1115(a) demonstration, the State must submit the Assurance of Compliance detailed in 42 CFR § 438.207(d) using the Network Adequacy and Access Assurances Report template provided by CMS.
- 7.4. Timing of Submission of Assurance of Adequate Capacity and Services. The State must begin submitting the Network Adequacy and Access Assurances Report for the single MCO plan that furnishes services to CSEDW beneficiaries during the mandatory lock-in period, authorized by this 1115(a) demonstration, by January 1, 2026. For the initial submissions in demonstration year (DY) 8, the State must tailor the Network Adequacy and Access Assurances Report submission based on operational readiness and data availability. For submissions in DY 9 through DY 11, the State must provide the complete set of data outlined in the Network Adequacy and Access Assurances Report for the managed care plan that furnishes services to CSEDW beneficiaries during the mandatory lock-in period authorized by this 1115(a) demonstration. The State must publish these reports on its public website.
- 7.5. Quarterly Appeals and Grievance Report. CMS reserves the right to request quarterly appeals and grievance data for all programs authorized under this 1115(a) demonstration. Beginning with DY 8, the State must submit 60 days after of the end of each quarter, appeals and grievance data for the managed care plan that furnishes services to CSEDW beneficiaries during the mandatory lock-in period authorized by this 1115(a) demonstration. In effectuating this requirement, the State must utilize the Appeals and Grievance Reporting Template provided by CMS.

8. REENTRY DEMONSTRATION INITIATIVE

8.1. Overview of Pre-Release Services and Program Objectives. This component of the demonstration will provide coverage for pre-release services up to 90 days immediately prior to the expected date of release to certain individuals who are inmates residing in state/local jails, state prisons, and youth correctional facilities (hereinafter "correctional facilities"). To qualify for services covered under this demonstration, individuals residing in correctional facilities must be eligible for Medicaid as determined pursuant to an application filed before or during incarceration and must have an expected release date no later than 90 days as further specified in the STCs below.

8.2. The objective of this component of the demonstration is to facilitate individuals' access to certain healthcare services and case management, provided by Medicaid participating providers, while individuals are incarcerated and allow them to establish relationships with community-based providers from whom they can receive services upon reentry to their communities. This bridge to coverage begins within a short time prior to release and is expected to promote continuity of coverage and care and improve health outcomes for justice-involved individuals. The reentry demonstration initiative provides short-term Medicaid enrollment assistance and pre-release coverage for certain services to facilitate successful care transitions, as well as improve the identification and treatment of certain chronic and other serious conditions to reduce acute care utilization in the period soon after release, and test whether it improves uptake and continuity of medication-assisted treatment (MAT) and other Substance Use Disorder (SUD) and behavioral health treatments, as appropriate for the individual.

During the demonstration, the state seeks to achieve the following goals:

- a. Increase coverage, continuity of care, and appropriate service uptake through assessment of eligibility and availability of coverage for benefits in correctional facility settings prior to release;
- b. Improve access to services prior to release and improve transitions and continuity of care into the community upon release and during reentry;
- c. Improve coordination and communication between correctional systems, Medicaid systems, managed care plans (as applicable), and community-based providers;
- d. Increase additional investments in health care and related services, aimed at improving the quality of care for individuals in correctional facility settings, and in the community to maximize successful reentry post-release;
- e. Improve connections between correctional facility settings and community services upon release to address physical and behavioral health needs, and health-related social needs;
- f. Reduce all-cause deaths in the near-term post-release;
- g. Reduce the number of emergency department visits and inpatient hospitalizations among recently incarcerated Medicaid individuals through increased receipt of preventive and routine physical and behavioral health care;
- h. Provide interventions for certain behavioral health conditions, including use of stabilizing medications like long-acting injectable antipsychotics and medication for addiction treatment for SUDs where appropriate, with the goal of reducing overdose and overdose-related death in the near-term post-release.

- i. Increase enrollee access to and utilization of appropriate SUD treatment services according to ASAM criteria, or another comparable, nationally recognized set of SUD program standards based on evidence-based SUD clinical guidelines.
- 8.3. **Qualifying Criteria for Pre-Release Services.** To qualify to receive services under this component of the demonstration, an individual must meet the following qualifying criteria:
 - a. Meet the definition of an inmate of a public institution, as specified in 42 CFR 435.1010, and be incarcerated in a correctional facility specified in STC 8.1;
 - b. Have been determined eligible for Medicaid;
 - c. Have an expected release date within 90 days;
 - d. Be 18 years of age or older; and
 - e. Meet the health-related criteria described below and further defined in Attachment G.
 - i. SUD, based on specified criteria as defined in Attachment G.
- 8.4. **Scope of Pre-Release Services.** The pre-release services authorized under the reentry demonstration initiative include the following services, which are described in Attachment G, Reentry Demonstration Initiative Services.
 - a. The covered pre-release services are:
 - i. Case management to assess and address physical and behavioral health needs, and health-related social needs:
 - ii. MAT for all types of SUDs as clinically appropriate, including coverage for medications in combination with counseling/behavioral therapies;
 - b. The state must also provide a 30-day supply of all prescription medications and over-the-counter drugs (as clinically appropriate), provided to the individual immediately upon release from the correctional facility, consistent with approved Medicaid or CHIP state plan coverage authority and policy.
 - c. The expenditure authority for pre-release services through this initiative constitutes a limited exception to the federal claiming prohibition for medical assistance furnished to inmates of a public institution at clause (A) following section 1905(a) of the Act ("inmate exclusion rule"). Benefits and services for inmates of a public institution that are not approved in the reentry demonstration initiative as described in these STCs and accompanying protocols, and not otherwise covered under the inpatient exception to the inmate exclusion rule remain subject to the inmate exclusion rule. Accordingly, other benefits and services covered under the West Virginia Medicaid State Plan, as relevant, that are not included in the above-described pre-release services (e.g., EPSDT

treatment services for qualifying Medicaid beneficiaries under age 21) are not available to qualifying individuals through the reentry demonstration initiative.

8.5. Participating Correctional Facilities. The pre-release services will be provided at state/local jails, state prisons, and youth correctional facilities, or outside of the correctional facilities, with appropriate transportation and security oversight provided by the correctional facility, subject to West Virginia's BMS approval of a facility's readiness, according to the implementation timeline described in STC 8.9. States must be mindful of and ensure the policies, procedures, and processes developed to support implementation of these provisions do not effectuate a delay of an individual's release or lead to increased involvement in the juvenile and adult justice systems. Correctional facilities that are also institutions for mental diseases (IMDs) are not allowed to participate in the reentry demonstration initiative.

8.6. Participating Providers.

- a. Licensed, registered, certified, or otherwise appropriately credentialed or recognized practitioners under West Virginia scope of practice statutes shall provide services within their individual scope of practice and, as applicable, receive supervision required under their scope of practice laws and must be enrolled as a Medicaid provider.
- b. Participating providers eligible to deliver services under the reentry demonstration initiative may be either community-based or correctional facilitybased providers.
- c. All participating providers and provider staff, including correctional providers, shall have necessary experience and receive appropriate training, as applicable to a given correctional facility, prior to furnishing demonstration-covered prerelease services under the reentry demonstration initiative.
- d. Participating providers of reentry case management services may be community-based or correctional providers who have expertise working with justice-involved individuals.
- 8.7. **Suspension of Coverage.** Upon entry of a Medicaid-enrolled individual into a correctional facility, West Virginia's BMS must not terminate and generally shall suspend their Medicaid coverage.
 - a. If an individual is not enrolled in Medicaid when entering a correctional facility, the state must ensure that such an individual receives assistance with completing an application for Medicaid and with submitting an application, unless the individual declines such assistance or wants to decline enrollment.
- 8.8. **Interaction with Mandatory State Plan Benefits for Eligible Juveniles**. To the extent West Virginia's reentry demonstration includes coverage otherwise required to be provided under section 1902(a)(84)(D) of the Act, and because this coverage is included in the base expenditures used to determine the budget neutrality expenditure limit, the state will claim for

- these expenditures and related transitional non-service expenditures under this demonstration as well as include this coverage in the monitoring and evaluation of this demonstration.
- 8.9. Reentry Demonstration Initiative Implementation Timeline. Delivery of pre-release services under this demonstration will be implemented as described below. All participating correctional facilities must demonstrate readiness, as specified below, prior to participating in this initiative (FFP will not be available in expenditures for services furnished to qualifying individuals who are inmates in a facility before the facility meets the below readiness criteria for participation in this initiative). The BMS will determine that each applicable facility is ready to participate in the reentry demonstration initiative under this demonstration based on a facility-submitted assessment (and appropriate supporting documentation) of the facility's readiness to implement:
 - a. Pre-release Medicaid application and enrollment processes for individuals who are not enrolled in Medicaid prior to incarceration and who do not otherwise become enrolled during incarceration;
 - b. The screening process to determine an individual's qualification for pre-release services, per the eligibility requirements described in STC 8.3;
 - c. The provision or facilitation of pre-release services for a period of up to 90 days immediately prior to the expected date of release, including the facility's ability to support the delivery of services furnished by providers in the community that are delivered via telehealth, as applicable;
 - d. Coordination amongst partners with a role in furnishing health care services to individuals who qualify for pre-release services, including, but not limited to, physical and behavioral health community-based providers, social service departments, and managed care plans;
 - e. Appropriate reentry planning, pre-release case management, and assistance with care transitions to the community, including connecting individuals to physical and behavioral health providers and their managed care plan (as applicable), and making referrals to case management and community supports providers that take place throughout the 90-day pre-release period, and providing individuals with covered outpatient prescribed medications and over-the-counter drugs (a minimum 30-day supply as clinically appropriate) upon release, consistent with approved Medicaid state plan coverage authority and policy;
 - f. Operational approaches related to implementing certain Medicaid requirements, including but not limited to applications, suspensions, notices, fair hearings, reasonable promptness for coverage of services, and any other requirements specific to receipt of pre-release services by qualifying individuals under the reentry demonstration initiative;
 - g. A data exchange process to support the care coordination and transition activities described in (d), (e), and (f) of this subsection subject to compliance with

- applicable federal, state, and local laws governing confidentiality, privacy, and security of the information that would be disclosed among parties;
- h. Reporting of data requested by the BMS to support program monitoring, evaluation, and oversight; and
- i. A staffing and project management approach for supporting all aspects of the facility's participation in the reentry demonstration initiative, including information on qualifications of the providers with whom the correctional facilities will partner for the provision of pre-release services.
- 8.10. Reentry Demonstration Initiative Implementation Plan. The state is required to submit a Reentry Demonstration Initiative Implementation Plan in alignment with the expectations outlined in the State Medicaid Director Letter (#23-003 Opportunities to Test Transition-Related Strategies to Support Community Reentry and Improve Care Transitions for Individuals who are Incarcerated). As such, the implementation plan will identify for each milestone, as well as each associated action, what the state anticipates to be the key implementation challenges and the state's specific plans to address these challenges. This will include any plans to phase in demonstration components over the lifecycle of the demonstration.

The state must submit the draft Implementation Plan to CMS no later than 120 calendar days after approval of the reentry demonstration initiative. The state must submit any required clarifications or revisions to its draft Implementation Plan no later than 60 calendar days after receipt of CMS feedback. The finalized Implementation Plan will be incorporated into the STCs as Attachment H titled "Reentry Demonstration Initiative Implementation Plan."

CMS will provide the state with a template to support developing the Implementation Plan.

8.11. Reentry Demonstration Initiative Reinvestment Plan. To the extent that the reentry demonstration initiative covers services that are the responsibility of and were previously provided or paid by the correctional facility with custody of qualifying individuals, the state must reinvest all new federal dollars, equivalent to the amount of FFP projected to be expended for such services, as further defined in the Reentry Demonstration Initiative Reinvestment Plan (Attachment I) and subject to CMS approval. The Reinvestment Plan will define the amount of reinvestment required over the term of the demonstration, based on an assessment of the amount of projected expenditures for which reinvestment is required pursuant to this STC. FFP projected to be expended for new services covered under the reentry demonstration initiative, defined as services not previously provided or paid by the correctional facility with custody of qualifying individuals prior to the facility's implementation of the reentry demonstration initiative (including services that are expanded, augmented, or enhanced to meet the requirements of the reentry demonstration initiative, with respect to the relevant increase in expenditures, as described in Attachment I the Reentry Demonstration Initiative Reinvestment Plan) is not required to be reinvested pursuant to this STC.

- a. Reinvestments in the form of non-federal expenditures totaling the amount of new federal dollars, as described above, must be made over the course of the demonstration period. Allowable reinvestments include, but are not limited to:
 - i. The state share of funding associated with new services covered under the reentry demonstration initiative, as specified in this STC;
 - ii. Improved access to behavioral and physical community-based health care services and capacity focused on meeting the health care needs and addressing the needs of individuals who are incarcerated (including those who are soon-to-be released), those who have recently been released, and those who may be at higher risk of criminal justice involvement, particularly due to untreated behavioral health conditions;
 - iii. Improved access to or quality of carceral health care services, including by covering new, enhanced, or expanded pre-release services authorized via the reentry demonstration initiative opportunity;
 - iv. Improved health information technology (IT) and data sharing subject to compliance with applicable federal, state, and local laws governing confidentiality, privacy, and security of the information that would be disclosed among parties;
 - v. Increased community-based provider capacity that is particularly attuned to the specific needs of, and able to serve, justice-involved individuals or individuals at risk of justice involvement;
 - vi. Expanded or enhanced community-based services and supports, including services and supports to meet the needs of the justice-involved population; and
 - vii. Any other investments that aim to support reentry, smooth transitions into the community, divert individuals from incarceration or re-incarceration, or better the health of the justice-involved population, including investments that are aimed at interventions occurring both prior to and following release from incarceration into the community.
- b. The reinvestment plan will describe whether privately-owned or -operated carceral facilities would receive any of the reinvested funds and, if so, the safeguards the state proposes to ensure that such funds are used for the intended purpose and do not have the effect of increasing profit or operating margins for privately-owned or -operated carceral facilities.
- c. Within six months of approval, the state will submit a Reentry Demonstration Initiative Reinvestment Plan (Attachment I) for CMS approval that memorializes the state's reinvestment approach. The Reinvestment Plan will also identify the types of expected reinvestments that will be made over the demonstration period. Actual reinvestments will be reported to CMS in Attachment I titled "Reentry Demonstration Initiative Reinvestment Plan."

8.12. Reentry Demonstration Initiative Planning and Implementation.

- The Reentry Demonstration Initiative Planning and Implementation Program will provide expenditure authority to fund supports needed for Medicaid pre-release application and suspension/unsuspension planning and purchase of certified electronic health record (EHR) technology to support Medicaid pre-release applications. In addition, reentry demonstration initiative planning and implementation funds will provide funding over the course of the demonstration to support planning and IT investments that will enable implementation of the reentry demonstration initiative services covered in a period for up to 90 days immediately prior to the expected date of release, and for care coordination to support reentry. These investments will support collaboration and planning among the BMS and Qualified Applicants listed in STC 8.12(d) below. The specific use of this funding will be proposed by the qualified applicant submitting the application, as the extent of approved funding will be determined according to the needs of the entity. Allowable expenditures are limited to only those that support Medicaid-related expenditures and/or demonstration-related expenditures (and not other activities or staff in the correctional facility) and must be properly cost-allocated to Medicaid. These allowable expenditures may include the following:
 - i. **Technology and IT Services.** Expenditures for the purchase of technology for Qualified Applicants which are to be used for assisting the reentry demonstration initiative population with Medicaid application and enrollment for demonstration coverage. This includes the development of electronic interfaces for Qualified Applicants listed in STC 8.12(d). to communicate with Medicaid IT systems to support Medicaid enrollment and suspension/unsuspension and modifications. This also includes support to modify and enhance existing IT systems to create and improve data exchange and linkages with Qualified Applicants listed in STC 8.12(d), in order to support the provision of pre-release services delivered in the period up to 90 days immediately prior to the expected date of release and reentry planning.
 - ii. Hiring of Staff and Training. Expenditures for Qualified Applicants listed in STC 8.12(d). to recruit, hire, onboard, and train additional and newly assigned staff to assist with the coordination of Medicaid enrollment and suspension/unsuspension, as well as the provision of pre-release services in a period for up to 90 days immediately prior to the expected date of release and for care coordination to support reentry for justice-involved individuals. Qualified Applicants may also require training for staff focused on working effectively and appropriately with justice-involved individuals.
 - iii. Adoption of Certified Electronic Health Record Technology. Expenditures for providers' purchase or necessary upgrades of certified electronic health record (EHR) technology and training for the staff that will use the EHR.

- iv. **Purchase of Billing Systems.** Expenditures for the purchase of billing systems for Qualified Applicants.
- v. **Development of Protocols and Procedures.** Expenditures to support the specification of steps to be taken in preparation for and execution of the Medicaid enrollment process, suspension/unsuspension process for eligible individuals, and provision of care coordination and reentry planning for a period for up to 90 days immediately prior to the expected date of release for individuals qualifying for reentry demonstration initiative services.
- vi. Additional Activities to Promote Collaboration. Expenditures for additional activities that will advance collaboration among West Virginia's Qualified Applicants in STC 8.12(d). This may include conferences and meetings convened with the agencies, organizations, and other stakeholders involved in the initiative.
- vii. **Planning.** Expenditures for planning to focus on developing processes and information sharing protocols to: (1) identifying individuals who are potentially eligible for Medicaid; (2) assisting with the completion of a Medicaid application; (3) submitting the Medicaid application to the county social services department or coordinating suspension/unsuspension; (4) screening for eligibility for pre-release services and reentry planning in a period for up to 90 days immediately prior to the expected date of release; (5) delivering necessary services to eligible individuals in a period for up to 90 days immediately prior to the expected date of release and care coordination to support reentry; and (6) establishing on-going oversight and monitoring process upon implementation.
- viii. Other activities to support a milieu appropriate for provision of prerelease services. Expenditures to provide a milieu appropriate for prerelease services in a period for up to 90 days immediately prior to the
 expected date of release, including accommodations for private space such
 as movable screen walls, desks, and chairs, to conduct assessments and
 interviews within correctional institutions, and support for installation of
 audio-visual equipment or other technology to support provision of prerelease services delivered via telehealth in a period for up to 90 days
 immediately prior to the expected date of release and care coordination to
 support reentry. Expenditures may not include building, construction, or
 refurbishment of correctional facilities.
- b. The state may claim FFP in Reentry Demonstration Initiative Planning and Implementation Program expenditures for no more than the annual amounts outlined in Table 1. In the event that the state does not claim the full amount of FFP for a given demonstration year, the unspent amounts will roll over to one or more demonstration years not to exceed this demonstration period and the state may claim the remaining amount in a subsequent demonstration year.

Table 1. Annual Limits of Total Computable Expenditures for Reentry Demonstration Initiative Planning and Implementation Program

	DY 7	DY 8	DY 9	DY 10	DY 11
Total Computable	\$4,000,000	\$3,000,000	\$3,000,000	\$750,000	N/A
Expenditures				,	

- c. Reentry Demonstration Initiative Planning and Implementation funding will receive the applicable administrative match for the expenditure.
- d. Qualified Applicants for the Reentry Demonstration Initiative Planning and Implementation Program will include the state Medicaid Agency, correctional facilities, other state agencies supporting carceral health, Probation Offices, and other entities as relevant to the needs of justice-involved individuals, including health care providers, as approved by the state Medicaid agency.

9. HEALTH-RELATED SOCIAL NEEDS (HRSN) SERVICES

- 9.1. Health-Related Social Needs (HRSN) Services. The state may claim FFP for expenditures for certain qualifying HRSN services identified in STC 9.2 and Attachment J, subject to the restrictions described below. Expenditures are limited to expenditures for items and services not otherwise covered under Title XIX, but consistent with Medicaid demonstration objectives that enable the state to continue to increase the efficiency and quality of care. All HRSN interventions must be evidence-based and clinically appropriate for the population of focus based on clinical and social risk factors. The state is required to align clinical and healthrelated social risk criteria across services and with other relevant, non-Medicaid social support agencies, to the extent possible and appropriate. The HRSN services may not supplant any other available funding sources such as housing supports available to the beneficiary through other local, state, or federal programs. The HRSN services will be the choice of the beneficiary; a beneficiary can opt out of HRSN services anytime; and the HRSN services do not absolve the state or its managed care plans, as applicable, of their responsibilities to make payment for other covered services. Under no circumstances will the state be permitted to condition Medicaid coverage, or coverage of any benefit or service, on a beneficiary's receipt of HRSN services. The state must submit additional details on covered services as outlined in STC 9.8 (Service Delivery) and Attachment J.
- 9.2. Allowable HRSN services. The state may cover the following HRSN services:
 - a. Case management services for access to housing (e.g., outreach and education; linkages to other state and federal benefit programs, benefit program application assistance, and benefit program application fees).
 - b. Housing Interventions, including:
 - i. Housing supports without room and board, including:
 - 1. Pre-tenancy navigation services (e.g., finding and securing housing).

- 2. One-time transition and moving costs other than rent, to assist with identifying, coordinating, securing, or funding one-time necessary services and modifications to help a person establish a basic household (e.g., security deposit, application and inspection fees, utilities activation fees and payment in arrears as necessary to reestablish utility service (capped at a total of six months of total arrear and prospective payments), movers, relocation expenses, pest eradication, pantry stocking (up to 30 days of food), cooking supplies, and the purchase of household goods and furniture). Allowable utilities include water, garbage, sewage, recycling, gas, electric, internet, and phone services. This does not include clothing.
- 3. Tenancy and sustaining services (e.g., eviction prevention, tenant rights education).

9.3. HRSN Intervention Duration and Frequency.

- a. The state will define HRSN service duration limitations in Attachment J, subject to CMS approval as indicated in STC 9.6.
- 9.4. **Excluded Services.** Excluded items, services, and activities that are not covered as HRSN services include, but are not limited to:
 - a. Construction (bricks and mortar) except as needed for approved medically necessary home modifications;
 - b. Capital investments;
 - c. Room and board;
 - d. Research grants and expenditures not related to monitoring and evaluation;
 - e. Services furnished to beneficiaries for which payment is not available under the inmate payment exclusion in the matter following the last numbered paragraph of section 1905(a) of the Act except case management of HRSN services provided as part of an approved reentry demonstration initiative;
 - f. Services provided to individuals who are not lawfully present in the United States;
 - g. Expenditures that supplant services and/or activities funded by other local, state and/or federal governmental entities;
 - h. General workforce activities, not specifically linked to Medicaid or Medicaid beneficiaries; and
 - i. Any other projects or activities not specifically approved by CMS as qualifying for demonstration coverage as a HRSN item or service under this demonstration.

- 9.5. Covered Populations. Expenditures for HRSN services may be made for the populations of focus specified in Attachment J consistent with this STC. To qualify to receive coverage for HRSN services, individuals must be Medicaid (or Medicaid demonstration)-eligible and have a documented medical/clinical need for the services and the services must be determined medically/clinically appropriate, as described STC 9.1, to address the documented need. Medical appropriateness must be based on clinical and health-related social risk factors. This determination must be documented in the beneficiary's care plan or medical record. Additional detail, including the clinical and other health related-social needs criteria, is outlined in Attachment J. Attachment K, the HRSN Service Matrix, describes the full list of clinical and social risk factors the state anticipates incorporating into Attachment J over the course of the demonstration at the time of the demonstration approval of the expenditure authority for HRSN services. While Attachment K reflects the full list of clinical and social risk factors to implement, the state is not required to implement all of the clinical and social risk factors outlined in Attachment K. Additionally, the state can later include additional clinical and social risk factors in compliance with STC 9.6 and 9.7.
- 9.6. Protocol for Assessment of Beneficiary Eligibility and Needs, and Provider Qualifications for HRSN Services. The state must submit, for CMS approval, a Protocol for Assessment of Beneficiary Eligibility and Needs, and Provider Qualifications to CMS no later than 90 days after approval of the HRSN expenditure authority. The protocol must include, as appropriate, a list of the HRSN services and service descriptions, the criteria for defining a clinically appropriate population of focus for each service, the process by which those criteria will be applied including care plan requirements and/or other documented processes, and provider qualification criteria for each service. Any changes to the initial scope of clinical and social risk factors reflected in Attachment K must be effectuated through the process indicated in STC 9.7. The state must resubmit a revised protocol if required by CMS feedback on the initial submission. The state may not claim FFP for HRSN services until CMS approves the initial protocol. Once the initial protocol is approved, the state can claim FFP in expenditures for HRSN services retrospectively to the date of approval of the expenditure authority for HRSN services. The approved protocol will be appended to the STCs as Attachment J.

If the state adds new HRSN services beyond those specified in STC 9.2 through a demonstration amendment, the state must also submit revisions to the Protocol to CMS no later than 90 days after the approval of the amendment to the demonstration. The Protocol revisions must include a list of the new services and service descriptions provided through all delivery systems applicable, the criteria for defining a clinically appropriate population of focus for each new service, the process by which those criteria will be applied including service plan requirements and/or other documented processes, and provider qualification criteria for each new service. The revised protocol must comply with applicable STCs.

Specifically, the protocol must include the following information:

a. A list of the covered HRSN services (not to exceed those allowed under STC 9.2), with associated service descriptions and service-specific provider qualification requirements.

- b. A description of the process for identifying beneficiaries with health-related social needs, including outlining beneficiary qualifications, implementation settings, screening tool selection, and rescreening approach and frequency, as applicable.
- c. A description of the process by which clinical criteria will be applied, including a description of the documented process wherein a provider, using their professional judgment, may determine the service to be clinically appropriate.
 - i. Plan to identify medical appropriateness based on clinical and social risk factors.
 - ii. Plan to publicly maintain these clinical and social risk criteria to ensure transparency for beneficiaries and other interested parties.
- d. A description of the process for developing care plans based on assessment of need.
 - i. Plan to initiate care plans and closed-loop referrals to social services and community providers based on the outcomes of screening.
 - ii. Description of how the state will ensure that HRSN screening and service delivery are provided to beneficiaries in ways that are culturally responsive and/or trauma informed, as appropriate.

9.7. Updates to the Protocol for Assessment of Beneficiary Eligibility and Needs and Provider Qualifications for HRSN Services:

- a. The state may choose to cover a subset of the HRSN services and/or beneficiary qualifying criteria specified in Attachment J and Attachment K. Certain changes to the state's service offerings and qualifying criteria, within what CMS has approved in Attachment K, do not require additional CMS approval. The state must follow the following process to notify CMS of any such HRSN service or qualifying criteria change in Attachment J:
 - i. The state must follow the same beneficiary notification procedures as apply in the case of changes to coverage and/or beneficiary service qualification criteria for state plan services, including with respect to beneficiaries who currently qualify for and/or are receiving services who may receive a lesser amount, duration, or scope of coverage as a result of the changes.
 - ii. The state must provide public notice.
 - iii. The state must submit a letter to CMS no less than 30 days prior to implementation describing the changes, which will be incorporated in the demonstration's administrative record.

- b. In addition to the requirements in a. above, if the state seeks to implement additional clinical and/or social risk factors than what are included in approved Attachment K, the state must follow the process below to update the protocol:
 - i. The state must provide a budget neutrality analysis demonstrating the state's expected cost for the additional population(s). The state may only add additional clinical and/or social risk factors through the protocol process described in this STC if CMS determines the criteria are allowable and doing so would not require an increase to the amount of the state's HRSN expenditure authority in Table 8.
 - ii. The state must receive CMS approval for the updated protocol prior to implementation of changes under this STC 9.7.b.
 - iii. The state is limited to submitting to CMS one update to its protocol per demonstration year as part of this process outlined in this STC 9.7.b. This restriction is not applicable to the process and scope of changes outlined in STC 9.7.a.
- 9.8. **Service Delivery.** HRSN services will be provided in the managed care delivery system(s) and delivered by HRSN service providers. Terms applicable to all HRSN services:
 - a. When HRSN services are provided to beneficiaries enrolled in Medicaid managed care, the following terms will apply:
 - i. HRSN services can be provided by managed care plans and paid on a non-risk basis and must be appropriately included in contracts. This can be accomplished by either a separate non-risk contract with a prepaid inpatient health plan (PIHP) or a prepaid ambulatory health plan (PAHP) (see the definition of "non-risk contract" at 42 CFR § 438.2) or as an amendment to a state's existing risk-based managed care plan contract to include a non-risk payment. The state must take measures to ensure there is no duplication of payments for either the delivery of such service or the administrative costs of delivering such services.
 - ii. For a non-risk contract or a non-risk payment, the managed care plan is not at financial risk for changes in utilization or for costs incurred under the contract or payment that do not exceed the upper payment limits specified in 42 CFR 447.362 and may be reimbursed by the state at the end of the contract period on the basis of the incurred costs, subject to the specified limits. For the purposes of this demonstration, fee-for-service as defined in 42 CFR 447.362 is the fee-for-service authorized in this demonstration for HRSN services paid on a fee-for-service basis by the state. The managed care plan contracts must clearly document the process and methodology for non-risk payments.
 - iii. When the state includes non-risk payments in a risk-based contract, the state must ensure all non-risk payments are separate and apart from risk-based payments and clearly define what services/populations are covered under

non-risk payments versus included in risk-based capitation rates. All of the costs of delivering services under a non-risk payment must be excluded from the development of the risk-based capitation rates for the risk-based contracts. Specifically, the costs of delivery the services as well as any costs of administering the non-risk payment must be excluded from the development of the risk-based capitation rates.

- iv. Prior written CMS approval pursuant to STC 9.9 is required before the state moves to incorporate the HRSN services into the risk-based capitation rates in Medicaid managed care. When the state incorporates the HRSN services into the risk-based capitation rates in Medicaid managed care, the state must comply with all applicable federal requirements, including but not limited to 42 CFR 438.4, 438.5, 438.6, and 438.7, and may no longer utilize non-risk payments for the services included in risk-based capitation rates.
- v. Any applicable HRSN services that are delivered by managed care plans in a risk arrangement, must be included in the risk-based managed care contracts and rate certifications submitted to CMS for review and approval in accordance with 42 CFR 438.3(a) and 438.7(a).
- vi. The state must monitor and provide narrative updates through its Quarterly and Annual Monitoring Reports on the inclusion of HRSN services in managed care programs.
- vii. All expenditures for HRSN services delivered under non-risk contracts must be excluded from MLR reporting. When HRSN services (i.e., HRSN services defined in STC 9.2 for the covered populations outlined in STC 9.5) are included in capitation rates paid to managed care plans under risk-based contracts, and only then, should HRSN services be reported in the medical loss ratio (MLR) reporting as incurred claims.
- viii. The state must develop an MLR monitoring and oversight process specific to HRSN services. This process must be submitted to CMS, for review and approval, no later than 6 months prior to the implementation of HRSN services in risk-based managed care contracts and capitation rates. The state should submit this process to CMS at DMCPMLR@cms.hhs.gov. This process must specify how HRSN services will be identified for inclusion in capitation rate setting and in the MLR numerator. The state's plan must indicate how expenditures for HRSN administrative costs and infrastructure, as applicable, will be identified and reported in the MLR as non-claims costs.
- b. CMS expects the state to have appropriate encounter data associated with each HRSN service. This is necessary to ensure appropriate fiscal oversight for HRSN services as well as monitoring and evaluation. This is also critical to ensure appropriate base data for Medicaid managed care rate development purposes as well as appropriate documentation for claims payment in managed care. Therefore, CMS requires that for HRSN services provided in a managed care delivery system, the state must include the name and definition of each

HRSN service as well as the coding to be used on claims and encounter data in the managed care plan contracts. For example, the state must note specific Healthcare Common Procedure Coding System (HCPCS) or Current Procedural Terminology costs that identify each HRSN service. CMS will also consider this documentation necessary for approval of any rate methodologies per STC 9.16.

- 9.9. Requirements for HRSN Services prior to being delivered in risk-based managed care. The state's plan to incorporate HRSN into risk-based managed care contracts must be submitted to CMS, for review and approval, no later than 6 months prior to the implementation of HRSN services in risk-based managed care contracts and capitation rates. At least 6 months prior to moving HRSN services approved under these STCs into risk-based Medicaid managed care contracts, the state must submit to CMS, for review and written prior approval, documentation that details the following information:
 - a. Each HRSN service defined in STC 9.2 and each covered population that will receive each HRSN service defined in STC 9.5 where the state is seeking CMS written approval to deliver services to populations through one or more risk-based managed care program(s). The applicable managed care program(s) for each service and population should also be specified.
 - b. If the HRSN service will be offered in all regions under each risk-based managed care program or if the offerings will be limited geographically.
 - c. The first rating period the state is seeking to start offering the HRSN service(s) through risk-based managed care. If the HRSN services will be delivered through risk-based managed care on a rolling basis, provide the timeline for each service and/or population.
 - d. The state's timeline to complete a readiness review pursuant to 438.66(d). Implementation may only begin when each managed care plan has been determined by the state to meet certain readiness and network requirements, including providing any documentation specified by CMS.
 - e. A transition of care plan that provides continuity of care for beneficiaries transitioning from another delivery system (e.g. FFS) or non-risk contracts into risk-based contracts.
 - f. A description of base data that the state and its actuary plan to use for capitation rate setting process to develop both the benefit and non-benefit costs, including the types of data used (FFS claims data, managed care encounter data, managed care plan financial data, etc.), and the data source(s) that will be used for capitation rate development. Consistent with Medicaid managed care rate development requirements under 42 CFR 438.5(c), CMS requires at least 3 years of encounter data or similar data (e.g. cost reports, claims data) for the HRSN services defined in STC 9.2 for the covered populations defined in STC 9.5 that will be incorporated into risk-based managed care. CMS will consider exceptions to the requirement for 3 years of base data for periods impacted by COVID-19.

- g. The methodology the state's actuary will use in the capitation rate setting process. This includes, but is not limited to, any trend factors and adjustments to the data the state and its actuary will apply to the base data in the capitation rate setting process. The methodology should also include information on the approach the actuary will take to incorporating the HRSN service(s) into capitation rate development (for example, if the actuary will create an add-on that will be applied to some or all existing rates cells, creating a separate rate cell, or some other method) and any changes to or new risk adjustments or acuity adjustments applied due to the inclusion of the HRSN services defined in STC 9.2 for the covered populations defined in STC 9.5.
- h. If the state is planning to delegate risk for the delivery of HRSN services to clinical providers, community organizations, and/or subcontractors for specific HRSN services, the capitation rate setting plan should include a description of these proposed delegated arrangements and/or sub-capitated payment arrangements that the state intends to use in the delivery of any HRSN services defined in STC 9.2 for covered populations defined in STC 9.5.
- i. Identification of any in lieu of services or settings (ILOSs) the state currently offers through its managed care programs and if there will be changes to those ILOSs as a result of the state moving these HRSN service(s) into risk-based managed care contracts.
- j. Because of the uncertainty associated with HRSN services and in alignment with past guidance about situations with high levels of uncertainty, CMS is requiring the state to implement a 2-sided risk mitigation strategy (such as a 2-sided risk corridor) to provide protection for state and federal governments, as well as managed care plans. The HRSN capitation rate setting plan should provide a description of the risk mitigation mechanism(s) that will be used in the transition of HRSN services to risk-based managed care. As part of plan to incorporate HRSN into risk-based managed care, the State will also need to develop an MLR monitoring and oversight process specific to HRSN services. This process must specify how HRSN services will be identified for inclusion in the MLR numerator. The state's plan must indicate how expenditures for HRSN administrative costs and HRSN infrastructure, as applicable, will be identified and reported by managed care plans as non-claims costs.
- k. All state directed payments the state plans to implement for any HRSN services defined in STC 9.2 for the covered populations defined in STC 9.5 that will be provided under risk-based contracts must comply with all applicable federal requirements, including but not limited to 438.6(c). The state should submit information to establish compliance for any state-directed payments for HRSN services to CMS at statedirectedpayment@cms.hhs.gov.
- 9.10. **Contracted Providers.** Managed care plan contracts must provide, applicable to all HRSN services:

- a. Managed care plans will contract with providers to deliver the HRSN services authorized under the demonstration and included in the managed care contract.
- b. Managed care plans must establish a network of providers and ensure the HRSN service providers have sufficient experience and training in the provision of the HRSN services being offered. HRSN service providers do not need to be licensed, however, staff offering services through HRSN service providers must be licensed when applicable (i.e., when the staff member is performing activities for which a licensure requirement applies in the state).
- c. The managed care plan and contracted providers will use rates set by the state for the provision of applicable HRSN services, consistent with state guidance for these services, and in compliance with all related federal requirements. Any state direction of managed care plan expenditures under risk-based contract(s) and risk-based payments would be considered a state directed payment subject to the requirements in 42 CFR 438.6(c).
- 9.11. **Provider Network Capacity.** Managed care plan contracts must ensure the HRSN services authorized under the demonstration are provided to qualifying beneficiaries in a timely manner and shall develop policies and procedures outlining the managed care plan's approach to managing provider shortages or other barriers to timely provision of the HRSN services, in accordance with the managed care plan contracts and other state Medicaid/operating agency guidance.
- 9.12. **Compliance with Federal Requirements.** The state shall ensure HRSN services are delivered in accordance with all applicable federal statutes and regulation.
- 9.13. **Person Centered Plan.** The state shall ensure there is a person-centered service plan for each beneficiary receiving HRSN services that is person-centered, identifies the beneficiary's needs and individualized strategies and interventions for meeting those needs, and developed in consultation with the beneficiary and the beneficiary's chosen support network, as appropriate. The service plan must be reviewed and revised as appropriate at least every 12 months, when the beneficiary's circumstances or needs change significantly, or at the beneficiary's request.
- 9.14. **Conflict of Interest.** The state shall ensure appropriate protections against conflicts of interest in HRSN service planning and delivery, including by ensuring that appropriate separation of service planning and service provision functions is incorporated into the state's conflict of interest policies.
- 9.15. CMS Approval of Managed Care Contracts. As part of the state's submission of associated managed care plan contracts to implement HRSN services through managed care, the state must include contract requirements including, but not limited to:
 - a. Beneficiary and plan protections, including but not limited to:
 - i. HRSN services must not be used to reduce, discourage, or jeopardize beneficiaries' access to covered services.

- ii. Beneficiaries always retain their right to receive covered service on the same terms as would apply if HRSN services were not an option.
- iii. Beneficiaries who are offered or who utilize an HRSN service retain all rights and protections afforded under 42 CFR Part 438.
- iv. Managed care plans are not permitted to deny a beneficiary a covered service on the basis that the beneficiary is currently receiving HRSN services, has requested those services, has previously qualified for or received those services, or currently qualifies or may qualify in the future for those services.
- v. Managed care plans are prohibited from requiring a beneficiary to receive HRSN services.
- b. Managed care plans must timely submit data requested by the state or CMS, including, but not limited to:
 - i. Data to evaluate the utilization and effectiveness of the HRSN services.
 - ii. Any data necessary to monitor health outcomes and quality of care metrics at the individual and aggregate level through encounter data and supplemental reporting on health outcomes and equity of care. When possible, metrics must be stratified by age, sex (including sexual orientation and gender identify), race, ethnicity, disability status and preferred language to inform health quality improvement efforts, which may thereby mitigate health disparities.
 - iii. Any data necessary to monitor appeals and grievances for beneficiaries.
 - iv. Documentation to ensure appropriate clinical support for the medical appropriateness of HRSN services.
 - v. Any data determined necessary by the state or CMS to monitor and oversee the HRSN services initiative.
- c. All data and related documentation necessary to monitor and evaluate the HRSN services initiative, including cost assessment, including but not limited to:
 - i. The managed care plans must submit timely and accurate encounter data to the state for beneficiaries who qualify for HRSN services. When possible, these encounter data must include data necessary for the state to stratify analyses by age, sex (including sexual orientation and gender identity), race, ethnicity, disability status and preferred language to inform health quality improvement efforts and subsequent efforts to mitigate health disparities undertaken by the state.
 - ii. Any additional information requested by CMS, the state, or another legally authorized oversight body to aid in ongoing evaluation of the HRSN services initiative or any independent assessment or analysis conducted by the state, CMS, or another legally authorized entity.

- iii. The state must monitor and provide narrative updates through its Quarterly and Annual Monitoring Reports its progress in building and sustaining its partnership with existing housing agencies to utilize their expertise and existing housing resources and to avoid duplication of efforts.
- iv. Any additional information determined reasonable, appropriate and necessary by CMS.
- 9.16. HRSN Rate Methodologies. For FFS payment methodologies and/or rates, the state must comply with the payment rate-setting requirements in 42 CFR Part 447, as though a state plan amendment were required, to establish any payment rate and/or methodology for HRSN services as approved under demonstration expenditure authority 6. The state must conduct state-level public notice under 42 CFR 447.205 prior to the implementation of the applicable FFS payment rates or methodologies for HRSN and maintain documentation of these FFP payment rates or methodologies on its website described in 42 CFR 447.203. The state may receive FFP for HRSN service expenditures authorized under this demonstration upon implementation of the FFS payment rates and/or methodologies for which it has conducted prior public notice and may begin claiming for this FFP (for dates of service no earlier than the effective date of approval for the relevant expenditure authority) no earlier than the date of submission of the payment rates and/or methodology to CMS for approval. However, any FFS payments to providers or claims for FFP prior to CMS approval of the payment rate or methodology must be reconciled to the ultimately approved FFS payment rate and/or methodology within one year of CMS's approval. All requirements for timely filing of claims for FFP continue to apply.

For managed care payments and rates (including capitation rates, non-risk payments, and state directed payments), the state must comply with all federal requirements, including those in 42 CFR Part 438 and these STCs. As applicable, the state must also notify CMS at least 60 days prior to intended implementation if it intends to direct its managed care plans on how to pay for HRSN services (i.e., state directed payments).

All rates/payment methodologies for HRSN services, for both FFS and managed care delivery systems, must be submitted to CMS for review and approval, including but not limited to fee-for-service payments as well as managed care capitation rates, any state directed payments that require prior written approval, and non-risk payments, as outlined in the STCs. For all payment methodologies and/or rates, for both FFS and managed care delivery systems, in addition to submitting the payment rates and/or methodology, the state must also submit all supporting documentation requested by CMS, including but not limited to how the rates and/or methodology were developed, state responses to any public comments on the rates and/or methodology (when applicable), and information about Medicaid non-federal share financing.

9.17. **Maintenance of Effort (MOE).** The state must maintain a baseline level of state funding for ongoing social services related to housing and housing transition supports for the duration of the demonstration, not including one-time or non-recurring funding. Within 90 days of demonstration approval, the state will submit a plan to CMS as part of the HRSN Implementation Plan required by STC 9.19 that specifies how the state will determine baseline spending on these services throughout the state. The annual MOE will be reported and

monitored as part of the Annual Monitoring Report described in STC 14.6, with any justifications, including declines in available state resources, necessary to describe the findings, if the level of state funding is less than the comparable amount of the pre-demonstration baseline.

9.18. Partnerships with State and Local Entities. To ensure that expenditures for HRSN services under this demonstration do not supplant any other available funding sources available to the beneficiary through other local, state, or federal programs, the state must have in place partnerships with other state and local entities (e.g., HUD Continuum of Care Program, local housing authorities) to assist beneficiaries in obtaining non-Medicaid funded housing supports, if available, upon the conclusion of temporary demonstration payment for such supports, in alignment with beneficiary needs identified in the beneficiary's care plan, as appropriate. The state will submit a plan to CMS as part of the HRSN Implementation Plan that outlines how it will put into place the necessary arrangements with other state and local entities and also work with those entities to assist beneficiaries in obtaining available non-Medicaid funded housing supports upon conclusion of temporary Medicaid payment as stated above. The plan must provide a timeline for the activities outlined. As part of the Monitoring Reports described in STC 14.6, the state will provide the status of the state's fulfillment of its plan and progress relative to the timeline, and whether and to what extent the non-Medicaid funded supports are being accessed by beneficiaries as planned. Once the state's plan is fully implemented, the state may conclude its status updates in the Monitoring Reports.

9.19. HRSN Implementation Plan

- a. The state is required to submit a HRSN Implementation Plan that will elaborate upon and further specify requirements for the provision of HRSN services and will be expected to provide additional details not captured in the STCs regarding implementation of demonstration policies that are outlined in the STCs. The state must submit the MOE information required by STC 9.17 no later than 90 calendar days after approval of demonstration expenditure authority for HRSN services. All other Implementation Plan requirements outlined in this STC must be submitted no later than 9 months after the approval of demonstration expenditure authority for HRSN services. The Implementation Plan shall be submitted to CMS but does not require CMS approval. CMS will ensure it is complete and contains sufficient detail for purposes of on-going monitoring. The state may update the implementation plan as initiatives are changed or added, with notification to CMS. The Implementation Plan will be appended as Attachment L.
- b. At a minimum, the Implementation Plan must provide a description of the state's strategic approach to implementing the policy, including timelines for meeting critical implementation stages or milestones, as applicable, to support successful implementation. The Implementation Plan does not need to repeat any information submitted to CMS under the Protocol for Assessment of Beneficiary Eligibility and Needs, Infrastructure Planning, and Provider Qualifications for HRSN services; however, as applicable, the information provided in the two deliverables must be aligned and consistent.

- c. The Implementation Plan must include information on, but not limited to, the following:
 - A plan for establishing and/or improving data sharing and partnerships with an array of health system and social services interested parties to the extent those entities are vital to provide needed administrative and HRSN-related data on screenings, referrals, and provision of services, which are critical for understanding program implementation and conducting demonstration monitoring and evaluation;
 - ii. Information about key partnerships related to HRSN service delivery, including plans for capacity building for community partners and for soliciting and incorporating input from impacted groups (e.g., community partners, health care delivery system partners, and beneficiaries);
 - iii. Plans for changes to IT infrastructure that will support HRSN-related data exchange, including development and implementation of data systems necessary to support program implementation, monitoring, and evaluation. These existing or new data systems should, at a minimum, collect data on beneficiary characteristics, qualification and consent to receive HRSN services, screening, referrals, and service provision;
 - iv. A plan for tracking and improving the share of demonstration beneficiaries in the state who are eligible and enrolled in federal, state, and local housing assistance programs, relative to the number of total eligible demonstration beneficiaries in the state (including those who are eligible but unenrolled);
 - v. An implementation timeline and considerations for demonstration evaluation that may be impacted by the timeline (e.g., in the case of a phased rollout of HRSN services), to facilitate robust evaluation designs;
 - vi. Information as required per STC 9.17 (MOE); and
 - vii. Information as required per STC 9.18 (Partnerships with State and Local Entities).

10. QUICK RESPONSE TEAMS

10.1. Quick Response Teams Overview

a. Beginning no earlier than July 1, 2026, West Virginia BMS will implement a new Medicaid benefit consistent with the benefit under Medicaid state plan authority, called Quick Response Teams (QRTs), for eligible Medicaid enrollees with a SUD. QRTs contact individuals who have experienced an overdose or other SUD-related emergency within 24-72 hours of the event to provide follow-up support, encouragement for recovery, and links to treatment and recovery options, if desired. The goal of QRTs is to prevent repeated overdoses and SUD emergencies by building trust and rapport with individuals in the critical time period immediately after a SUD emergency to encourage the individual to seek treatment.

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- b. Under the pilot, QRTs will be coordinated by participating providers, that elect and are approved by BMS to provide this benefit, to qualified beneficiaries who meet the eligibility requirements described below.
- c. This pilot will allow West Virginia to standardize QRTs and evaluate and assess their effectiveness before transitioning the authority for QRTs from the 1115 demonstration to the state plan.
- d. The expenditure authority for QRTs cannot supplant any other funding sources for QRTs that are available through federal programs.
- 10.2. **Eligibility**. To qualify for the QRT benefit, a Medicaid beneficiary must meet the following conditions:
 - a. Have a diagnosed or suspected SUD;
 - b. Have experienced an overdose or other substance use-related emergency within the 24-72 hours prior to contact with a QRT;
 - c. Receive QRT services from an eligible provider that offers the QRT benefit in accordance with BMS policies and procedures; and
 - d. Cannot be simultaneously receiving community-based mobile crisis intervention services.

10.3. Service Description.

- a. QRT visits must occur in the 24–72-hour time period after an overdose or other SUD-related emergency.
- b. QRT services must be recommended by a licensed practitioner.
- c. QRTs may provide one or more of the following service components during a visit:
 - i. Brief assessment.
 - ii. Provision of naloxone and patient education on the use of naloxone.
 - iii. Peer support services.
 - iv. Brief interventions.
 - v. Referrals and linkages to substance use treatment services.
 - vi. Development of a care plan.
 - vii. Support and education for family members and/or individuals living with the beneficiary on the symptoms of an overdose and the common characteristics of addiction when for the direct benefit of the beneficiary.

d. QRT services cannot be delivered to a member who is currently admitted to an inpatient facility.

10.4. **QRT Providers**

- a. To be eligible to coordinate QRTs, a provider must offer the QRT benefit in accordance with BMS standards, and providers must meet the following guidelines:
 - i. Be enrolled in Medicaid and certified to provide Medicaid services.
 - ii. Require the staff participating in QRTs, or overseeing the QRT benefit, to participate in QRT-specific training developed and offered by BMS or BMS's designated contractor.
 - iii. Undergo a readiness review by BMS and BMS's designated contractor to ensure that they are capable to offer the QRT benefit in accordance with BMS standards that will be detailed in BMS guidance.
 - iv. Participate in ongoing training and technical assistance, as requested or identified by BMS's designated contractor or BMS through ongoing monitoring, to meet BMS standards.
 - v. Comply with any billing and data reporting requirements established by BMS to support research, evaluation, and performance monitoring efforts including, but not limited to, satisfactory claims submission, data and quality reporting, and survey participation.
- b. The following provider organizations can coordinate QRTs and serve as QRT hubs:
 - i. Licensed behavioral health clinics
 - ii. Community mental health clinics
 - iii. Federally qualified health centers
 - iv. Certified Community Behavioral Health Clinics (CCBHCs)
- c. QRTs will consist of at least two individuals. The following practitioners delivering care at eligible providers can deliver QRT services:
 - Clinical individual (e.g., a social worker), with at least a bachelor's degree in a field of human services authorized to do a mental health assessment per BMS policy, who is supervised by an individual with a minimum of a master's degree.
 - ii. A certified peer recovery support specialist, per requirements in STC 6.1.

- d. In addition to the necessary education, experience, and/or certifications and qualifications required for their respective positions listed above, QRT staff need to have the following training:
 - i. Motivational interviewing.
 - ii. Trauma-informed care.
 - iii. Person-centered treatment concepts.
 - iv. Cultural competency.
 - v. Understanding and familiarity with local behavioral health and social service resources.
 - vi. Understanding of Medicaid documentation needs.
- e. QRTs must be supervised by an individual with a master's level degree (e.g., a licensed social worker).

10.5. Program Oversight

- a. BMS shall monitor the ongoing performance of QRT providers and QRTs and identify and support providers and QRT staff requiring further training or technical assistance in accordance with BMS set standards, to be outlined in BMS guidance.
- b. BMS will provide training, technical assistance and monitoring to providers throughout the implementation process. The training and technical assistance will be provided through a qualified contractor designated by BMS, and will include staff training, provider readiness reviews, and ongoing technical assistance during the pilot.
- 10.6. **Transition to State Plan Authority.** During the demonstration period, the state must transition the 1115 expenditure authority for QRTs to state plan authority. In DY 10, the state must develop and submit state plan amendments to transition QRTs. The state and CMS will work to approve the state plan amendments no later than December 31, 2029.

11. RECOVERY-RELATED SUPPORT SERVICES

- 11.1. **Recovery-Related Support Services Overview.** Recovery-related support services (RRSS) assist and support individuals who are working and/or who desire to work. These services include rehabilitative services and supports that align with the state plan rehabilitation benefit and that help individuals manage behavioral health challenges, develop strategies for engaging in work, assist in resolving workplace issues, and help individuals address their recovery needs while at work.
- 11.2. **Person Centered Treatment Plan.** RRSS is initiated by a comprehensive assessment of an individual's strengths, needs, and treatment goals. This assessment includes, among other psychosocial domains, employment and/or educational goals and the services and supports

needed to attain those goals. Services are described in a person-centered treatment plan that may include skill building, care coordination, and counseling to help an individual navigate and access resources, manage behavioral health symptoms, meet recovery-related goals, and remain engaged in RRSS.

- 11.3. **Covered Populations.** Individuals eligible to receive RRSS are adults in West Virginia Medicaid who have a SUD and are expected to benefit from RRSS. Additional qualifications include:
 - a. Has been unable to be gainfully employed for at least 90 consecutive days in the past 12 months, and
 - b. Is unlikely to succeed in a competitive work setting without additional support or accommodation, and
 - c. Has at least one or more of the following conditions or circumstances:
 - i. A history of repeated avoidable emergency department visits or crisis utilization.
 - ii. A chronic health condition and/or co-occurring conditions.
 - iii. Is being discharged from a correctional or medical facility.
 - iv. Is at high risk of institutionalization.
 - v. Is transitioning from an institutional setting to a home- or community-based setting.
- 11.4. **Services under RRSS.** Covered services are those that are coverable under the state plan rehabilitation benefit, including:
 - a. A comprehensive rehabilitative assessment or intake process that is routinely completed at intake or admission and includes physical, behavioral, and psychosocial assessments, including employment, social and educational needs and/or goals, and treatment planning domains.
 - b. Skill building and care coordination to navigate and access community, state, and/or federal resources that support recovery-related goals, including employment goals.
 - c. Coordination with the treatment team.
 - d. Psychosocial rehabilitation and/or clinical counseling interventions that help the individual manage behavioral health challenges and barriers as they work toward sustaining their employment goals and that help the individual maintain engagement with services and supports.
- 11.5. **Excluded RRSS.** Excluded items, services, and activities that are not covered as RRSS include, but are not limited to:

- a. Completing benefits paperwork or applications on an individual's behalf.
- b. Specialized vocational or career-focused assessments that are not part of the rehabilitation service assessment and treatment planning process.
- c. Systematic job development and networking with employers.
- d. Direct support with helping an individual find and procure a job (e.g., resume writing, completing applications, or scheduling or participating in interviews).
- e. Interventions with prospective employers to develop employment opportunities specifically tailored to an individual's abilities.
- f. Job coaching and other interventions that are targeted to helping the individual succeed in a specific job-related task (i.e., "hard skills").
- g. Intervention with an individual's employer to resolve an issue regarding the individual's work performance or workplace conditions not related to specific behavioral health symptoms or need for support or accommodation.
- h. Outreach activities that do not involve direct support or contact with individual.
- 11.6. **Organizational Provider Types.** These provider types can coordinate RRSS and serve as RRSS hubs: Licensed Behavioral Health Centers, including Community Mental Health Centers, and CCBHCs.
- 11.7. **Individual Provider Types and Qualifications.** These individual provider types can provide RRSS:
 - a. All licensed social workers;
 - b. Case managers, who hold a Master's or Bachelor's degree in a Human Services field. Case managers would also need to meet the additional qualifications/requirements specified in STC 11.8.
 - c. Peer Recovery Support Specialists (PRSS) who meet all PRSS requirements as defined by STC 6.1. PRSS providing this service would also need to meet the additional qualifications/requirements specified in STC 11.8.
- 11.8. **Unlicensed Providers.** Unlicensed providers (i.e., case managers and PRSS) must meet the following specifications:
 - a. Undergo and successfully complete training modules which align with the <u>Substance Abuse and Mental Health Services Administration (SAMHSA)</u> for delivery of these RRSS.
 - b. Training in recovery and rehabilitative services concepts, including personcentered communication and planning.

- c. Have awareness of the available community resources related to RRSS in the surrounding geographic area.
- d. Be supervised by experienced staff as part of a staffing plan that includes licensed clinical staff as appropriate.

12. COST SHARING

12.1. Cost sharing imposed upon individuals under the demonstration is consistent with the provisions of the approved state plan.

13. DELIVERY SYTEM

13.1. No modification to the current West Virginia Medicaid delivery system are proposed through this demonstration. West Virginia Medicaid beneficiaries will continue to receive services through the delivery system.

14. MONTITORING AND REPORTING REQUIREMENTS

14.1. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in the amount of \$5,000,000 per deliverable (federal share) 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. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

The following process will be used: 1) 30 calendar days after the deliverable(s) were due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) 30 calendar days after CMS has notified the state in writing that the deliverable(s) were not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable(s) into alignment with CMS requirements:

- a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
- b. For each deliverable, the state may submit a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay, the steps the state has taken to address such issue(s), and the state's anticipated date of submission. Should CMS agree in writing to the state's request, a corresponding extension of the deferral process described below can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.

- c. If CMS agrees to an interim corrective process in accordance with subsection (b) above, and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) that meet the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.
- d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.
- e. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations, and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.
- 14.2. **Deferral of Federal Financial Participation (FFP) from IMD claiming for Insufficient Progress Toward Milestones.** Up to \$5,000,000 in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones and goals as evidenced by reporting on the milestones in Implementation Plan and the required performance measures in the monitoring protocol agreed upon by the state and CMS. Once CMS determines the state has not made adequate progress, up to \$5,000,000 will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made.
- 14.3. **Submission of Post-Approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs, unless CMS and the state mutually agree to another timeline.
- 14.4. **Compliance with Federal Systems Updates.** 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.
- 14.5. **Monitoring Protocol.** The state must submit to CMS a Monitoring Protocol no later than 150 calendar days after the approval of the demonstration extension. The state must submit a revised Monitoring Protocol within 60 calendar days after receipt of CMS's comments. Once approved, the Monitoring Protocol will be incorporated in the STCs as Attachment E. In

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addition, the state must submit an updated or a separate Monitoring Protocol for any amendments to the demonstration no later than 150 calendar days after the approval of the extension. Such amendment Monitoring Protocols are subject to same requirement of revisions and CMS approval, as described above.

At a minimum, the Monitoring Protocol must affirm the state's commitment to conduct Quarterly and Annual Monitoring Reports in accordance with CMS's guidance and technical assistance and using CMS-provided reporting templates, as applicable and relevant for different policies. Any proposed deviations from CMS's guidance should be documented in the Monitoring Protocol. The Monitoring Protocol must describe the quantitative and qualitative elements on which the state will report through Quarterly and Annual Monitoring Reports. For the overall demonstration as well as specific policies where CMS provides states with a suite of quantitative monitoring metrics (e.g., those described under the performance metrics section in STC 14.6), the state is required to calculate and report such metrics leveraging the technical specifications provided by CMS, as applicable. The Monitoring Protocol must specify the methods of data collection and timeframes for reporting on the demonstration's progress as part of the Quarterly and Annual Monitoring Reports. In alignment with CMS guidance, the Monitoring Protocol must additionally specify the state's plans and timeline on reporting metrics data stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, primary language, disability status, sexual orientation and gender identity, and geography) and demonstration component.

For the SUD component, the Monitoring Protocol must include an assurance of the state's commitment and ability to report information relevant to each of the program implementation areas listed in STC 5.2, and information relevant to the state's HIT Plan described in STC 5.3; a description of 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 STC 14.6; and a description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and target will be benchmarked against performance in best practice settings.

For the HRSN services and the reentry initiative authorized through this demonstration, the Monitoring Protocol requires specifying a selection of quality of care and health outcomes metrics and population stratifications based on CMS's upcoming guidance on the Disparities Sensitive Measure Set, and outlining the corresponding data sources and reporting timelines, as applicable to the demonstration initiatives and populations. This set of measures consists of metrics known to be important for addressing disparities in Medicaid/CHIP (e.g., the National Quality Forum (NQF) "disparities-sensitive" measures) and prioritizes key outcome measures and their clinical and non-clinical (i.e., social) drivers. The Monitoring Protocol must also outline the state's planned approaches and parameters to track implementation progress and performance relative to the goals and milestones, as provided in the Implementation Plan for the HRSN services.

The state will also be expected to set up its HRSN service delivery system to allow screening of beneficiaries for identified needs, and to develop an appropriate closed-loop referral system or other feedback loop to ensure beneficiaries receive service referrals and provisions, and

provide any applicable update on this process via the Monitoring Reports, in alignment with information provided in the Monitoring Protocol.

In addition, the state must describe in the Monitoring Protocol methods and the timeline to collect and analyze non-Medicaid administrative data to help calculate applicable monitoring metrics. These sources may include but are not limited to data related to carceral status, Medicaid eligibility, and the health care needs of individuals who are incarcerated and returning to the community. Across data sources, the state must make efforts to consult with relevant non-Medicaid agencies to collect and use data in ways that support analyses of data on demonstration beneficiaries and subgroups of beneficiaries, in accordance with all applicable requirements concerning privacy and the protection of personal information.

For the qualitative elements (e.g., operational updates as described in STC 14.6(a), CMS will provide the state with guidance on narrative and descriptive information, which will supplement the quantitative metrics on key aspects of the demonstration policies. The quantitative and qualitative elements will comprise the state's Quarterly and Annual Monitoring Reports.

- 14.6. Monitoring Reports. The state must submit three Quarterly Monitoring Reports and one Annual Monitoring Report each DY. The fourth quarter information that would ordinarily be provided in a separate Quarterly Report should be reported as distinct information within the Annual Monitoring Report. The Quarterly Monitoring Reports are due no later than 60 calendar days following the end of each demonstration quarter. The Annual Monitoring Report (including the fourth-quarter information) is due no later than 90 calendar days following the end of the DY. The state must submit a revised Monitoring Report within 60 calendar days after receipt of CMS's comments, if any. The reports will include all required elements as per 42 CFR 431.428 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. The Quarterly and Annual Monitoring Reports must follow the framework to be 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.
 - a. Operational Updates Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports must provide sufficient information to document key operation and other challenges, underlying causes of challenges, and how challenges are being addressed. The discussion should also include any issues or complaints identified by individuals; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. In addition, Monitoring Reports should describe key achievements, as well as the conditions and efforts to which these successes can be attributed. Monitoring Reports should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
 - b. <u>Performance Metrics</u> Per applicable CMS guidance and technical assistance, the performance metrics will provide data to demonstrate how the state is progressing toward meeting the goals and milestones including relative to their

projected timelines – of the demonstration's program and policy implementation and infrastructure investments, and transitional non-service expenditures, as applicable and must cover all key policies under this demonstration including, but not limited to, behavioral health, home and community-based services, HRSN, Reentry, QRT, RRSS, PRSS, and SUD components. Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to individuals and the uninsured population, as well as on beneficiaries' outcomes as well as outcomes of care, quality and cost of care, and access to care. This should also include the results of beneficiary satisfaction or experience of care surveys, if conducted, and grievances and appeals.

- i. Specifically, the state must undertake standardized reporting on categories of metrics including, but not limited to: beneficiary participation in demonstration components, primary and specialist provider participation, utilization of services, quality of care, and health outcomes. The reporting of metrics focused on quality of care and health outcomes must be aligned with the demonstration's policies and objectives populations. Such reporting must also be stratified by key demographic subpopulations of interest (e.g., by sex, age, race/ethnicity, primary language, disability status, sexual orientation and gender identity, and geography), and by demonstration components, to the extent feasible. Subpopulation reporting will support identifying any existing shortcomings or disparities in quality of care and health outcomes and help track whether the demonstration's initiatives help improve outcomes for the state's Medicaid population, including the narrowing of any identified disparities.
- ii. For HRSN components, in addition to reporting on the metrics described above, the state must track beneficiary participation, screening, receipt of referrals and social services over time, as well as narratively report on the adoption of information technology infrastructure to support data sharing between the state or partner entities assisting in the administration of the demonstration and social services organizations, and the contracted providers of applicable services (e.g., managed care plans and their contracted HRSN providers). In alignment with STC 9.16, the state must additionally monitor and provide narrative updates on its progress in building and sustaining its partnership with existing housing agencies, leverage their expertise and existing housing resources instead of duplicating services. Furthermore, the state's enrollment and renewal metrics must also capture baseline data and track progress via Monitoring Reports for the percent of Medicaid renewals completed ex-parte (administratively), as well as the percentage of Medicaid beneficiaries enrolled in other public benefit programs (such as SNAP and WIC) for which they are eligible.
- iii. As applicable, if the state, health plans, or health care providers will contract or partner with organizations to implement the demonstration, the state must use monitoring metrics that track the number and characteristics of contracted

- or participating organizations in specific demonstration programs and corresponding payment-related metrics; these metrics are specifically relevant for the state's HRSN initiatives.
- iv. For the SUD component, the state's monitoring must cover metrics in alignment with the respective milestones as outlined in the State Medicaid Director Letter (SMDL) dated November 1, 2017 (SMD #17–003).
- v. The state's selection and reporting of quality of care and health outcome metrics outlined above must also accommodate the Reentry Demonstration Initiative. In addition, the state is required to report on metrics aligned with tracking progress with implementation and toward meeting the milestones of the Reentry Demonstration Initiative. CMS expects such metrics to include, but not be limited to, administration of screenings to identify individuals who qualify for pre-release services, utilization of applicable pre-release and postrelease services as defined in STC 8.4, provision of health or social service referral pre-release, participants who received case management pre-release and were enrolled in case management post-release, and take-up of data system enhancements among participating correctional facility settings. In addition, the state is expected to monitor the number of individuals served and types of services rendered under the demonstration. Also, in alignment with the state's Reentry Initiative Implementation Plan, the state must also provide in its Monitoring Reports narrative details outlining its progress with implementing the initiative, including any challenges encountered and how the state has addressed them or plans to address them. This information must also capture the transitional, non-service expenditures, including enhancements in the data infrastructure and information technology.

The required monitoring and performance metrics must be included in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

- c. <u>Budget Neutrality and Financial Reporting Requirements</u> Per 42 CFR § 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on the Form CMS-64.
- d. <u>Evaluation Activities and Interim Findings</u> Per 42 CFR § 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, 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.

14.7. **Reentry Demonstration Initiative Mid-Point Assessment.** The state must contract with an independent entity to conduct a mid-point assessment of the Reentry Demonstration Initiative and complete a Reentry Demonstration Initiative Mid-Point Assessment.

The Mid-Point Assessment must integrate all applicable implementation and performance data from the first 2.5 years of implementation of the Reentry Demonstration Initiative. The report must be submitted to CMS by the end of the third year of the demonstration. In the event that the Reentry Demonstration Initiative is implemented at a timeline within the demonstration approval period, the state and CMS will agree to an alternative timeline for submission of the Mid-Point Assessment. The state must submit a revised Mid-Point Assessment within 60 calendar days after receipt of CMS's comments, if any. If requested, the state must brief CMS on the report.

The state must require the independent assessor to provide a draft of the Mid-Point Assessment to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies used, the findings on demonstration progress and performance, including identifying any risks of not meeting milestones and other operational vulnerabilities, and recommendations for overcoming those challenges and vulnerabilities. In the design, planning, and execution of the Mid-Point Assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: provider participation in the state's Reentry Demonstration Initiative, eligible individuals, and other key partners in correctional facility and community settings.

For milestones and measure targets at medium to high risk of not being achieved, the state and CMS will collaborate to determine whether modifications to the Reentry Demonstration Initiative Implementation Plan and the Monitoring Protocol are necessary for ameliorating these risks, with any modifications subject to CMS approval.

Elements of the Mid-Point Assessment must include, but not be limited to:

- a. An examination of progress toward meeting each milestone and timeframe approved in the Reentry Demonstration Initiative Implementation Plan and toward meeting the targets for performance metrics as approved in the Monitoring Protocol;
- b. A determination of factors that affected achievement on the milestones and progress toward performance metrics targets to date;
- c. A determination of factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets; and
- d. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state's Reentry Demonstration Initiative

Implementation Plan or to pertinent factors that the state can influence that will support improvement.

CMS will provide additional guidance for developing the state's Reentry Initiative Mid-Point Assessment.

- 14.8. **SUD Mid-Point Assessment.** The state must contract with an independent entity to conduct an independent Mid-Point Assessment by December 31, 2027. This timeline will allow for the Mid-Point Assessment Report to capture approximately the first two-and-a-half years of demonstration program data, accounting for data run-out and data completeness. In addition, if applicable, the state should use the prior approval period experiences as context, and conduct the Mid-Point Assessment in light of the data from any such prior approval period(s). In the design, planning, and conduct of the Mid-Point Assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to representatives of MCOs, health care providers (including SUD treatment providers), beneficiaries, community groups, and other key partners.
 - a. The state must require that the assessor provide a Mid-Point Assessment Report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations, and any recommendations. The state must provide a copy of the report to CMS no later than 60 calendar days after December 31, 2027, and the state must brief CMS on the report. The state must submit a revised Mid-Point Assessment Report within 60 calendar days after receipt of CMS's comments, if any.
 - b. For milestones and measure targets at medium to high risk of not being achieved, the state must submit to CMS proposed modifications to the SUD Implementation Plan and SUD Monitoring Protocol, for ameliorating these risks. Modifications to any of these plans or protocols are subject to CMS approval.
 - c. Elements of the Mid-Point Assessment must include at least:
 - i. An examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plan, and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol;
 - ii. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date;
 - iii. A determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets;
 - iv. For milestones or targets identified by the independent assessor as at medium to high risk of not being met, recommendations for adjustments in the state's SUD Plan or to other pertinent factors that the state can influence that will support improvement; and

- v. An assessment of whether the state is on track to meet the budget neutrality requirements in these STCs.
- 14.9. Corrective Action Plan Related to Demonstration Monitoring. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A corrective action plan could include a temporary suspension of implementation of demonstration programs in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS will withdraw an authority, as described in STC 3.10, when metrics indicate substantial, sustained directional change inconsistent with the state's demonstration goals, and the state has not implemented corrective action. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.
- 14.10. **Close-Out Operational Report**. Within 120 calendar days after 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. In consultation with CMS, and per guidance from CMS, the state will include an evaluation of the demonstration (or demonstration components) that are to phase out or expire without extension along with the Close-Out Report. Depending on the timeline of the phase-out during the demonstration approval period, in agreement with CMS, the evaluation requirement may be satisfied through the Interim and/or Summative Evaluation Reports stipulated in STCs 17.10 and 17.11, respectively.
 - c. The state will present to and participate in a discussion with CMS on the Close-Out Report.
 - d. The state must take into consideration CMS' comments for incorporation into the final Close-Out Report.
 - e. A revised Close-Out Report is due to CMS no later than 30 calendar days after receipt of CMS' comments.
 - f. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 14.1.
- 14.11. Monitoring Calls. CMS will convene periodic conference calls with the state.
 - a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to) any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends

- in reported data on metrics and associated mid-course adjustments, budget neutrality, enrollment and access and progress on evaluation activities.
- b. CMS will provide updates on any pending actions, 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.
- 14.12. **Post Award Forum.** Pursuant to 42 CFR 431.420(c), within 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 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 Monitoring Report associated with the year in which the forum was held, as well as in its compiled Annual Monitoring Report.

15. GENERAL FINANCIAL REQUIREMENTS

- 15.1. **Allowable Expenditures.** This demonstration project is approved for authorized demonstration expenditures applicable to services rendered and for costs incurred during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.
- 15.2. Standard Medicaid Funding Process. The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures under this Medicaid section 1115 demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 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 30 days after the end of each quarter, the state shall submit form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on 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.
- 15.3. **Sources of Non-Federal Share.** As a condition of demonstration approval, the state certifies that its funds that make up the non-federal share are obtained from permissible state and/or local funds that, unless permitted by law, are not other federal funds. The state further certifies that federal funds provided under this section 1115 demonstration must not be used as the non-federal share required under any other federal grant or contract, except as permitted by law. CMS approval of this demonstration does not constitute direct or indirect approval of any underlying source of non-federal share or associated funding mechanisms and all sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable implementing regulations. CMS reserves the right to deny FFP in expenditures for which it determines that the sources of non-federal share are impermissible.
 - a. If requested, the state must submit for CMS review and approval documentation of any sources of non-federal share that would be used to support payments under the demonstration.
 - b. If CMS determines that any funding sources are not consistent with applicable federal statutes or regulations, the state must address CMS's concerns within the time frames allotted by CMS.
 - c. Without limitation, CMS may request information about the non-federal share sources for any amendments that CMS determines may financially impact the demonstration.

- 15.4. **State Certification of Funding Conditions**. As a condition of demonstration approval, the state certifies that the following conditions for non-federal share financing of demonstration expenditures have been met:
 - a. If units of state or local government, including health care providers that are units of state or local government, supply any funds used as non-federal share for expenditures under the demonstration, the state must certify that state or local monies have been expended as the non-federal share of funds under the demonstration in accordance with section 1903(w) of the Act and applicable implementing regulations.
 - b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the non-federal share of expenditures under the demonstration, the state must obtain CMS approval for a cost reimbursement methodology. This methodology must include a detailed explanation of the process, including any necessary cost reporting protocols, by which the state identifies those costs eligible for purposes of certifying public expenditures. The certifying unit of government that incurs costs authorized under the demonstration must certify to the state the amount of public funds allowable under 42 CFR 433.51 it has expended. The federal financial participation paid to match CPEs may not be used as the non-federal share to obtain additional federal funds, except as authorized by federal law, consistent with 42 CFR 433.51(c).
 - c. The state may use intergovernmental transfers (IGT) to the extent that the transferred funds are public funds within the meaning of 42 CFR 433.51 and are transferred by units of government within the state. Any transfers from units of government to support the non-federal share of expenditures under the demonstration must be made in an amount not to exceed the non-federal share of the expenditures under the demonstration.
 - d. Under all circumstances, health care providers must retain 100 percent of their payments for or in connection with furnishing covered services to beneficiaries. Moreover, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local governments, or third parties to return and/or redirect to the state any portion of the Medicaid payments in a manner inconsistent with the requirements in section 1903(w) of the Act and its implementing regulations. 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.
 - e. The State Medicaid Director or his/her designee certifies that all state and/or local funds used as the state's share of the allowable expenditures reported on the

- CMS-64 for this demonstration were in accordance with all applicable federal requirements and did not lead to the duplication of any other federal funds.
- 15.5. **Financial Integrity for Managed Care Delivery Systems.** As a condition of demonstration approval, the state attests to the following, as applicable:
 - a. All risk-based managed care organization, prepaid inpatient health plan (PIHP), and prepaid ambulatory health plan (PAHP) payments, comply with the requirements on payments in 42 CFR 438.6(b)(2), 438.6(c), 438.6(d), 438.60, and 438.74.
- 15.6. Requirements for Health Care-Related Taxes and Provider Donations. As a condition of demonstration approval, the state attests to the following, as applicable:
 - a. Except as provided in paragraph (c) of this STC, all health care-related taxes as defined by Section 1903(w)(3)(A) of the Act and 42 CFR 433.55 are broadbased as defined by Section 1903(w)(3)(B) of the Act and 42 CFR 433.68(c).
 - b. Except as provided in paragraph (c) of this STC, all health care-related taxes are uniform as defined by Section 1903(w)(3)(C) of the Act and 42 CFR 433.68(d).
 - c. If the health care-related tax is either not broad-based or not uniform, the state has applied for and received a waiver of the broad-based and/or uniformity requirements as specified by 1903(w)(3)(E)(i) of the Act and 42 CFR 433.72.
 - d. The tax does not contain a hold harmless arrangement as described by Section 1903(w)(4) of the Act and 42 CFR 433.68(f).
 - e. All provider-related donations as defined by 42 CFR 433.52 are bona fide as defined by Section 1903(w)(2)(B) of the Social Security Act, 42 CFR 433.66, and 42 CFR 433.54.
- 15.7. **State Monitoring of Non-federal Share.** If any payments under the demonstration are funded in whole or in part by a locality tax, then the state must provide a report to CMS regarding payments under the demonstration no later than 60 days after demonstration approval. This deliverable is subject to the deferral as described in STC X. This report must include:
 - a. A detailed description of and a copy of (as applicable) any agreement, written or otherwise agreed upon, regarding any arrangement among the providers including those with counties, the state, or other entities relating to each locality tax or payments received that are funded by the locality tax;
 - b. Number of providers in each locality of the taxing entities for each locality tax;
 - c. Whether or not all providers in the locality will be paying the assessment for each locality tax;
 - d. The assessment rate that the providers will be paying for each locality tax;

- e. Whether any providers that pay the assessment will not be receiving payments funded by the assessment;
- f. Number of providers that receive at least the total assessment back in the form of Medicaid payments for each locality tax;
- g. The monitoring plan for the taxing arrangement to ensure that the tax complies with section 1903(w)(4) of the Act and 42 CFR 433.68(f); and
- h. Information on whether the state will be reporting the assessment on the CMS form 64.11A as required under section 1903(w) of the Act.
- 15.8. **Extent of Federal Financial Participation for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the following demonstration expenditures, subject to the budget neutrality expenditure limits described in the STCs in section 2:
 - a. Administrative costs, including those associated with the administration of the demonstration;
 - b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
 - c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.
- 15.9. **Program Integrity.** The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.
- 15.10. **Medicaid Expenditure Groups.** Medicaid Expenditure Groups (MEG) are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The Master MEG Chart table provides a master list of MEGs defined for this demonstration.

Table 2. Master MEG Chart

MEG	Which BN Test Applies?	WOW Per Capita	WOW Aggregate	ww	Brief Description
SUD IMD	Нуро 1	X		X	All expenditures for medical assistance, including SUD treatment costs in an IMD, incurred by an enrollee in the month the enrollee had an IMD stay for those in fee-for-service; All expenditures for medical assistance, including SUD treatment costs in an IMD, incurred by an enrollee in the month the enrollee had an IMD stay, if the stay was over 15 days, for those in managed care
PRSS Services	Нуро 2	X		X	Expenditures for PRSS services for enrollees with SUD
Quick Response Teams	Нуро 2	X		X	Expenditures for QRT services for qualifying beneficiaries
Recovery-Related Support Services	Нуро 2	X		X	Expenditures for RRSS for qualifying beneficiaries with SUD
Reentry Services	Нуро 3	X		X	Expenditures for targeted services that are otherwise covered under Medicaid provided to qualifying beneficiaries for up to 90 days immediately prior to the expected date of release from participating correctional facilities
Reentry Non- Services	Нуро 3		X	X	Expenditures for planning and supporting the reentry demonstration initiative
HRSN Services	SHAC		X	X	Expenditures for approved HRSN initiatives
SUD ADM	N/A				All additional administrative costs that are directly attributable to the demonstration and not described elsewhere and are not subject to budget neutrality.

15.11. **Reporting Expenditures and Member Months**. The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00307/3). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the

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expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

- a. Cost Settlements. The state will report any cost settlements attributable to the demonstration 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) or line 7. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.
- b. Premiums and Cost Sharing Collected by the State. The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by demonstration year on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.
- c. **Pharmacy Rebates.** Because pharmacy rebates are included in the base expenditures used to determine the budget neutrality expenditure limit, the state must report the portion of pharmacy rebates applicable to the demonstration on the appropriate forms CMS-64.9 WAIVER and 64.9P waiver for the demonstration, and not on any other CMS-64.9 form (to avoid double counting). The state must have 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 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. Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.
- d. **Administrative Costs.** The state will 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. Unless indicated otherwise on the MEG Charts and in the STCs in section 2, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

- e. **Member Months.** As part of the Quarterly and Annual Monitoring Reports described in section X, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. 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, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months each contribute two eligible member months per person, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.
- f. Budget Neutrality Specifications Manual. The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state's Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

Table 3. MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 or 64.10 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
SUD IMD	All expenditures for medical assistance, including SUD treatment costs in an IMD, incurred by an enrollee in the month the enrollee had an IMD stay for those in fee-for-services or in the month the enrollee had an IMD stay, if the stay was over 15 days, for those in managed care	N/A	Follow standard CMS-64.9 Category of Service Definitions	Date of Service	MAP	Y	1/1/18	12/31/29
PRSS Services	Expenditures for PRSS services for enrollees with SUD	N/A	Follow standard CMS-64.9 Category of Service Definitions	Date of Service	MAP	Y	1/1/25	12/31/29
Quick Response Teams	Expenditures for QRT services for qualifying beneficiaries	N/A	Follow standard CMS-64.9 Category of Service Definitions	Date of Service	MAP	Y	7/1/26	12/31/29
Recovery- Related Support Services	Expenditures for RRSS for qualifying beneficiaries with SUD	N/A	Follow standard CMS-64.9 Category of Service Definitions	Date of Service	MAP	Y	1/1/26	12/31/29
Reentry Services	Expenditures for targeted services that are otherwise covered under Medicaid provided to qualifying beneficiaries for up to 90 days immediately prior to the expected date of release from participating correctional facilities	N/A	Follow standard CMS-64.9 Category of Service Definitions	Date of Service	MAP	Y	1/1/26	12/31/29
Reentry Non- Services	Expenditures for planning and supporting the reentry demonstration initiative	N/A	Follow standard CMS-64.10 Category of Service Definitions	Date of Payment	ADM	N	1/1/25	12/31/28
HRSN Services	Expenditures for approved HRSN initiatives	N/A	Follow standard CMS-64.9 Category of Service Definitions	Date of Service	MAP	Y	1/1/26	12/31/29
SUD ADM	Administrative costs that are directly attributable to the demonstration	N/A	Follow standard CMS-64.10 Category of Service Definitions	Date of Payment	ADM	N	1/1/18	12/31/29

ADM – administration; DY – demonstration year; MAP – medical assistance payments; MEG – Medicaid expenditure group;

15.12. **Demonstration Years.** Demonstration Years (DY) for this demonstration are defined in the table below.

Table 4. Demonstration Years

Demonstration Year 7	January 1, 2025 to December 31, 2025	12 months
Demonstration Year 8	January 1, 2026 to December 31, 2026	12 months
Demonstration Year 9	January 1, 2027 to December 31, 2027	12 months
Demonstration Year 10	January 1, 2028 to December 31, 2028	12 months
Demonstration Year 11	January 1, 2029 to December 31, 2029	12 months

- 15.13. **Budget Neutrality Monitoring Tool.** The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the performance metrics database and analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing the demonstration's actual expenditures to the budget neutrality expenditure limits described in section 16. CMS will provide technical assistance, upon request.³
- 15.14. Claiming Period. The state will report all claims for expenditures subject to the budget neutrality expenditure limit (including any cost settlements) within two 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 years after the conclusion or termination of the demonstration. During the latter two year period, the state will 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.
- 15.15. **Future Adjustments to Budget Neutrality.** CMS reserves the right to adjust the budget neutrality expenditure limit:
 - a. To be consistent with enforcement of laws and policy statements, including regulations and guidance, regarding impermissible provider payments, health care related taxes, or other payments. CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during

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³ Per 42 CFR 431.420(a)(2), states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and 431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS's current approach is to include language in STCs requiring, as a condition of demonstration approval, that states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget neutrality limit. CMS has obtained Office of Management and Budget (OMB) approval of the monitoring tool under the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and states agree to use the tool as a condition of demonstration approval.

- the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.
- b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.
- c. The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.
- 15.16. **Budget Neutrality Mid-Course Correction Adjustment Request.** No more than once per demonstration year, the state may request that CMS make an adjustment to its budget neutrality agreement based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.
 - a. Contents of Request and Process. In its request, the state must provide a description of the expenditure changes that led to the request, together with applicable expenditure data demonstrating that due to these expenditures, the state's actual costs have exceeded the budget neutrality cost limits established at demonstration approval. The state must also submit the budget neutrality update described in STC 15.16(c). If approved, an adjustment could be applied retrospectively to when the state began incurring the relevant expenditures, if appropriate. Within 120 days of acknowledging receipt of the request, CMS will determine whether the state needs to submit an amendment pursuant to STC 3.7. CMS will evaluate each request based on its merit and will approve requests when the state establishes that an adjustment to its budget neutrality agreement is necessary due to changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside of the state's control, and/or that result from a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

- b. **Types of Allowable Changes.** Adjustments will be made only for actual costs as reported in expenditure data. CMS will not approve mid-demonstration adjustments for anticipated factors not yet reflected in such expenditure data. Examples of the types of mid-course adjustments that CMS might approve include the following:
 - i. Provider rate increases that are anticipated to further strengthen access to care;
 - ii. CMS or State technical errors in the original budget neutrality formulation applied retrospectively, including, but not limited to the following: mathematical errors, such as not aging data correctly; or unintended omission of certain applicable costs of services for individual MEGs;
 - iii. Changes in federal statute or regulations, not directly associated with Medicaid, which impact expenditures;
 - iv. State legislated or regulatory change to Medicaid that significantly affects the costs of medical assistance;
 - v. When not already accounted for under Emergency Medicaid 1115 demonstrations, cost impacts from public health emergencies;
 - vi. High cost innovative medical treatments that states are required to cover; or,
 - vii. Corrections to coverage/service estimates where there is no prior state experience (e.g., SUD) or small populations where expenditures may vary widely.
- c. **Budget Neutrality Update.** The state must submit an updated budget neutrality analysis with its adjustment request, which includes the following elements:
 - i. Projected without waiver and with waiver expenditures, estimated member months, and annual limits for each DY through the end of the approval period; and,
 - ii. Description of the rationale for the mid-course correction, including an explanation of why the request is based on changes to the state's Medicaid expenditures that are unrelated to the demonstration and/or outside the state's control, and/or is due to a new expenditure that is not a new demonstration-covered service or population and that is likely to further strengthen access to care.

16. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

- 16.1. **Limit on Title XIX Funding.** The state must be subject to a limit on the amount of federal Medicaid funding that the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit consists of four Hypothetical Budget Neutrality Tests, and a Capped Hypothetical Budget Neutrality Test, as described below. CMS's assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.
- 16.2. **Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis as described in Table 2, Master MEG Chart and Table 3, MEG Detail for Expenditure and Member Month Reporting. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions, however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.
- 16.3. Calculation of the Budget Neutrality Limits and How They Are Applied. To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.
- 16.4. **Main Budget Neutrality Test.** This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests, including "capped hypotheticals". Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS.
- 16.5. **Hypothetical Budget Neutrality.** When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), or when a WOW spending baseline for certain WW expenditures is difficult to estimate due to variable and volatile cost data resulting in anomalous trend rates, CMS considers these expenditures to be "hypothetical," such that the expenditures are treated as if the state could have received FFP for them absent the demonstration. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they

were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the expenditures on those services. When evaluating budget neutrality, however, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures; that is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state's WW hypothetical spending exceeds the Hypothetical Budget Neutrality Test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending through savings elsewhere in the demonstration or to refund the FFP to CMS.

16.6. **Hypothetical Budget Neutrality Test 1: SUD IMD.** The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test 1 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 5. Hypothetical Budget Neutrality Test 1

MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 7	DY 8	DY 9	DY 10	DY 11
SUD IMD	PC	Both	5.1%	\$4,306.84	\$4,525.93	\$4,756.17	\$4,998.12	\$5,252.38

16.7. Hypothetical Budget Neutrality Test 2: PRSS Services, Recovery-Related Support Services, and Quick Response Teams. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 2. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test 2 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 6. Hypothetical Budget Neutrality Test 2

MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 7	DY 8	DY 9	DY 10	DY 11
PRSS Services	PC	Both	5.1%	\$647.26	\$680.19	\$714.79	\$751.15	\$789.36
Recovery- Related Support Services	PC	Both	5.0%	N/A	\$50.38	\$52.91	\$55.57	\$58.36
Quick Response Teams	PC	Both	5.0%	N/A	\$400.00	\$420.08	\$441.16	\$463.30

16.8. Hypothetical Budget Neutrality Test 3: Reentry Demonstration Initiative Expenditures.

The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 3. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test 3 are counted as WW expenditures under the Main Budget Neutrality Test.

Table 7. Hypothetical Budget Neutrality Test 3

MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 7	DY 8	DY 9	DY 10	DY 11
Reentry Services	PC	Both	5.0%	N/A	\$905.74	\$951.34	\$999.24	\$1,049.55
Reentry Non- Services	Agg	Both	N/A	\$4,000,000	\$3,000,000	\$3,000,000	\$750,000	N/A

16.9. Supplemental HRSN Aggregate Ceiling (SHAC) Hypothetical Budget Neutrality for Evidence-Based HRSN Initiatives. When expenditure authority is provided for specified

HRSN initiatives in the demonstration (in this approval, as specified in Section 9), CMS considers these expenditures to be "supplemental HRSN aggregate ceiling (SHAC)" expenditures; that is, the expenditures are eligible to receive FFP up to a specific aggregate spending cap per demonstration year, based on the state's expected expenditures. States can also receive FFP for capacity-building, infrastructure, and operational costs for the HRSN initiatives; this FFP is limited by a sub-cap of the aggregate spending cap and is determined by CMS based on the amount the state expects to spend. Like all hypothetical expenditures, SHAC expenditures do not need to be offset by savings, and cannot produce savings; however, unspent expenditure authority allocated for HRSN infrastructure in a given demonstration year can be applied to HRSN services in the same demonstration year. Any unspent HRSN services expenditure authority may not be used to fund HRSN infrastructure. To allow for SHAC expenditures and to prevent them from resulting in savings that would apply to the rest of the demonstration, CMS currently applies a separate, independent SHAC Budget Neutrality Test, which subjects SHAC expenditures to pre-determined aggregate limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If actual HRSN initiative spending is less than the SHAC Budget Neutrality Test's expenditure limit for a given demonstration year, the difference is not considered demonstration savings. Unspent HRSN expenditure authority under the cap for each demonstration year can be carried, shifted, or transferred across future demonstration years. However, unspent HRSN expenditure authority cannot roll over to the next demonstration approval period. If the state's SHAC spending exceeds the SHAC Budget Neutrality Test's expenditure limit, the state agrees (as a condition of CMS approval) to refund any FFP in excess of the cap to CMS. Demonstration savings from the Main Budget Neutrality Test cannot be used to offset excess spending for the SHAC.

16.10. SHAC Budget Neutrality Test: HRSN. The table below identifies the MEGs that are used for the SHAC Budget Neutrality Test. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the SHAC Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from the SHAC Budget Neutrality Test cannot be offset by savings under the Main Budget Neutrality Test or the Hypothetical Budget Neutrality Tests.

Table 8. SHAC Budget Neutrality Test

MEG	PC or Agg	WOW Only, WW Only, or Both	Trend Rate	DY 7	DY 8	DY 9	DY 10	DY 11
HRSN Services	Agg	Both	N/A	N/A	\$6,791,359	\$14,382,315	\$22,843,474	\$24,188,239

- 16.11. Composite Federal Share. The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to 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 by total computable demonstration expenditures for the same 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. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, 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 to method. Each Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.
- 16.12. **Exceeding Budget Neutrality.** CMS will enforce budget neutrality over the life of this demonstration period, which extends from January 1, 2025 to December 31, 2029. If at the end of the demonstration approval period any of the Hypothetical Budget Neutrality Tests have been exceeded, the excess federal funds will be returned to CMS. If the Demonstration is terminated prior to the end of the budget neutrality agreement, the budget neutrality test shall be based on the time elapsed through the termination date.
- 16.13. **Corrective Action Plan.** If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan to CMS for approval. CMS will use the threshold levels in the table below as a guide for determining when corrective action is required.

Table 9. Budget Neutrality Test Corrective Action Plan Calculation

Demonstration	Cumulative Target Definition	Percentage
DY 7	Cumulative budget neutrality limit plus:	2.0 percent
DY 7 through DY 8	Cumulative budget neutrality limit plus:	1.5 percent
DY 7 through DY 9	Cumulative budget neutrality limit plus:	1.0 percent
DY 7 through DY 10	Cumulative budget neutrality limit plus:	0.5 percent
DY 7 through DY 11	Cumulative budget neutrality limit plus:	0.0 percent

17. EVALUATION OF THE DEMONSTRATION

- 17.1. Cooperation with Federal Evaluators and Learning Collaborative. As required under 42 CFR 431.420(f), the state must 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 must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. This may also include the state's participation—including representation from the state's contractors, independent evaluators, and organizations associated with the demonstration operations, as applicable—in a federal learning collaborative aimed at cross state technical assistance, and identification of lessons learned and best practices for demonstration measurement, data development, implementation, monitoring, and 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 Section 14.1.
- 17.2. **Independent Evaluator.** The state must use 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 Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.
- 17.3. **Draft Evaluation Design**. The state must submit, for CMS comment and approval, a draft Evaluation Design no later than 180 calendar days after the approval date of the demonstration. 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 draft Evaluation Design must be drafted in accordance with Attachment A (Developing the Evaluation Design) of these STCs, and any applicable evaluation guidance and technical assistance for the demonstration's policy components. The Evaluation Design must also be developed in alignment with CMS guidance on applying robust evaluation approaches, such as quasi-experimental methods like difference-in-differences and interrupted time series, as well as establishing valid comparison groups and assuring causal inferences in demonstration evaluations. In addition to these requirements, if determined appropriate for the communities impacted by the demonstration, the state is encouraged to consider implementation approaches involving randomized control trials and staged rollout (for example, across geographic areas, by service setting, or by beneficiary characteristic)—as these implementation strategies help create strong comparison groups and facilitate robust evaluation.

The state is strongly encouraged to use the expertise of the independent party in the development of the draft Evaluation Design. The draft Evaluation Design also must include a

timeline for key evaluation activities, including the deliverables outlined in STC 17.10 and 17.11.

For any amendment to the demonstration, the state will be required to update the approved Evaluation Design to accommodate the amendment components. The amended Evaluation Design must be submitted to CMS for review no later than 180 calendar days after CMS's approval of the demonstration amendment. Depending on the scope and timing of the amendment, in consultation with CMS, the state may provide the details on necessary modifications to the approved Evaluation Design via the monitoring reports. The amendment Evaluation Design must also be reflected in the state's Interim and Summative Evaluation Reports, described below.

- 17.4. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within 60 calendar days after receipt of CMS's comments, if any. 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 to the state's website within 30 calendar 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 and Annual Monitoring Reports. Once CMS approves the Evaluation Design, if the state wishes to make changes, the state must submit a revised Evaluation Design to CMS for approval if the changes are substantial in scope; otherwise, in consultation with CMS, the state may include updates to the Evaluation Design in monitoring Reports.
- 17.5. **Evaluation Questions and Hypotheses.** Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Reports) of these STCs, the evaluation deliverables must include a discussion of the evaluation questions and hypotheses that the state intends to test. In alignment with applicable CMS evaluation guidance and technical assistance, the evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact and its effectiveness in achieving the goals.

Proposed measures should be selected from nationally recognized sources and national measures sets, where possible. Measures sets could include CMS's 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; Consumer Assessment of Health Care Providers and Systems (CAHPS); the Behavioral Risk Factor Surveillance System (BRFSS) survey; and/or measures endorsed by NQF.

CMS underscores the importance of the state undertaking a well-designed beneficiary survey and/or interviews to assess, for instance, beneficiary understanding of and experience with the various demonstration policy components, including but not limited to beneficiary experiences with access to and quality of care and the HRSN demonstration components, recovery related support services, and reentry. In addition, the state is strongly encouraged to evaluate the implementation of the demonstration components in order to better understand whether implementation of certain key demonstration policies happened as envisioned during the demonstration design process and whether specific factors acted as facilitators of—or barriers

to—successful implementation. Implementation research questions can also focus on beneficiary and provider experience with the demonstration. The implementation evaluation can inform the state's crafting and selection of testable hypotheses and research questions for the demonstration's outcome and impact evaluations and provide context for interpreting the findings.

The hypothesis testing should include, where possible, assessment of both process and outcome measures. The evaluation must study outcomes, such as likelihood of enrollment and enrollment continuity, and various measures of access, utilization, and health outcomes, as appropriate and in alignment with applicable CMS evaluation guidance and technical assistance, for the demonstration policy components. Hypotheses must cover all policies and goals of the demonstration and should be crafted not only to evaluate whether overall demonstration goals were achieved but also the extent to which each component contributed to outcomes. Where demonstration components offer tailored service to specific populations, evaluation hypotheses must include an assessment of whether these programs improved quality of care outcomes and access to health care for the targeted population while also promoting the desired administrative and fiscal efficiencies. The evaluation questions and hypotheses should address the impacts of the following demonstration initiatives, including but not be limited to:

a. Evaluation hypotheses for the HRSN demonstration components must focus on areas such as assessing the effectiveness of the HRSN services in mitigating identified needs of beneficiaries. Such assessment is expected to use applicable demonstration monitoring and other data on prevalence and severity of beneficiaries' HRSNs and the provision of beneficiary utilization of HRSN services. Furthermore, the HRSN evaluation must include analysis of how the initiatives affect utilization of preventive and routine care; utilization of and costs associated with potentially avoidable, high-acuity health care; utilization of hospital and institutional care; and beneficiary physical and mental health outcomes.

In addition, the state must coordinate with its managed care plans to secure necessary data—for a representative beneficiary population eligible for the HRSN services—to conduct a robust evaluation of the effectiveness of the HRSN services in mitigating identified needs of beneficiaries. Such an assessment will require setting up a data infrastructure and/or data sharing arrangement to collect data on beneficiary screening and rescreening and prevalence and severity of beneficiaries' HRSNs, among others. If the data system is not operational to capture necessary data for a quantitative evaluation by the time the state's evaluation activities must be conducted, the state must provide applicable qualitative assessment to this effect leveraging suitable primary data collections efforts (e.g., beneficiary surveys).

Hypotheses must be designed to help understand the impact of housing supports and case management activities on beneficiary health outcomes and experience. In alignment with the demonstration's objectives to improve outcomes for the state's overall beneficiary populations eligible for the HRSN initiatives, the state must also include research questions and hypotheses focused on understanding

the impact of the HRSN initiatives on advancing health quality, including through the reduction of health disparities, for example, by assessing the effects of the initiatives in reducing disparities in health care access, quality of care, or health outcomes at the individual, population, and/or community level.

The evaluation must also assess whether and how local investments in housing supports change over time in concert with new Medicaid funding toward those services. In addition, considering how the demonstration's HRSN expenditures are being treated for purposes of budget neutrality, the evaluation of the HRSN initiative must include a cost analysis to support developing comprehensive and accurate cost estimates of providing such services. Evaluation of the HRSN initiative is also required to include a robust assessment of potential improvements in the quality and effectiveness of downstream services that can be provided under the state plan authority, and associated cost implications.

b. Evaluation of the Reentry Demonstration Initiative must be designed to examine whether the initiative expands Medicaid coverage through increased enrollment of eligible individuals, and efficient high-quality pre-release services that promote continuity of care into the community post-release. In addition, in alignment with the goals of the Reentry Demonstration Initiative in the state, the evaluation hypotheses must focus on, but not be limited to: cross-system communication and coordination; connections between correctional and community services; access to and quality of care in correctional and community settings; preventive and routine physical and behavioral health care utilization; non-emergent emergency department visits and inpatient hospitalizations; and all-cause deaths.

The state must also provide a comprehensive analysis of the distribution of services rendered by type of service over the duration of up to 90-days coverage period before the individual's expected date of release—to the extent feasible—and discuss in the evaluation any relationship identified between the provision and timing of particular services with salient post-release outcomes, including: utilization of acute care services for chronic and other serious conditions, overdose, and overdose- and suicide-related and all-cause deaths in the period soon after release. In addition, the state is expected to assess the extent to which this coverage timeline facilitated providing more coordinated, efficient, and effective reentry planning; enabled pre-release management and stabilization of clinical, physical, and behavioral health conditions; and helped mitigate any potential operational challenges the state might have otherwise encountered in a more compressed timeline for coverage of pre-release services.

The demonstration's evaluation efforts will be expected to include the experiences of correctional and community providers, including challenges encountered, as they develop relationships and coordinate to facilitate transition of individuals into the community. Finally, the state must conduct a comprehensive cost analysis to support developing estimates of implementing the Reentry Demonstration Initiative, including covering associated services.

- c. Hypotheses for the SUD program must include an assessment of the objectives of the SUD component of this section 1115 demonstration. Examples include, but are not limited to, initiative and engagement; compliance with treatment, utilization of health services (e.g., emergency department and inpatient hospital settings), and a reduction in key outcomes, such as deaths due to overdose.
- d. In addition, the state must develop hypotheses and research questions in alignment with goals of demonstration components, such as QRT, RRSS, and PRSS.
- e. As part of its evaluation efforts, the state must conduct a demonstration cost assessment to include, but not be limited to, administrative costs of demonstration implementation and operation, Medicaid health services expenditures, and provider uncompensated care costs. The state must analyze the cost and budgetary effects of the HRSN and reentry demonstration initiatives. In addition, the state must use findings from hypothesis tests aligned with other demonstration goals and cost analyses to assess the demonstration's effects on the fiscal sustainability of the state's Medicaid program.

Finally, the state must accommodate data collection and analyses stratified by key subpopulations of interest (e.g., by sex, age, race/ethnicity, primary language, disability status, and geography). Such stratified data analyses will provide a fuller understanding of existing disparities in access to and quality of care and health outcomes, and help inform how the demonstration's various policies might support reducing such disparities.

- 17.6. **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.
- 17.7. **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.

- 17.8. **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. Presentations may be conducted remotely.
- 17.9. **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.
- 17.10. **Interim Evaluation Reports.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for extension of the demonstration, the Evaluation Report should be posted to the state's website with the application for public comment.
 - a. The interim evaluation report will discuss evaluation progress and present findings to date as per the approved Evaluation Design.
 - b. For demonstration authority or any components within the demonstration that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority, to be collaboratively determined by CMS and the state.
 - c. If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted, or one year prior to the end of the demonstration, whichever is sooner. If the state made changes to the demonstration in its application for extension, the research questions, hypotheses and a description of how the design was adapted should be included. If the state is not requesting an extension for a demonstration, an Interim Evaluation report is due one 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 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report, if any.
 - e. Once approved by CMS, the state must post the final Interim Evaluation Report to the state's Medicaid website within 30 calendar days.
 - f. The Interim Evaluation Report must comply with Attachment B (Preparing the Interim and Summative Evaluation Reports) of these STCs.

- 17.11. **Summative Evaluation Report.** The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within 18 months of the end of the approval period represented by these STCs. The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Interim and Summative Evaluation Reports) of these STCs, and in alignment with the approved Evaluation Design.
 - a. Unless otherwise agreed upon in writing by CMS, the state shall submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft, if any.
 - b. Once approved by CMS, the state must post the final Summative Evaluation Report to the state's Medicaid website within 30 calendar days of approval by CMS.
- 17.12. Corrective Action Plan Related to Evaluation. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of an extension process when associated with the state's Interim Evaluation Report, or as part of the review of the Summative Evaluation Report. A corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 3.10. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.
- 17.13. **Public Access**. The state shall post the final documents (e.g., Implementation Plans, Monitoring Protocols, Monitoring Reports, Mid-Point Assessments, Close-Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 calendar days of approval by CMS.
- 17.14. **Additional Publications and Presentations.** For a period of 12 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 30 calendar 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. This requirement does not apply to the release or presentation of these materials to state or local government officials.

18. SCHEDULE OF STATE DELIVERABLES FOR THE DEMONSTRATION PERIOD

Due	Deliverable	STC	
	Administrative		
30 calendar days after demonstration approval	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter	
	Post Approval Protocols		
90 calendar days after SUD program approval date	SUD Implementation Plan and Health IT Plan	STC 5.2 and 5.3	
150 calendar days after approval date	Monitoring Protocol(s)	STC 14.5	
120 calendar days after approval date	Reentry Demonstration Initiative Implementation Plan	STC 8.10	
6 months after approval date	Reentry Demonstration Initiative Reinvestment Plan	STC 8.11	
90 calendar days after approval date	Protocol for Assessment of Beneficiary Eligibility and Needs, and Provider Qualifications for HRSN Services.	STC 9.6	
9 months after approval date	HRSN Implementation Plan	STC 9.19	
	Evaluations		
180 calendar days after approval date	Submit Evaluation Design	STC 17.3	
One year prior to the expiration of the demonstration	Submit Interim Evaluation Report	STC 17.10	
Within 18 months after approval period ends	Submit Summative Evaluation Report	STC 17.11	
No later than 60 calendar days after December 31, 2027	Submit SUD Mid-point Assessment	STC 14.8	
By the end of the third year of demonstration	Submit Reentry Demonstration Initiative Mid-Point Assessment	STC 14.7	
	Quarterly/Annual/Final Reports		
Annual Deliverable: Due no later than 60 calendar days after January 1, starting in DY 8 (CY 2026)	Network Adequacy and Access Assurances Report	STC 7.4	

Quarterly Deliverables: Due 60 calendar days after the end of each quarter, starting in DY 8 (CY 2026)	Appeals and Grievance Report	STC 7.5
Quarterly Deliverables, except 4 th quarter: Due 60 calendar days after the end of each quarter	Quarterly Monitoring Reports	STC 14.6
90 calendar days after end of demonstration year	Annual Monitoring Reports	STC 14.6
60 calendar days after the end of each quarter.	Quarterly Expenditure Reports (CMS 64)	STC 14.6
90 calendar days after end of each demonstration year	Annual Budget Neutrality Reports	STC 14.6
Close-out Report due 120 calendar days after the end of the demonstration	Close-out Report	STC 14.10

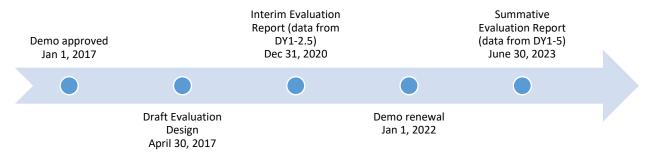
Attachment A Developing the Evaluation Design

Introduction

Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. To that end, for states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. 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 provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data. Evaluations should include findings about 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).

Submission Timelines

There is a specified timeline for the state's submission of its draft Evaluation Design and subsequent evaluation reports. The graphic below depicts an example of this timeline for a 5-year demonstration. 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) calendar days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Designs

CMS expects Evaluation Designs to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html. If the state needs technical assistance using this outline or developing the Evaluation Design, the state should contact its demonstration team.

All states with section 1115 demonstrations are required to conduct Interim and Summative Evaluation Reports, and the Evaluation Design is the roadmap for conducting these evaluations.

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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. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

The format for the Evaluation Design is as follows:

- **A.** General Background Information;
- **B.** Evaluation Questions and Hypotheses;
- **C.** Methodology;
- **D.** Methodological Limitations;
- E. Attachments.

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 description of the population groups impacted by the demonstration.
- 4. A brief description of the demonstration and history of its implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration.
- 5. 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.

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

- 1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the evaluation questions align with the hypotheses and the goals of the demonstration.
- 2. Address how the hypotheses and research questions promote the objectives of Titles XIX and/or XXI.
- 3. 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 can be measured.
- 4. 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, which includes information about the goals and features of the demonstration, is a particularly effective modeling tool when working to improve health and health care through specific interventions. A driver diagram

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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.

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, that the results are statistically valid and reliable, and that it builds upon other published research, using references where appropriate.

This section also provides evidence that the demonstration evaluation will use the best available data. The state should report on, control for, and make appropriate adjustments for the limitations of the data and their effects on results, and discuss the generalizability of results. This section should provide enough transparency to explain what will be measured and how, in sufficient detail so that another party could replicate the results. Table A below is an example of how the state might want to articulate the analytic methods for each research question and measure. Specifically, this section establishes:

- 1. *Methodological Design* Provide information on how the evaluation will be designed. For example, whether the evaluation will utilize pre/post data comparisons, pre-test or post-test only assessments. If qualitative analysis methods will be used, they must be described in detail.
- 2. Target and Comparison Populations Describe the characteristics of the target and comparison populations, incorporating 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. The state also should include information about how it will define the numerators and denominators. Furthermore, the state should ensure the measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval. When selecting metrics, the state shall identify opportunities for improving quality of care and health outcomes, and controlling cost of care. The state also should incorporate benchmarking and comparisons to national and state standards, where appropriate. The state also should 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.) 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. 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.

- 5. Data Sources Explain from where the data will be obtained, describe any efforts to validate and clean the data, and discuss the quality and limitations of the data sources. If the state plans to collect primary data (i.e., data collected specifically for the evaluation), include the methods by which the data will be collected, the source of the proposed questions and responses, and the frequency and timing of data collection. Additionally, copies of any proposed surveys must be provided to CMS for approval before implementation.
- 6. *Analytic Methods* This section includes the details of the selected quantitative and/or qualitative analysis measures that will 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).
 - b. Explain how the state will isolate the effects of the demonstration from other initiatives occurring in the state at the same time (e.g., through the use of comparison groups).
 - c. Include a discussion of how propensity score matching and difference-indifferences designs may be used to adjust for differences in comparison populations over time, if applicable.
 - d. Consider the application of sensitivity analyses, as appropriate.
- 7. *Other Additions* The state may provide any other information pertinent to the Evaluation Design for the demonstration.

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

Research Question Hypothesis 1	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
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 more detailed information about the limitations of the evaluation. This could include limitations about the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize these 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.

CMS also recognizes that there may be certain instances where a state cannot meet the rigor of an evaluation as expected by CMS. In these instances, the state should document for CMS why it is not able to incorporate key components of a rigorous evaluation, including comparison groups and baseline data analyses. For example, if a demonstration is long-standing, it may be difficult for the state to include baseline data because any pre-test data points may not be relevant or comparable. Other examples of considerations include:

- 1. When the demonstration is:
 - a. Non-complex, unchanged, or has previously been rigorously evaluated and found to be successful; or
 - b. 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;
 - b. No or minimal appeals and grievances;
 - c. No state issues with CMS-64 reporting or budget neutrality; and
 - d. No Corrective Action Plans for the demonstration.

E. Attachments

- 1. **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation and prepare objective Evaluation Reports. The Evaluation Design should include a "No Conflict of Interest" statement signed by the independent evaluator.
- 2. **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated costs, 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, if CMS finds that the draft Evaluation Design is not sufficiently developed, or if the estimates appear to be excessive.

3.	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 milestones for the development and submission of the Interim and Summative Evaluation Reports. 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

Both state and federal governments need rigorous quantitative and qualitative evidence to inform policy decisions. To that end, for states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate information about these policies. 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 provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data. Evaluations should include findings about 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).

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 a deliverables timeline for a 5-year demonstration. 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 the Interim and Summative Evaluation Reports to the state's website within thirty (30) calendar days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.



Expectations for Evaluation Reports

All states with Medicaid section 1115 demonstrations are required to conduct evaluations that are 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). 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. When conducting analyses and developing the evaluation reports, every effort should be made to follow the methodology outlined in the approved Evaluation Design. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

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When applying 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.

CMS expects Interim and Summative Evaluation Reports to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html. If the state needs technical assistance using this outline or developing the evaluation reports, the state should contact its demonstration team.

Intent of this Attachment

Title XIX of the Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's evaluation report submissions must provide comprehensive written presentations of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Attachment 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.

Required Core Components of Interim and Summative Evaluation Reports

The Interim and Summative Evaluation Reports present research and findings about the section 1115 demonstration. It is important that the reports 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. The evaluation reports 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.

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).

- **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 issue/s 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 description of the population groups impacted by the demonstration.
 - 4. 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.
 - 5. 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. Additionally, the state should explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable).

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

- 1. Identify the state's hypotheses about the outcomes of the demonstration, and discuss how the goals of the demonstration align with the evaluation questions and hypotheses.
- 2. Address how the research questions / hypotheses of this demonstration promote the objectives of titles XIX and XXI.
- 3. 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.
- 4. 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.
- **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, (using references), meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

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An Interim Evaluation 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 Report.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used. The state also should report on, control for, and make 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, in sufficient detail so that another party could replicate the results. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

- 1. *Methodological Design* Whether the evaluation included an assessment of pre/post or post-only data, with or without comparison groups, etc.
- 2. *Target and Comparison Populations* Describe the target and comparison populations, describing inclusion and exclusion criteria.
- 3. *Evaluation Period* Describe the time periods for which data will be collected.
- 4. Evaluation Measures List the measures used to evaluate the demonstration and their respective measure stewards.
- 5. Data Sources Explain from where the data were obtained, and efforts to validate and clean the data.
- 6. *Analytic Methods* Identify specific statistical testing which was 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.
- **E. Methodological Limitations** This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.
- **F. Results** In this section, the state presents and uses the quantitative and qualitative data to demonstrate whether and to what degree the evaluation questions and hypotheses of the demonstration were addressed. The findings should visually depict the demonstration results, using tables, charts, and graphs, where appropriate. This section should include findings from the statistical tests conducted.
- **G. Conclusions** In this section, the state will present the conclusions about the evaluation results. Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically, the state should answer the following questions:
 - 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. If the state did not fully achieve its intended goals, why not?

- 3. What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?
- H. 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 interpretations 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.
- I. Lessons Learned and Recommendations This section of the evaluation report involves the transfer of knowledge. Specifically, it should include potential "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders. Recommendations for improvement can be just as significant as identifying current successful strategies. Based on the evaluation results, the state should address the following questions:
 - 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?

Attachment C SUD Implementation Plan [Reserved]

Attachment D Health IT Plan [Reserved]

Attachment E **Monitoring Protocol [Reserved]**

Attachment F **Evaluation Design [Reserved]**

Attachment G Reentry Demonstration Initiative Qualifying Conditions and Services

Table 1. Health Care Need Criteria Definitions for Reentry Demonstration Initiative

Qualifying Condition	Definition
Substance Use Disorder (SUD)	A person with a "Substance Use Disorder" (SUD) shall either:
	i. Meet SUD criteria, according to the criteria of the current edition of the Diagnostic and Statistical Manual of Mental Disorders or the International Statistical Classification of Diseases and Related Health Problems; OR
	ii. Have a suspected SUD diagnosis that is identified through an SBIRT and is currently being assessed through an evidence-based tool, such as those validated by the National Institute on Drug Abuse (NIDA).

Table 2. Reentry Service Definitions

Covered Service	Definition	
Case Management	Case management will be provided in the period up to 90 days immediately prior to the expected date of release and is intended to facilitate reentry planning into the community. Reentry case management will be designed to build a bridge between the correctional facility and the community. Services will assess and help address physical needs, behavioral health needs, and health-related social needs.	
	Service components will include:	
	 Conducting a health risk assessment, as appropriate. 	
	Comprehensive assessment and reassessment to determine the needs of the individual. Assessment will include input from the individual's clinician or treatment team and correctional facility's or contractor's reentry planning team.	
	Development of a person-centered reentry care plan, which includes a description of pre- and post- reentry services to address behavioral, physical, social, educational, and other health-related social	

	needs. The plan will extend beyond the individual's expected date of release for continued care.
	Obtaining informed consent, when needed, to furnish services and/or to share information with other entities to improve coordination of care.
	 Linking individual to the designated Medicaid managed care plan care coordinator/care manager for post-release follow up.
	• Linkage and referral per the person-centered treatment plan, including ensuring that necessary appointments with physical and behavioral health care providers, including arranged prior to release.
	 Ability to share data as permitted by state and federal law with managed care plans, and physical and behavioral health providers to enable timely and seamless hand-offs to support continuity of care.
	 Monitoring and follow-up activities, including activities and contacts that are necessary to ensure that the care plan is effectively implemented and adequately addresses the needs of the eligible individual, and which may be with the individual, family members, service providers, or other entities or individuals and conducted as frequently as necessary. Services provided to family or other collaterals are for the direct benefit of the beneficiary, in accordance with the care plan.
	 Conducting follow-up with community-based providers to ensure engagement was made with individual and community-based providers as soon as possible and no later than 30 days from release.
	• Conducting follow up with the individual to ensure engagement with community-based providers, behavioral health services, and other aspects of discharge/reentry planning, as necessary, no later than 30 days from release.
Medication Assisted Treatment (MAT) Services	MAT is inclusive of the medications in addition to accompanying counseling services.
cuement (MIII) services	MAT for Opioid Use Disorders (OUD) includes medications approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and biological products licensed under section

	 351 of the Public Health Service Act (42 U.S.C. 262) to treat opioid use disorders as authorized by the Social Security Act Section 1905(a)(29). MAT for Alcohol Use Disorders (AUD) and Non-Opioid Substance Use Disorders includes FDA-approved drugs and services to treat AUD and other SUDs. Psychosocial services delivered in conjunction with MAT for OUD as covered in the State Plan 1905(a)(29) MAT benefit, and MAT for AUD and Non-Opioid Substance Use Disorders as covered in the State Plan 1905(a)(13) rehabilitation benefit, including assessment; counseling; patient education; prescribing, administering, dispensing, ordering, monitoring, and/or managing MAT.
30-day Supply of Prescription Medications	Individuals will receive a minimum 30-day supply of covered outpatient prescribed medications and over-the counter drugs, including a plan for follow up of injectable administration if needed, as clinically appropriate upon release, consistent with the WV approved Medicaid State Plan.

Attachment H Reentry Demonstration Initiative Implementation Plan [Reserved]

Attachment I Reentry Demonstration Initiative Reinvestment Plan [Reserved]

Attachment J Assessment of Beneficiary Eligibility and Needs and Provider Qualifications for HRSN Services Protocol [Reserved]

Attachment K HRSN Service Matrix

Service Category	Service	Adult Medicaid beneficiaries (ages 18+) with a SUD diagnosis who are currently receiving SUD treatment
	Case management for housing	X
	Housing navigation and tenancy support*	x
	One-time transition and moving costs <u>other</u> <u>than</u> rent	х
Housing/Home Environment interventions	Caregiver respite without room and board	
without room and board	Utility assistance	
Without room and board	Day Habilitation Programs	
	Sobering centers (<24 hour stay)	
	Medically Necessary Home Remediations	
	Home/environmental accessibility modifications	
	Short-term pre-procedure housing	
Housing interventions <u>with</u> Room and Board (Episodic Interventions)	Short-term Recuperative care	
	Short-term post-transition housing	
	Caregiver respite with room and board	
Housing interventions with Room and Board	First month stent as a transitional service	
(Rent Only Interventions)	Short-term rental assistance	
Nutrition interventions	Case management services for access to food/nutrition	
without food	Nutrition counseling and instruction	
	Home Delivered meals	
Nutrition interventions with food	Pantry stocking	
with 1000	Medically Tailored Meals	
	Nutrition prescriptions	

^{*}Includes Housing transition and navigation services, Pre-tenancy navigation services, and Tenancy sustaining services

	Service	Population	Social Risk Factor	Clinical Criteria for the pop
	Case management for housing	Adult Medicaid beneficiaries (ages 18+) with a SUD diagnosis who are currently receiving SUD treatment	Homelessness/At risk of homelessness, or Housing instability	High service utilization
	Housing navigation and tenancy support*	Adult Medicaid beneficiaries (ages 18+) with a SUD diagnosis who are currently receiving SUD treatment	Homelessness/At risk of homelessness, or Housing instability	High service utilization
Housing/Home Environment interventions without room and	One-time transition and moving costs other than rent	Adult Medicaid beneficiaries (ages 18+) with a SUD diagnosis who are currently receiving SUD treatment	1. Homelessness/At risk of homelessness	High service utilization
board	Caregiver respite without room and board			
	Utility assistance			
	Day Habilitation Programs			
	Sobering centers (<24 hour stay)			
	Medically Necessary Home Remediations			
	Home/environmental accessibility modifications			
Housing	Short-term pre-procedure housing			
interventions <u>with</u>	Short-term Recuperative care			
Room and Board	Short-term post-transition housing			
(Episodic Interventions)	Caregiver respite with room and board			
Housing	First month's rent, as a transitional			
interventions with	service			
Room and Board (Rent Only Interventions)	Short-term rental assistance			

Clinical Risk Factor	Clinical Criteria Detail	
High Service Utilization	The individual has a high utilization of services as a result of their SUD diagnosis. This could be indicated by frequent and/or long ED or inpatient stays, and/or frequent utilization of outpatient SUD services in the past 12 months. Frequent would be defined as more than four ED visits and/or hospitalizations in the past 12 months, or more than one inpatient stay in the same timeframe.	

Social Risk Factor	Social Criteria Detail
Homelessness/At Risk of Homelessness	The individual is experiencing one of the following conditions: 1. Homelessness (i.e., lacking a fixed, regular, and adequate nighttime residence); 2. At risk of homelessness (i.e., at risk of losing their primary nighttime residence), or "Homelessness" and "at risk of homelessness" would be further defined in accordance with definitions specified in 24 CFR 91.5.
Housing Instability	Has a history of frequent moves or loss of housing (frequent meaning more than once in the past six months)

Attachment L HRSN Implementation Plan [Reserved]