

SEP 30 2019

Cynthia Beane
Commissioner, West Virginia Department of Health and Human Resources
350 Capitol Street
Room 251
Charleston, WV 25301

Dear Ms. Beane:

Under section 1115 of the Social Security Act (the Act), the Secretary of Health and Human Services (HHS) may approve any experimental, pilot, or demonstration project that, in the judgment of the Secretary, is likely to assist in promoting the objectives of certain Act programs including Medicaid. Congress enacted section 1115 of the Act to ensure that federal requirements did not “stand in the way of experimental projects designed to test out new ideas and ways of dealing with the problems of public welfare recipients.” S. Rep. No. 87-1589, at 19 (1962), *as reprinted in* 1962 U.S.C.C.A.N. 1943, 1961. As relevant here, section 1115 of the Act allows the Secretary to waive compliance with the Medicaid program requirements of section 1902 of the Act, to the extent and for the period he finds necessary to carry out the demonstration project. In addition, section 1115 of the Act allows the Secretary to provide federal financial participation for demonstration costs that would not otherwise be considered as federally matchable expenditures under section 1903 of the Act, to the extent and for the period prescribed by the Secretary.

For the reasons discussed below, the Centers for Medicare & Medicaid Services (CMS) is approving West Virginia’s request to amend West Virginia’s section 1115 demonstration project, entitled “Creating a Continuum of Care for Medicaid Enrollees with Substance Use Disorders” (Project Number 11-W-0028516) (the “demonstration”). This amendment is effective on September 30, 2019, or as otherwise stated, through December 31, 2022, in accordance with section 1115(a) of the Act.

CMS’s approval of this section 1115(a) demonstration amendment is subject to the limitations specified in the attached expenditure authorities, waivers, Special Terms and Conditions (STCs), and any supplemental attachments defining the nature, character, and extent of federal involvement in this project. The state may deviate from the Medicaid state plan requirements only to the extent those requirements have been specifically listed as waived or as not applicable to expenditures or individuals covered by expenditure authority.

Objectives of the Medicaid Program

As noted above, the Secretary may approve a demonstration project under section 1115 of the Act if, in his judgment, the demonstration is likely to assist in promoting the objectives of title XIX. The purposes of Medicaid include an authorization of appropriation of funds to “enabl[e]

each State, as far as practicable under the conditions in such State, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care.” Act § 1901. This provision makes clear that an important objective of the Medicaid program is to furnish medical assistance and other services to vulnerable populations. But, there is little intrinsic value in paying for services if those services are not advancing the health and wellness of the individual receiving them, or otherwise helping the individual attain independence. Therefore, we believe an objective of the Medicaid program, in addition to furnishing services, is to advance the health and wellness needs of its beneficiaries, and that it is appropriate for the state to structure its demonstration project in a manner that prioritizes meeting those needs.

Section 1115 demonstration projects present an opportunity for states to experiment with reforms that go beyond just routine medical care and focus on interventions that drive better health outcomes and quality of life improvements, and that may increase beneficiaries’ financial independence. Such policies may include those designed to address certain health determinants and those that encourage beneficiaries to engage in health-promoting behaviors and to strengthen engagement by beneficiaries in their personal health care plans. These tests will necessarily mean a change to the status quo. They may have associated administrative costs, particularly at the initial stage, and section 1115 acknowledges that demonstrations may “result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing.” Act § 1115(d)(1). But in the long term, they may create incentives and opportunities that help enable many beneficiaries to enjoy the numerous personal benefits that come with improved health and financial independence.

Section 1115 demonstration projects also provide an opportunity for states to test policies that ensure the fiscal sustainability of the Medicaid program, better “enabling each [s]tate, as far as practicable under the conditions in such [s]tate” to furnish medical assistance, Act § 1901, while making it more practicable for states to furnish medical assistance to a broader range of persons in need. For instance, measures designed to improve health and wellness may reduce the volume of services consumed, as healthier, more engaged beneficiaries tend to consume fewer medical services and are generally less costly to cover. Further, measures that have the effect of helping individuals secure employer-sponsored or other commercial coverage or otherwise transition from Medicaid eligibility may decrease the number of individuals who need financial assistance, including medical assistance, from the state. Such measures may enable states to stretch their resources further and enhance their ability to provide medical assistance to a broader range of persons in need, including by expanding the services and populations they cover.¹ By the same

¹ States have considerable flexibility in the design of their Medicaid programs, within federal guidelines. Certain benefits are mandatory under federal law, but many benefits may be provided at state option, such as prescription drug benefits, vision benefits, and dental benefits. Similarly, states have considerable latitude to determine whom their Medicaid programs will cover. Certain eligibility groups must be covered under a state’s program, but many states opt to cover additional eligibility groups that are optional under the Medicaid statute. The optional groups include a new, non-elderly adult population (ACA expansion population) that was added to the Act at section 1902(a)(10)(A)(i)(VIII) by the Patient Protection and Affordable Care Act (ACA). Coverage of the ACA expansion population became optional as a result of the Supreme Court’s decision in *NFIB v. Sebelius*, 567 U.S. 519 (2012).

token, such measures may also preserve states' ability to continue to provide the optional services and coverage they already have in place.

Our demonstration authority under section 1115 of the Act allows us to offer states more flexibility to experiment with different ways of improving health outcomes and strengthening the financial independence of beneficiaries. Demonstration projects that seek to improve beneficiary health and financial independence improve the well-being of Medicaid beneficiaries and, at the same time, allow states to maintain the long-term fiscal sustainability of their Medicaid programs and to provide more medical services to more Medicaid beneficiaries. Accordingly, such demonstration projects advance the objectives of the Medicaid program.

Background on Medicaid Coverage in West Virginia's 1115 Demonstration

West Virginia's section 1115 demonstration was initially approved in October 2017, with a demonstration period of January 2018 through December 2022. The main goals of this statewide demonstration are to improve the quality of care and population health outcomes for Medicaid beneficiaries with Substance Use Disorder (SUD) and to increase access to SUD treatment services. The demonstration provides the state the ability to receive Federal Financial Participation (FFP) for beneficiaries in Institutions for Mental Diseases (IMDs) with SUD.

In August 2019, the state submitted a request to amend its section 1115 demonstration in order to grant the authority for beneficiaries in the Children with Serious Emotional Disorders Waiver (CSEDW), which uses 1915(c) authority, be placed into a single specialized managed care organization (MCO). The amendment is not impacting the SUD service delivery.

Extent and Scope of the Demonstration Amendment

The nature of this amendment is to provide expenditure authority which will permit beneficiaries in the existing CSEDW 1915(c) waiver program to be placed into a single MCO, and will have no impact on benefits, eligibility, monitoring, evaluation, or requirements set forth in the original 1115 extension request. The 1915(c) waiver outlines the eligibility and benefits for this population. Under a 1915(c) waiver, a beneficiary ordinarily must have a choice of MCOs as required under section 1902(a)(23), and have the right under section 1903(m)(2)(A)(6) to disenroll from the MCO in which he or she is enrolled. This amendment to the section 1115 demonstration will use expenditure authority to permit FFP to be provided in the MCO contract notwithstanding non-compliance with section 1903(m)(2)(A)(vi). The CSEDW will allow West Virginia to provide an array of Home and Community Based Services (HCBS) that enable children who would otherwise require institutionalization to remain in their homes and communities. In addition, it is anticipated that this waiver will reduce the number of children

Accordingly, several months after the *NFIB* decision was issued, CMS informed the states that they "have flexibility to start or stop the expansion." CMS, *Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid* at 11 (Dec. 10, 2012). In addition to expanding Medicaid coverage by covering optional eligibility groups and benefits beyond what the Medicaid statute requires, many states also choose to cover benefits beyond what is authorized by statute by using expenditure authority under section 1115(a)(2) of the Act. For example, recently, many states have been relying on this authority to expand the scope of services they offer to address substance use disorders beyond what the statute explicitly authorizes.

housed both in-state and out-of-state Psychiatric Residential Treatment Facilities (PRTFs) and shorten the lengths of stay for children who require acute care in PRTFs. These services include case management, independent living/skills building, job development, respite care, assistive equipment, transportation, and other services.

The state would like to enroll eligible children in a single, specialized MCO best equipped to provide coordinated care in a seamless and cost-effective way. With this amendment, the state will have authority to automatically enroll CSEDW beneficiaries on a mandatory basis into a single MCO and not provide for a right to disenroll and still keep CSEDW benefits.

Determination that the Demonstration Project is Likely to Assist in Promoting Medicaid's Objectives

In its consideration of the demonstration extension, CMS examined whether the demonstration was likely to assist in improving health outcomes, whether it would address health determinants that influence health outcomes, and whether it would incentivize beneficiaries to engage in their own health care and achieve better health outcomes. CMS has determined the demonstration is likely to promote Medicaid objectives, and the waiver and expenditure authorities sought are necessary and appropriate to carry out the demonstration. For reasons discussed below, the Secretary has determined that the demonstration, as amended, is likely to assist in promoting the objectives of the Medicaid program.

Increasing access to high quality and integrated mental health services for children with SED is expected to lead to positive health outcomes for beneficiaries and improve program sustainability for the state.

This demonstration amendment will promote the objectives of Medicaid by authorizing a seamless and cost-effective way to provide high-quality treatment to children with SED through a single specialized MCO focused on children with SED. The specialized MCO will focus on serving children with SED and will create a network of providers best suited to serve these vulnerable beneficiaries. The state also anticipates to reduce Medicaid costs by reducing the amount of the children who require institutional services and can remain in the community by utilizing HCBS services.

Consideration of Public Comments

The state provided public notice for this amendment in accordance with the public notice process and tribal consultation process required by 59 FR 59249 and STC 7. During the CSEDW application period the State met with relevant West Virginia government agencies, as the State stakeholder group, to discuss the current system for CSED. West Virginia also engaged with numerous external stakeholders from different disciplines in the regions of the State. External stakeholders attended public forums held from November 27 – 30, 2018, strategically located throughout the State. Over the course of five stakeholder meetings, over 100 participants provided information, shared insights, and prioritized services to assist with waiver development. The participants represented a wide range of service agencies, providers, schools, and MCOs. West Virginia solicited feedback using these facilitated forums to identify priority services for

the CSEDW. Notifications for these events were issued via West Virginia's email listserv and Fall Provider Workshops. During these public forums, the state provided an overview presentation regarding the potential CSEDW and followed it with a facilitated discussion with participants. At the conclusion of each public forum, participants were asked to complete a brief survey, comprising questions that would garner additional insight and feedback for West Virginia.

The State also posted the CSEDW online for a 30-day public comment period beginning on April 23, 2019. The public comment period was inclusive of a press announcement which was made available on the West Virginia Department of Health and Human Resources (DHHR) website. A notice of the comment period was placed in the State's largest newspaper, the Charleston Gazette Mail, appearing on April 23, 2019, as well as on West Virginia's and the Children with SED websites. A flyer was sent to the licensed behavior health centers (LBHCs), the multi-agency State stakeholder group, and all participants from the public forums who requested notification. A log of the comments received and West Virginia's responses is available on the West Virginia website for public review at:

<https://dhhr.wv.gov/bms/Programs/WaiverPrograms/CSEDW/Pages/SED.aspx>.

Finally, DHHR kicked off a monthly Child Welfare Collaborative meeting series in November 2018 that is open to the public and serves as a common forum for sharing information and ideas. A listserv has been established for sharing news and coordinating efforts. During these meetings, DHHR representatives have provided updates on both the CSEDW and specialized MCO transition (among other topics), and responded to questions from the community.

The comments that West Virginia received were generally supportive of the 1915(c) waiver and bringing in additional services for children with SED. They note that West Virginia currently does not have enough of these services throughout the state and this 1915(c) waiver will provide essential services to this vulnerable population. West Virginia also incorporated a large amount of the feedback provided from the public into the application submitted to CMS. No comments were related to the restriction of a single MCO providing these services, which is the authority the 1115 amendment provides.

The federal comment period for the amendment was open from August 7, 2019 through September 6, 2019. In summary, two comments were received during the comment period, both from individuals. One comment expressed concern about limiting choice to a single MCO, and their negative experiences in dealing with an MCO in the past. WV believes that having a single specialized MCO that focuses on the treatment and care of children with SED will create a network that will provide the most effective care for caring for these vulnerable beneficiaries. The second comment expressed concern about the lock-in period, restricting beneficiaries to one MCO, and beneficiaries losing Medicaid coverage if they chose not to use the only MCO provider for the CSEDW. West Virginia will not drop coverage for beneficiaries who do not use the specialized MCO for CSEDW benefits. Those beneficiaries will remain covered by Medicaid and still have access to EPSDT and other services under the state plan. They will not have access to the additional benefits provided through the CSEDW, as those are specialized benefits provided only through the MCO. However, beneficiaries with SED will have the freedom of choice to not participate in the CSEDW and retain Medicaid state plan benefits, only.

Other Information

CMS's approval of this demonstration is conditioned upon compliance with the enclosed list of waiver and expenditure authorities and the STCs defining the nature, character and extent of anticipated federal involvement in the project. The award is subject to our receiving your written acknowledgement of the award and acceptance of these STCs within 30 days of the date of this letter.

Your project officer is Michael Trieger. Mr. Trieger's contact information is as follows:

Michael Trieger
Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
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E-mail: Michael.Trieger1@cms.hhs.gov

Official communications regarding program matters should be sent simultaneously to Mr. Trieger and to Ms. Sabrina Tillman-Boyd, in our Division of Medicaid Field Operations East. Ms. Tillman-Boyd's address is:

Sabrina Tillman-Boyd
Acting Deputy Director, Regional Operations Group East Director,
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If you have questions regarding this approval, please contact Ms. Judith Cash, Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (410) 786-9686. We look forward to continuing to partner with you and your staff throughout the course of the West Virginia's Creating a Continuum of Care for Medicaid Enrollees with Substance Use Disorders demonstration.

Sincerely,



Calder Lynch
Acting Deputy Administrator and Director

Enclosure

cc: Sabrina Tillman-Boyd, Acting Deputy Director, Regional Operations Group East
Dan Belnap, West Virginia State Lead, Division of Medicaid Field Operations East

**CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY**

NUMBER: 11-W-00307/3

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

AWARDEE: West Virginia Department of Health and Human Services

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

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

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

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

1. Residential Treatment for Individuals with Substance Use Disorder (SUD).

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

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

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

4. Expenditures Related to Administrative Simplification and Delivery Systems.

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

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

**CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS**

NUMBER: 11-W-00307/3

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

AWARDEE: West Virginia Department of Health and Human Services

I. PREFACE

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

The STCs have been arranged into the following subject areas:

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

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

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

II. PROGRAM DESCRIPTION AND OBJECTIVES

The Substance Use Disorder (SUD) demonstration is a demonstration program to test a new paradigm for the delivery of SUD services for all Medicaid enrollees. The SUD program

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

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

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

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

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.
2. **Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly

identified as not applicable in the expenditure authority documents (of which these terms and conditions are part), must apply to the demonstration.

3. **Changes in Medicaid Law, Regulation, and Policy.** The state must, within the time frames specified in law, regulation, or policy statement, come into compliance with any changes in federal law, regulation, or policy statement, affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is expressly identified as not applicable.
4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy Statements.** To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration, as necessary, to comply with such change. The modified budget neutrality agreement will be effective upon the implementation of the change.
 - A. If mandated changes in the federal law require state legislation, the changes must take effect on the day such state legislation becomes effective, or on the day such legislation was required to be in effect under the federal law.
5. **State Plan Amendments.** The state shall not be required to submit title XIX state plan amendments for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid state plan is affected by a change to the demonstration, a conforming amendment to the state plan will be required, except as otherwise noted in these STCs.
6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, enrollee rights, delivery systems, cost sharing, evaluation design, sources of non-federal share of funding and budget neutrality must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Social Security Act (the Act). The state must not implement changes to these elements without prior approval by CMS. Amendments to the demonstration are not retroactive and FFP will not be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below.
7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than one hundred twenty (120) days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the state to submit required reports and other deliverables in a timely fashion according to the

deadlines specified herein. Amendment requests must include, but are not limited to, the following:

- A. An explanation of the public process used by the state, consistent with the requirements of STC 14, to reach a decision regarding the requested amendment;
 - B. A data analysis which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include total computable “with waiver” and “without waiver” expenditure estimates as well as the current federal share of the “with waiver” and “without waiver” estimates. The data analysis shall contain both summary and detailed level expenditure data through the current approval period using the most recent actual expenditures that illustrates the change in the “with waiver” expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
 - C. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation; and
 - D. If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.
8. **Extension of the Demonstration.** No later than twelve (12) months prior to the expiration date of the demonstration, the governor or chief executive officer of the state must submit to CMS notification that it expects to cover individuals under the Medicaid state plan or through some other type of coverage, a demonstration extension request, or a phase-out plan consistent with the requirements of STC 9.

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

9. **Demonstration Phase-Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.
- A. Notification of Suspension or Termination: The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit its notification letter and a draft phase-out plan to CMS no less than five (5) months before the effective date of the demonstration’s suspension or termination. Prior to submitting the draft plan to CMS, the state must publish on its website the draft plan for a thirty (30) day public comment period. In addition, if applicable, the state must conduct tribal consultation in accordance with its approved tribal consultation state plan amendment. Once the thirty (30) day public comment period has ended, the state

- must provide a summary of each public comment received, the state's response to the comment and how the state incorporated the received comment into a revised phase-out plan.
- B. The state must obtain CMS approval of the phase-out plan prior to the implementation of the phase-out activities. Implementation of transition and phase-out activities must be no sooner than fourteen (14) days after CMS approval of the plan.
 - C. Phase-out Plan Requirements: The state must include, at a minimum, in its plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility for the affected beneficiaries, and ensure ongoing coverage for eligible individuals, as well as any community outreach activities.
 - D. Phase-out Procedures: The state must comply with all notice requirements found in 42 CFR 431.206, 431.210 and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration participants as outlined in 42 CFR 431.220 and 431.221. If a demonstration participant requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category as discussed in October 1, 2010, state Health Official Letter #10- 008.
 - E. Federal Financial Participation (FFP): If the project is terminated or any relevant waivers suspended by the state, FFP shall be limited to normal closeout costs associated with terminating the demonstration including services and administrative costs of disenrolling participants.
10. **CMS Right to Terminate or Suspend.** CMS may suspend or terminate, subject to adequate public notice, the demonstration in whole or in part at any time before the date of expiration, whenever it determines, following a hearing, that the state has materially failed to comply with the terms of the project. CMS will promptly notify the state in writing of the determination and the reasons for the suspension or termination, together with the effective date.
11. **Finding of Non-Compliance.** The state does not relinquish its rights to challenge the CMS finding that the state materially failed to comply.
12. **Withdrawal of Waiver Authority.** CMS reserves the right to withdraw waivers or expenditure authorities at any time it determines that continuing the waivers or

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

13. **Adequacy of Infrastructure.** The state must ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.
14. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the public notice procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

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

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

IV. SUBSTANCE USE DISORDER (SUD) DEMONSTRATION

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

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

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

Table One: SUD Demonstration Benefits (with Expenditure Authority)

ASAM Level of Care*	SUD Demonstration Benefit	Medicaid Authority	Costs Not Otherwise Matchable
N/A	Targeted Case Management	State plan	Services provided to short-term residents
N/A	Naloxone Administration Services	State plan	Services provided to short-term residents
0.5	Screening, Brief Intervention and Referral to Treatment	State plan	
1	Peer Recovery Support Services	Section 1115 demonstration	Services provided to short-term residents
1	Outpatient Services	State plan	
2.1	Intensive Outpatient Services	State plan	
2.5	Partial Hospitalization Services	State plan	

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

3.1	Clinically Managed Low Intensity Residential Services	Section 1115 demonstration	Services provided to short-term residents
3.3	Clinically Managed Population-Specific High Intensity Residential Services	Section 1115 demonstration	Services provided to short-term residents
3.5	Clinically Managed High Intensity Residential Services	Section 1115 demonstration	Services provided to short-term residents
3.7	Medically Monitored Intensive Inpatient Services	State plan	Services provided to short-term residents
4	Medically Managed Intensive Inpatient Services	State plan	
1-WM	Ambulatory Withdrawal Management Services	State plan	
2-WM	Ambulatory Withdrawal Management Services	State plan	

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

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

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

Peer Recovery Support Services

Peer recovery support services are designed and delivered by individuals in recovery from substance use disorder (peer recovery coach) to provide counseling support to help prevent relapse and promote recovery. Services can be provided by appropriately trained staff when working under the supervision of a competent behavioral health professional (as defined by the State). A peer recovery coach must be certified through a West Virginia Department of Health and Human Resources-approved training program that provides peer support providers with a basic set of competencies necessary to perform the peer support function. The peer must demonstrate the ability to support the recovery of others from substance use disorders. Similar to other provider types, ongoing continuing educational requirements for peer support providers must be in place.

Residential Treatment Services

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

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

- a. Residential treatment services are provided in a West Virginia Bureau of Medical Services (BMS)-certified facility that has been enrolled as a Medicaid provider and assessed by BMS as delivering care consistent with ASAM Levels 3.1, 3.3, 3.5,

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

- b. Residential treatment services can be provided in settings of any size.
- c. The state's average length of stay for individuals admitted into all BMS-certified facilities at all levels of care is thirty (30) days.
- d. The implementation date for residential treatment services is July 1, 2018.
- e. Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

Covered services include:

- a. Clinically-directed therapeutic treatment to facilitate recovery skills, relapse prevention, and emotional coping strategies.
- b. Addiction pharmacotherapy and drug screening;
- c. Motivational enhancement and engagement strategies;
- d. Counseling and clinical monitoring;
- e. Withdrawal management and related treatment designed to alleviate acute emotional, behavioral, cognitive, or biomedical distress resulting from, or occurring with, an individual's use of alcohol and other drugs;
- f. Regular monitoring of the individual's medication adherence;
- g. Recovery support services;

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

Opioid Treatment Program Services (methadone treatment services)

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

Covered services include:

- a. Linkage to psychological, medical, and psychiatric consultation.
- b. Access to emergency medical and psychiatric care through connections with more intensive levels of care.
- c. Access to evaluation and ongoing primary care.
- d. Ability to conduct or arrange for appropriate laboratory and toxicology tests including urine drug screenings.
- e. Availability of licensed physicians to evaluate and monitor use of methadone, buprenorphine products or naltrexone products and of pharmacists and nurses to dispense and administer these medications.
- f. Individualized, person-centered assessment and treatment.
- g. Assessing, ordering, administering, reassessing, and regulating medication and dose levels appropriate to the individual; supervising withdrawal management from opioid analgesics, including methadone, buprenorphine products or naltrexone products; overseeing and facilitating access to appropriate treatment for opioid use disorder.
- h. Medication for other physical and mental health illness is provided, as needed, either

on-site or through collaboration with other providers. Cognitive, behavioral, and other substance use disorder-focused therapies, reflecting a variety of treatment approaches, provided to the individual on an individual, group, and/ or family basis.

- i. Optional substance use care coordination provided, including integrating behavioral health into primary care and specialty medical settings through interdisciplinary care planning and monitoring individual progress and tracking individual outcomes; supporting conversations between buprenorphine-waivered practitioners and behavioral health professionals to develop and monitor individualized service plans; linking individuals with community resources to facilitate referrals and respond to social service needs; tracking and supporting individuals when they obtain medical, behavioral health, or social services outside the practice.
- j. Referral for screening for infectious diseases such as HIV, hepatitis B and C, and tuberculosis at treatment initiation and then at least annually or more often based on risk factors.

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

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

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

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

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

V. GENERAL REPORTING REQUIREMENTS

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

- A. Thirty (30) days after the deliverable was due, CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submission of required deliverables.
- B. For each deliverable, the state may submit a written request for an extension to submit the required deliverable. Extension requests that extend beyond the current calendar quarter must include a Corrective Action Plan (CAP).
 - i. CMS may decline the extension request;
 - ii. Should CMS agree in writing to the state’s request, a corresponding extension of the deferral process described below can be provided; and
 - iii. If the state’s request for an extension includes a CAP, CMS may agree to or further negotiate the CAP as an interim step before applying the deferral.
- C. The deferral would be issued against the next quarterly expenditure report following the written deferral notification.
- D. When the state submits the overdue deliverables(s) that are accepted by CMS, the deferral(s) will be released.
- E. As the purpose of a section 1115 demonstration is to test new methods of operation or services, and timely and complete submission of required deliverables is necessary for effective testing, a state’s failure to submit all required deliverables may preclude a state from renewing a demonstration or obtaining a new demonstration.
- F. CMS will consider with the state an alternative set of operational steps for implementing the intended deferral to align the process with the state’s existing deferral process, for example, which quarter the deferral applies to and how the deferral is released.

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

STCs.

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

- A. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
- B. Ensure all 1115, Transformed Medicaid Statistical Information System (T-MSIS), and other data elements that have been agreed to are provided; and
- C. Submit deliverables through the appropriate system as directed by CMS.

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

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

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

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

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

- B. The Quarterly and Annual Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.
1. Operational Updates - The reports shall provide sufficient information to document key operational and other challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held.
 2. Performance Metrics – Any required monitoring and performance metrics must be included in writing in the Quarterly and Annual Reports. Information in the reports will follow the framework provided by CMS and be provided in a structured manner that supports federal tracking and analysis.
 3. Budget Neutrality and Financial Reporting Requirements – The state must provide an updated budget neutrality workbook that includes established baseline and member months data with every Quarterly and Annual Report that meets all the reporting requirements for monitoring budget neutrality set forth in section VII. General Financial Requirements of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly expenditures associated with the populations affected by this demonstration on the Form CMS-64.
Evaluation Activities and Interim Findings. The state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed. The state shall specify, for CMS approval, a set of performance and outcome metrics, including their specifications, reporting cycles, level of reporting (e.g., the state, health plan and provider level, and segmentation by population) to support rapid cycle assessments in trends for monitoring and evaluation of the demonstration.

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

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

- B. Total annual expenditures for the demonstration population for each DY, with administrative costs reported separately;
 - C. Total contributions, withdrawals, balances, and credits; and
 - D. Yearly enrollment reports for demonstration enrollees for each DY (enrollees include all individuals enrolled in the demonstration) that include the member months, as required to evaluate compliance with the budget neutrality agreement.
27. **Close Out Operational Report.** Within one hundred twenty (120) days prior to the expiration of the demonstration, the state must submit a draft Close Out Report to CMS for comments.
- A. The draft Close Out Report must comply with the most current Guidance from CMS.
 - B. The state will present to and participate in a discussion with CMS on the Close-Out Report.
 - C. The state must take into consideration CMS' comments for incorporation into the final Close-Out Report.
 - D. The Final Close-Out Report is due to CMS no later than thirty (30) days after receipt of CMS' comments.
 - E. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 20.
28. **State Data Collection.** The state must collect data and information necessary to oversee service utilization and rate setting by provider/plan, comply with the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) and the Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set), collectively referred to as the CMS Child and Adult Core Measure Sets for Medicaid and CHIP, and comply with other existing federal measure sets.
- A. The state will use this information in ongoing monitoring of individual well-being, provider/plan performance, and continuous quality improvement efforts, in addition to complying with CMS reporting requirements.
 - B. The state must maintain data dictionary and file layouts of the data collected.
 - C. The raw and edited data will be made available to CMS within thirty (30) days of a written request.

29. **Monitoring Calls.** CMS will convene periodic conference calls with the state.
- A. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration.
 - B. CMS will provide updates on any amendments or concept papers under review, as well as federal policies and issues that may affect any aspect of the demonstration.
 - C. The state and CMS will jointly develop the agenda for the calls.
 - D. Areas to be addressed during the monitoring call include, but are not limited to:
 - 1. Transition and implementation activities;
 - 2. Stakeholder concerns;
 - 3. Operations and performance;
 - 4. Enrollment;
 - 5. Cost sharing;
 - 6. Quality of care;
 - 7. Beneficiary access;
 - 8. Benefit package and wrap around benefits;
 - 9. Audits;
 - 10. Lawsuits;
 - 11. Financial reporting and budget neutrality issues;
 - 12. Progress on evaluation activities and contracts;
 - 13. Related legislative developments in the state; and
 - 14. Any demonstration changes or amendments the state is considering.

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

VI. EVALUATION OF THE DEMONSTRATION

31. **Independent Evaluator.** At the beginning of the demonstration period, the state must arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The independent party must sign an agreement to conduct the demonstration evaluation in accord with the CMS-approved, Draft Evaluation Design, which will meet the requirements described in 42 C.F.R. 431.424 and the guidance provided in Attachment B: “Developing the Evaluation Design.” For scientific integrity, every effort should be made to follow the approved methodology. State evaluation must follow the approved methodology; however, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.
32. **Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A of these STCs. The state must submit, for CMS comment and approval, a Draft Evaluation Design with implementation timeline, for the demonstration to CMS no later than one hundred eighty (180) days after the effective date of these STCs. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state may choose to use the expertise of the independent party in the development of the Draft Evaluation Design.
33. **Evaluation Design Approval and Updates.** The state must submit a revised Draft Evaluation Design within sixty (60) days after receipt of CMS’ comments. Upon CMS approval of the Draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the Quarterly Reports and Annual Reports.
34. **Evaluation Questions and Hypotheses.** Consistent with attachments A and B of these STCs the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. CMS recommends hypotheses include an assessment of the objectives of SUD section 1115 demonstrations, to include (but is not limited to): initiation and compliance with treatment, appropriate utilization of health services (emergency department and inpatient hospital settings), and a reduction in key outcomes such as deaths due to overdose.

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

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

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

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

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

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

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

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

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

- A. The interim evaluation report will discuss evaluation progress and present findings to date as per the approved evaluation design.
 - B. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
 - C. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions, hypotheses and how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
 - D. The state must submit the final Interim Evaluation Report sixty (60) days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.
 - E. The Interim Evaluation Report must comply with Attachment B of these STCs.
40. **Summative Evaluation Report.** The state must submit a draft Summative Evaluation Report for the demonstration's current approval period within eighteen (18) months of the end of this approval period. The draft Summative Evaluation Report must include the information in the approved Evaluation Design. Refer to Attachment B for additional information on the evaluation report.
- A. Unless otherwise agreed upon in writing by CMS, the state shall submit the final Summative Evaluation Report within sixty (60) days of receiving comments from CMS on the draft.
 - B. The final Summative Evaluation Report must be posted to the state's Medicaid website within thirty (30) days of approval by CMS.
41. **Public Access.** The state shall post the final documents (e.g., Quarterly and Annual Reports, Final Operational Report, approved Evaluation Design, Final Interim Evaluation Report(s), Final Summative Evaluation Report(s), and the Final Evaluation Report) on the state's Medicaid website within thirty (30) days of approval by CMS.
42. **Additional Publications and Presentations.** For a period of twenty-four (24) months following CMS approval of the final reports, CMS will be notified prior to presentation of other reports and related publications (including, for example, journal articles), by the

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

XII. GENERAL FINANCIAL REQUIREMENTS

43. **Quarterly Expenditure Reports.** The state must complete quarterly expenditure reports through the Medicaid and Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in section 2500 of the State Medicaid Manual, for services provided through this demonstration and that are subject to budget neutrality. CMS shall provide FFP for allowable demonstration expenditures only as long as they do not exceed the pre-defined limits on the costs incurred as specified in section VIII (Monitoring Budget Neutrality).
44. **Reporting Expenditures Subject to the Title XIX Budget Neutrality Expenditure Limit.** The following describes the reporting of expenditures subject to the budget neutrality limit:
- a. **Tracking Expenditures.** In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in section 2500 of the state Medicaid Manual. All demonstration expenditures claimed under the authority of title XIX of the Act and subject to the budget neutrality expenditure limit must be reported each quarter on separate Forms CMS-64.9 Waiver and/or CMS-64.9P Waiver, identified by the demonstration project number (11-W-00307/3) assigned by CMS, including the project number extension, which indicates the DY in which services were rendered.
 - b. **Cost Settlements.** For monitoring purposes, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (form CMS-64.9P Waiver) for the summary sheet line 10B, in lieu of lines 9 or 10C. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual.
 - c. **Pharmacy Rebates.** The state may propose a methodology for assigning a portion of pharmacy rebates to the demonstration services, in a way that reasonably reflects the actual rebate-eligible pharmacy utilization of those populations, and which reasonably identifies pharmacy rebate amounts with DYs. Use of the methodology is subject to the approval in advance by the CMS Regional Office, and changes to the methodology must be approved in advance by the Regional Office. A portion of pharmacy rebates assigned to the demonstration using the approved methodology will be reported on the appropriate Forms CMS-64.9 Waiver for the demonstration and not on any other CMS-64.9 form to avoid double-counting. Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.

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

- i. EG 1 – “SUD IMD” – This EG corresponds to Expenditure Authority #1 (Residential Treatment for Individuals with SUD) which includes all medical assistance expenditures including residential treatment costs with dates of service in a month when the beneficiary was a patient in an IMD.
- ii. EG 2 – “Methadone and Peer Support” – This EG corresponds to Expenditure Authorities #2 (Methadone Treatment) and #3 (Peer Recovery Support Services) which includes the PMPM cost of methadone and peer recovery support services.

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

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

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

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

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

48. **Standard Medicaid Funding Process.** The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable Medicaid expenditures on the quarterly Form CMS-37. In addition, the estimate of matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each FFY on the Form CMS-37 (narrative section) for both the Medical Assistance Payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state’s estimate, as approved by CMS. Within thirty (30) days after the end of each quarter, the state must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter just ended. CMS shall reconcile expenditures reported on the Form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.
49. **Extent of Federal Financial Participation for the Demonstration.** Subject to CMS approval of the source(s) of the non-federal share of funding, CMS shall provide FFP at the applicable federal matching rates for the demonstration as a whole as outlined below, subject to the budget neutrality limits described in section VIII.
- a. Administrative costs, including those associated with the administration of the demonstration; and
 - b. Net expenditures and prior period adjustments, made under approved Expenditure Authorities granted through section 1115(a)(2) of the Act, with dates of service during the operation of the demonstration and consistent with the applicable STC requirements.
50. **Sources of Non-Federal Share.** The state must certify that matching non-federal share of funds for the demonstration are state/local monies. The state further assures that such funds shall not be used as the match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval
- a. CMS may review at any time the sources of the non-federal share of funding for the demonstration. The state agrees that all funding sources deemed unacceptable

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

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

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

- a. Units of government, including governmentally operated health care providers, may certify that state or local tax dollars have been expended as the non-federal share of funds under the demonstration.
- b. To the extent the state utilizes certified public expenditures (CPEs) as the funding mechanism for title XIX (or under section 1115 authority) payments, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
- c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for payments under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such tax revenue (state or local) used to satisfy demonstration expenditures. The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.
- d. The state may use intergovernmental transfers to the extent that such funds are derived from state or local tax revenues and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments. Under all circumstances, health care providers must retain one hundred (100) percent of the claimed expenditure. Moreover, no pre-arranged agreements (contractual or otherwise) exist between health care providers and state and/or local government to return and/or redirect any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, (including health care provider-related taxes), fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

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

VIII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

53. **Limit on Title XIX Funding.** The state must be subject to a limit on the amount of federal title XIX funding that the state may receive on approved demonstration service expenditures incurred during the period of approval of the demonstration. The limit is determined by using a per capita cost method, and budget neutrality expenditure caps are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. The data supplied by the state to CMS to set the annual caps is subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit. CMS’ assessment of the state’s compliance with these annual limits will be done using the Schedule C report from the CMS-64.
54. **Risk.** The state must be at risk for the per capita cost (as determined by the method described below) for demonstration eligibles under this budget neutrality agreement, but not for the number of demonstration eligibles. Because CMS provides FFP for all demonstration eligibles, West Virginia must not be at risk for changing economic conditions that impact enrollment levels. However, by placing West Virginia at risk for the per capita costs for current eligibles, CMS assures that the federal demonstration expenditures do not exceed the level of expenditures had there been no demonstration.
55. **Budget Neutrality Expenditure Limit.** The budget neutrality test includes an allowance for hypothetical services. The expected costs of the hypothetical services are reflected in the “without waiver” budget neutrality expenditure limit. The state must not accrue budget neutrality “savings” from the hypothetical services.

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

Methadone and Peer Supports PMPM Note: The DY 1 PMPM includes six (6) rather than twelve (12 months of peer supports; and, as a result, the PMPM for this EG is lower in DY 1.	5.4%	\$1.85	\$3.32	\$3.50	\$3.69	\$3.89
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Composite Federal Share Ratio. The federal share of the budget neutrality expenditure limit is calculated by multiplying the limit times the Composite Federal Share. The Composite Federal Share is the ratio calculated by dividing the sum total of federal financial participation (FFP) received by the state on actual demonstration expenditures during the approval period, as reported through the Medicaid Budget and Expenditure System/State Children’s Health Insurance Program Budget and Expenditure System (MBES/CBES) and summarized on Schedule C with consolidation of additional allowable demonstration offsets such as, but not limited to, premium collections and pharmacy rebates, by total computable demonstration expenditures for the same period as reported on the same forms. For the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed-upon method.

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

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

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

IX. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

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