

September 30, 2022

Ms. Farah Hanley
Chief Deputy for Health
Michigan Department of Health and Human Services
400 South Pine Street
Lansing, MI 48933

Dear Ms. Hanley:

The Centers for Medicare & Medicaid Services (CMS) is approving Michigan's (the "state") request to amend the section 1115(a) demonstration titled, "Michigan 1115 Behavioral Health Demonstration" (Project Number 11-W-00305/5) (the "demonstration") to extend the expenditure authority expiration date of September 30, 2022 to September 30, 2023, for the 1915(i)-like services currently approved under the demonstration to better enable the state to transition these services to the state plan. As of October 1, 2022, this expenditure authority is extended through September 30, 2023, upon which date, unless extended or otherwise amended, it will expire.

CMS' approval is subject to the limitations specified in the attached waiver authorities, expenditure authorities and Special Terms and Conditions (STC). The state may deviate from Medicaid state plan requirements only to the extent those requirements have been listed as not applicable to expenditures under the demonstration.

Michigan's section 1115 demonstration is currently approved until September 30, 2024. Under this demonstration, the state is currently approved for the following expenditure authorities: 1) Expenditures for services, including substance use disorder (SUD) and withdrawal management services, provided to individuals who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD); 2) Expenditures for all Prepaid Inpatient Health Plan (PIHP) services, including case management and health education services that are not available to other Medicaid beneficiaries, to the extent that not all services for categorically needy individuals will be equal in amount, duration, and scope; and 3) Expenditures for 1915(i)-like home and community-based (HCBS) services provided to individuals starting October 1, 2019, and originally ending September 30, 2022, to allow time for the state to develop and implement a framework for performing independent assessments of financial and functional eligibility. As discussed below, CMS is approving a one-year extension of this expenditure authority for 1915(i)-like services, so that authority will now end on September 30, 2023.

Extent and Scope of Demonstration Amendment

By October 1, 2022, the state was responsible for transitioning these 1915(i)-like services into the Medicaid state plan. However, due to the strain that the COVID-19 public health emergency placed upon its healthcare system, staff, and resources, the state was unable to complete the transition of these 1915(i)-like services into the Medicaid state plan by September 30, 2022. The state has met the majority of milestones outlined in the STCs as part of the transition, but Michigan requested one additional year to complete the transition. CMS is approving this amendment to provide the state flexibility to extend the expenditure authority expiration date by one year, from September 30, 2022 to September 30, 2023 for the 1915(i)-like services currently approved under the demonstration to be transitioned to the Medicaid state plan. Along with approval of this amendment, CMS will also provide technical assistance to support the state with this transition. The approval of the amendment is likely to assist in promoting the objectives of the Medicaid statute because it will allow the state to maintain access to 1915(i)-like benefits for beneficiaries enrolled in the demonstration. This, in turn, will increase the chances of these individuals having a positive outcome from the benefits received from the Medicaid program.

Consideration of Public Comments

To increase the transparency of demonstration projects, sections 1115(d)(1) and (2) of the Social Security Act (the Act) direct the Secretary to issue regulations providing for two periods of public comment on a state’s application for a section 1115 demonstration that would result in an impact on eligibility, enrollment, services, cost-sharing, or financing. The first comment period occurs at the state level before submission of the section 1115 application, and the second comment period occurs at the federal level after the application is received by the Secretary.

As enacted by the Affordable Care Act (ACA), and incorporated under section 1115(d)(2)(A) and (C) of the Act, comment periods should be “sufficient to ensure a meaningful level of public input,” but the statute imposed no additional requirement on the states or the Secretary to provide an individualized response to address those comments, as might otherwise be required under a general rulemaking. Accordingly, the implementing regulations issued in 2012 provide that CMS will review and consider all comments received by the deadline, but will not provide individualized written responses to public comments (42 CFR 431.416(d)(2)).

The federal public comment period opened on August 2, 2022 and closed September 1, 2022. CMS received one public comment, and the commenter supported approval of the amendment.

After carefully reviewing the demonstration proposal and the public comment received during the federal comment period, CMS has concluded that the demonstration is likely to assist in promoting the objectives of Medicaid.

Monitoring and Evaluation

The monitoring and evaluation requirements are not changing with this amendment. Consistent with the requirements in the STCs, the state is required to continue submitting Quarterly and Annual Monitoring Reports consistent with the CMS-approved Monitoring Protocol. Also, the

state is required to include evaluation of the services included in this amendment through the date of the transition of these services to the Medicaid state plan in the Interim and Summative Evaluation Reports, consistent with the CMS-approved Evaluation Design. CMS also requests that the state provide updates on the progress made on milestones toward successfully transitioning the 1915(i)-like services to the state plan in the Quarterly and Annual Monitoring Reports, as appropriate.

Other Information

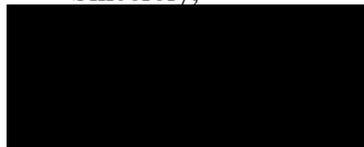
CMS' approval of this amendment is conditioned upon compliance with the enclosed amended set of expenditure authorities and the STCs defining the nature, character and extent of anticipated federal involvement in the demonstration. The award is subject to our receiving your acknowledgement of the award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

Your project officer for this demonstration is Ms. Katherine Friedman. She is available to answer any questions concerning this amendment. Ms. Friedman's contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-25-26
7500 Security Boulevard
Baltimore, MD 21244-1850
E-mail: Katherine.Friedman@cms.hhs.gov

If you have any questions regarding this approval, please contact Ms. Judith Cash, Director, State Demonstrations Group, Center for Medicaid and CHIP Services at (410) 786-9686.

Sincerely,



Deputy Administrator and Director

Enclosure

cc: Keri Toback, Monitoring Lead, Medicaid and CHIP Operations Group

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

NUMBER: 11-W-00305/5

TITLE: Michigan 1115 Behavioral Health Demonstration

AWARDEE: Michigan Department of Health and Human Services (MDHHS)

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Michigan (the state) for the items identified below (which would not otherwise be included as matchable expenditures under section 1903 of the Act) shall, for the period April 5, 2019 through September 30, 2024, unless otherwise specified, be regarded as matchable expenditures under the state's Medicaid state plan.

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 substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD).

2. Time-Limited Expenditure Authority for 1915(i)-Like Services. Expenditures for 1915(i)-like home and community based (HCBS) services provided to individuals starting October 1, 2019, and ending September 30, 2023. During this period, the state will develop and implement a framework for performing independent assessments of financial and functional eligibility. As of October 1, 2023, all individuals will receive 1915(i) services in the State Plan Amendment effective on that date.

3. PrePaid Inpatient Health Plan (PIHP) Services. Expenditures for all PIHP services including case management and health education services that are not available to other Medicaid beneficiaries to the extent that not all services for categorically needy individuals will be equal in amount, duration, and scope. The state will be required to ensure that all beneficiaries use a specific regional PIHP plan and to restrict disenrollment from them. The state is also granted the authority to restrict freedom of choice of provider for the demonstration eligible population.

**CENTERS FOR MEDICARE AND MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS (STCs)**

NUMBER: 11-W-00305/5

TITLE: Michigan 1115 Behavioral Health Demonstration

AWARDEE: Michigan Department of Health and Human Services (MDHHS)

I. PREFACE

The following are the special terms and conditions (STCs) for the “Michigan 1115 Behavioral Health Demonstration” section 1115(a) Medicaid demonstration (the “demonstration”) to enable the Michigan (the “state”) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable under section 1903 of the Social Security Act (the “Act”), which are separately enumerated. These STCs set forth conditions and limitations on those 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 this demonstration. These STCs neither grant additional expenditure authorities, nor expand upon those separately granted. The STCs are effective as of April 5, 2019, through September 30, 2024, unless otherwise specified. The state expects to begin implementation October 1, 2019.

The STCs have been arranged into the following subject areas:

- I. [Preface](#)
- II. [Program Description and Objectives](#)
- III. [General Program Requirements](#)
- IV. [Eligibility and Enrollment](#)
- V. [Substance Use Disorder \(SUD\) Program](#)
- VI. [Cost Sharing](#)
- VII. [Delivery System](#)
- VIII. Eligibility Transition for HCBS State Plan Benefit
- IX. [General Reporting Requirements](#)
- X. [Monitoring](#)
- XI. [Evaluation of the Demonstration](#)
- XII. [General Financial Requirements Under Title XIX](#)
- XIII. [Monitoring Budget Neutrality for the Demonstration](#)
- XIV. [Schedule of Deliverables for 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: Reserved for Evaluation Design](#)
[Attachment D: OUD/SUD Implementation Plan](#)
[Attachment E: Reserved for OUD/SUD Monitoring Protocol](#)

II. PROGRAM DESCRIPTION AND OBJECTIVES

On June 21, 2016, Michigan submitted an 1115 demonstration request entitled *Pathway to Integration*. The purpose of this demonstration was to allow Michigan to broaden the crucial component of residential substance disorder services in the state's existing network of SUD providers and SUD benefits to provide a broader continuum of care for beneficiaries seeking help with a SUD, including withdrawal management services in residential treatment facilities that meet the definition of an Institution for Mental Disease (IMD). Benefits under this demonstration were to be provided through a managed care delivery system. The state believed that offering a full continuum of SUD treatment and recovery supports based on American Society of Addiction Medicine (ASAM) criteria or other nationally recognized, SUD-specific program standards, would result in improved health outcomes and sustained recovery for this population.

This demonstration sought to accomplish these efforts by:

- Establishing an integrated behavioral health delivery system that included a flexible and comprehensive SUD benefit and the Michigan continuum of care;
- Enhancing provider competency related to the use of ASAM criteria or other nationally recognized, SUD-specific program standards, for patient assessment and treatment;
- Expanding the treatment continuum of residential care including medically necessary use of qualified residential treatment facilities regardless of the size of the facility, withdrawal management programming and medication assisted treatment and recovery;
- Expanding the use of recovery coach delivered support services; and
- Establishing coordination of care models between SUD providers, primary care and other behavioral health providers.

After careful review and consideration by CMS, the demonstration was approved on April 5, 2019. The expenditure authorities permitted by the demonstration will remain in effect until September 30, 2024, unless otherwise stated.

At the time of approval of the 1115 SUD demonstration, CMS stated its intent to continue to work with Michigan on the state's goals for expanded access to services, use of needs-based eligibility criteria, and streamlined program financing and management through the use of the appropriate authorities. Michigan authorized a managed care arrangement with the Prepaid Inpatient Health Plans (PIHP) using 1915 authority called the "Managed Specialty Services and Supports Program". This arrangement allowed the PIHP to perform eligibility evaluations and determinations for beneficiaries receiving 1915(b)(3) services. However, the 1915(b) waiver

was not renewed, and with this amendment request, the state sought authority for the delivery system be moved to the 1115 demonstration. Following CMS' guidance, effective October 1, 2019, Michigan intends to transition most of the specialty behavioral health services and supports currently covered under section 1915(b)(3) authority to the equivalent of a section 1915(i) State Plan benefit, initially through 1115(a)(2) expenditure authority under this demonstration. In accordance with 1915(i)(1)(F) of the Social Security Act and 42 CFR 441.720 and 441.730, Michigan's PIHP will not be able to function in the same manner under this new authority due to not being a "separate agency of the state" nor will the state have sufficient time to move this currently delegated function back to the administration of a state agency. Consequently, Michigan was required to complete all evaluations and re-evaluations of beneficiaries enrolled in and/or seeking 1915(i) State Plan benefits by October 1, 2022 as stipulated in section VIII. After this date, beneficiaries were to be covered under section 1915(i) pursuant to a State Plan Amendment effective on that date. Upon approval of this amendment request, on September 27, 2019, the 1115 demonstration name will also be changed from *Michigan Pathway to Integration* to the *Michigan 1115 Behavioral Health* demonstration.

However, due to the COVID-19 Public Health Emergency (PHE), the state had to shift staff and resources to focus on the pandemic, and was unable to meet the October 1, 2022 deadline to transition the 1915(i)-like HCBS services from the 1115 authority to the Medicaid state plan. The state submitted an amendment to receive flexibility to extend the expenditure authority expiration date of September 30, 2022 to September 30, 2023. The state proposed to have these services transitioned to the state plan by October 1, 2023. After careful review and consideration of this amendment request, CMS granted the state one more year to complete the transition process and thus this expenditure authority is authorized through September 30, 2023.

III. GENERAL PROGRAM REQUIREMENTS

- 1. Compliance with Federal Non-Discrimination Laws.** The state must comply with applicable federal civil rights laws relating to non-discrimination in services and benefits in its programs and activities. 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 Affordable Care Act (Section 1557). Such compliance includes providing reasonable modifications to individuals with disabilities under the ADA, Section 504, and Section 1557 in eligibility and documentation requirements, to ensure they understand program rules and notices, in establishing eligibility for an exemption from community engagement requirements on the basis of disability, and to enable them to meet and document community engagement requirements, as well as meeting other program requirements necessary to obtain and maintain benefits.
- 2. Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program, expressed in federal law, regulation, and written policy, not expressly waived or identified as not applicable in the expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

- 3. Changes in Medicaid Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid program 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 of an operational nature without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 calendar days in advance of the expected approval date of the amended STCs to allow the state to provide comment.
- 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. Further, the state may seek an amendment to the demonstration (as per STC 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 day such state legislation becomes effective, or on the last day such legislation was required to be in effect under federal law, whichever is sooner.
- 5. State Plan Amendments.** The state will not be required to submit title XIX state plan amendments (SPAs) 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 appropriate state plan may be required, except as otherwise noted in these STCs. In all such instances, the Medicaid state plan governs.
- 6. Changes Subject to the Amendment Process.** If not otherwise specified in these STCs, 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 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 7, except as provided in STC 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 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 reports required in the approved STCs 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. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
- b. A data analysis worksheet 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” status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detail 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;
- c. An explanation of the public process used by the state consistent with the requirements of STC 13; and,
- d. If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.

8. Extension of the Demonstration. States that intend to request a demonstration extension under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in statute. Otherwise, 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 either a demonstration extension request that meets federal requirements at 42 CFR 431.412(c) or a transition and phase-out plan consistent with the requirements of STC 9.

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 a notification letter and a draft transition and phase-out plan to CMS no less than six (6) 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 13, 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. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its transition and 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 administrative reviews of Medicaid 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. Transition and Phase-out Plan Approval. 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 comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, 431.211, and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. 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. 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 prior to termination as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 C.F.R. 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).
- 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. Enrollment Limitation during Demonstration Phase-Out. 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. Federal Financial Participation (FFP). FFP will 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.

10. Expiring Demonstration Authority. For demonstration authority that expires prior to the demonstration's expiration date, the state must submit a demonstration authority expiration

plan to CMS no later than six (6) months prior to the applicable demonstration authority's expiration date, consistent with the following requirements:

- a. Expiration Requirements. The state must include, at a minimum, in its demonstration authority expiration 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 prior to the termination of the demonstration authority for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities.
- b. Expiration Procedures. The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, 431.211, and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. 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. 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 prior to termination as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).
- c. Federal Public Notice. CMS will conduct a 30-day federal public comment period consistent with the process outlined in 42 CFR 431.416 in order to solicit public input on the state's demonstration authority expiration plan. CMS will consider comments received during the 30-day period during its review of the state's demonstration authority expiration plan. The state must obtain CMS approval of the demonstration authority expiration plan prior to the implementation of the expiration activities. Implementation of expiration activities must be no sooner than fourteen (14) calendar days after CMS approval of the demonstration authority expiration plan.
- d. Federal Financial Participation (FFP). FFP will be limited to normal closeout costs associated with the expiration of the demonstration authority including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

11. Withdrawal of Expenditure Authority. CMS reserves the right to withdraw expenditure authorities at any time it determines that continuing the expenditure authorities would no longer be in the public interest or promote the objectives of title XIX. CMS must 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 expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the expenditure authority,

including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

12. 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.

13. 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 tribal and Indian Health Program/Urban Indian Health 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 7 or extension, are proposed by the state.

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.

14. Federal Financial Participation (FFP). No federal matching for state expenditures under 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.

15. Common Rule Exemption. The state shall 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 program – including procedures for obtaining Medicaid benefits or services, possible changes in or alternatives to Medicaid programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. The Secretary 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 46.101(b)(5).

IV. ELIGIBILITY AND ENROLLMENT

16. Eligibility Groups Affected by the Demonstration. Under the demonstration, there is no change to Medicaid eligibility. Standards for eligibility remain set forth under the state plan. All affected groups derive their eligibility through the Medicaid state plan, and are subject to all applicable Medicaid laws and regulations in accordance with the Medicaid state plan. All

Medicaid eligibility standards and methodologies for these eligibility groups remain applicable.

V. SUBSTANCE USE DISORDER (SUD) PROGRAM

17. Opioid Use Disorder/Substance Use Disorder Program. Effective upon CMS’ approval of the OUD/SUD Implementation Plan, the demonstration benefit package for Michigan Medicaid recipients must include OUD/SUD treatment services, including short term residential services provided in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD), which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Michigan Medicaid recipients who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance, including OUD/SUD benefits that would otherwise be matchable if the beneficiary were not residing in an IMD. Michigan must aim for a statewide average length of stay of 30 days in residential treatment settings, to be monitored pursuant to the OUD/SUD Monitoring Protocol as outlined in STC 19 below, to ensure short-term residential treatment stays. Under this demonstration, beneficiaries will have access to high quality, evidence-based OUD and other SUD treatment services ranging from medically supervised withdrawal management to on-going chronic care for these conditions in cost-effective settings while also improving care coordination and care for comorbid physical and mental health conditions. Such services will be delivered through the prepaid inpatient health plan (PIHP) delivery system.

The coverage of OUD/SUD treatment services and withdrawal management services during short-term residential and inpatient stays in IMDs will expand Michigan’s current SUD benefit package available to all Michigan Medicaid recipients as outlined in Table 1. OUD/SUD treatment services and withdrawal management services approved through the state plan as well as expenditure authority to cover and provide FFP for such services for individuals residing in an IMD approved through this demonstration will be available to all Michigan Medicaid recipients who meet medical necessity criteria for services. 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.

Table 1: Michigan OUD/SUD Benefits Coverage with Expenditure Authority

OAD/SUD Benefit	Medicaid Authority	Expenditure Authority
Early Intervention Services	State plan (Individual services covered)	
Ambulatory Withdrawal Management	State plan	
Outpatient Services	State plan (<i>Individual services covered</i>)	
Intensive Outpatient Services	State plan (<i>Individual services covered</i>)	

Opioid Treatment Program Services	State Plan	Services provided to individuals in IMDs
Office Based Opioid Treatment Services	State Plan	Services provided to individuals in IMDs
Residential Treatment	State plan (<i>Individual services covered</i>)	Services provided to individuals in IMDs
Medically Supervised Withdrawal Management	State plan	Services provided to individuals in IMDs
Inpatient Services	State plan (<i>Individual Services covered</i>)	Services provided to individuals in IMDs
SUD Support Services	State plan (<i>Individual services covered</i>)	Services provided to individuals in IMDs

The state attests that the services indicated in Table 1 above, as being covered under Medicaid state plan authority are currently covered in the Michigan Medicaid state plan.

18. OUD/SUD Implementation Plan. The state must submit a OUD/SUD Implementation Plan within 90 calendar days after approval of the OUD/SUD program under this demonstration. The state may not claim FFP for services provided in IMDs until CMS has approved the SUD Implementation Plan. CMS is approving the OUD/SUD Implementation Plan concurrently with this demonstration. The approved OUD/SUD Implementation Plan appears as [Attachment D](#) and may be altered only with CMS approval. After approval of the OUD/SUD Implementation Plan, FFP will be available prospectively, not retrospectively. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral. At a minimum, the OUD/SUD Implementation Plan will describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives of the OUD/SUD component of this demonstration program:

- a. **Access to Critical Levels of Care for OUD and other SUDs:** Service delivery for new benefits, including residential treatment and withdrawal management, within 12-24 months of OUD/SUD program 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 patient placement assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of OUD/SUD program 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 SUD program demonstration approval;
- d. **Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities:** Currently, residential treatment service providers must be a licensed organization, pursuant to the residential service provider qualifications described in the *State Administrative Rules for the Licensure of Substance Use Disorder Programs*. The state will 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 OUD/SUD program 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 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 SUD program 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 SUD program demonstration approval;
- g. **Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for OUD:** An assessment of the availability of providers in the key 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 SUD program demonstration approval;
- h. **Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and 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 SUD program demonstration approval.

19. OUD/SUD Monitoring Protocol. The state must submit a OUD/SUD Monitoring Protocol within 150 calendar days after approval of the OUD/SUD Demonstration. The OUD/SUD Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. Once approved, the OUD/SUD Monitoring Protocol will be incorporated into the STCs, as Attachment E. At a minimum, the SUD Monitoring Plan Protocol must include reporting relevant to each of the program implementation areas listed in STC 18. The SUD Monitoring Protocol must 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 Section VIII of the demonstration. In addition, the SUD Monitoring Protocol must identify a baseline, and a target to be achieved by the end of the demonstration. Where possible, baselines must be informed by state data, and targets will be benchmarked against performance in best practice settings. CMS will closely monitor demonstration spending on services in IMDs to ensure adherence to budget neutrality requirements. Progress on the performance measures identified in the Monitoring Protocol must be reported via the quarterly and annual monitoring reports.

20. Mid-Point Assessment. The state must conduct an independent mid-point assessment by December 31, 2022. The state must require that the assessor must collaborate with key stakeholders, including representatives of MCOs, SUD treatment providers, beneficiaries, and other key partners in the design, planning and conducting of the mid-point assessment. The state must require that the assessment will include 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. The state must require that the assessment include a determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date, and a determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and about the risk of possibly missing those milestones and performance targets. The state must require that the mid-point assessment also provide a status update of budget neutrality requirements. For each milestone or measure target at medium to high risk of not being met, the state must require that the assessor provide, for consideration by the state, recommendations for adjustments in the state’s implementation plan or to pertinent factors that the state can influence that will support improvement. The state must require that the assessor provide a 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. The state must brief CMS on the report. For milestones and measure targets at medium to high risk of not being achieved, the state will

submit to CMS modifications to the SUD Implementation Plan and SUD Monitoring Plan for ameliorating these risks subject to CMS approval.

21. Deferral for Insufficient Progress Towards Milestones and Failure to Report

Measurement Data. If the state does not demonstrate sufficient progress on milestones, as specified in the Implementation Protocol, as determined by CMS, or fails to report data as approved in the Monitoring Protocol Monitoring Protocol, CMS will defer funds in the amounts specified in STC 40 and STC 41 for each incident of insufficient progress or failure to report in each reporting quarter.

22. OUD/SUD Evaluation Design. The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, the Evaluation Design to including the SUD program with implementation timeline, 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 must use an independent evaluator to develop the draft Evaluation Design.

- a. 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 and Annual Reports, including any required Rapid Cycle Assessments specified in these STCs. 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.
- b. Evaluation Questions and Hypotheses Specific to the OUD/SUD Program. Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) 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 must have at least one evaluation question and hypothesis. The hypothesis testing must include, where possible, assessment of both process and outcome measures. Proposed measures must 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).

23. SUD Health Information Technology (Health IT). The state must provide CMS with an assurance that it has a sufficient health IT infrastructure/"ecosystem" at every appropriate

level (i.e. state, delivery system, health plan/MCO and individual provider) to achieve the goals of the demonstration—or it must submit to CMS a plan to develop the infrastructure/capabilities. This SUD Health IT Plan must be submitted to CMS within 90 days of the approval of the SUD program within this demonstration. The state’s failure to submit the SUD Health IT Plan by this deadline may result in a funding deferral as provided by STC 21. The SUD Health IT Plan must detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The SUD Health IT Plan must also be used to identify areas of SUD health IT ecosystem improvement.

- a. The SUD Health IT section of the SUD Implementation Plan must include implementation milestones and dates for achieving them (see Attachment [D]).
- b. The SUD Health IT Plan must be aligned with the state’s broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state’s Behavioral Health (BH) “Health IT” Plan.
- c. The SUD Health IT Plan must describe the state’s goals, each DY, to enhance the state’s prescription drug monitoring program’s (PDMP)¹.
- d. The SUD Health IT Plan must address how the state’s PDMP will enhance ease of use for prescribers and other state and federal stakeholders.² The SUD Health IT Plan must also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan must describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients’ history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.
- e. The SUD Health IT Plan must, as applicable, describe the state’s capabilities to leverage a master patient index (or master data management service, etc.) in support of SUD care delivery. Additionally, the SUD Health IT Plan must describe current and future capabilities regarding PDMP queries—and the state’s ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state must also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.
- f. The SUD Health IT Plan will describe how the activities described in (a) through (e) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.³
- g. In developing the SUD Health IT Plan, the state may use the following resources:

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.*

³ Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*. MMWR Morb Mortal Wkly Rep 2017;66.

- h. The state may use resources at Health IT.Gov (<https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/>) in “Section 4: Opioid Epidemic and Health IT.”
- i. The state 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>. The state must review the “1115 Health IT Toolkit” for health IT considerations in conducting an assessment and developing its SUD Health IT Plan.
- j. The state may request from CMS technical assistance to conduct an assessment and develop plans to ensure it has the specific health IT infrastructure with regards to PDMP plans and, more generally, to meet the goals of the demonstration.
- k. The state must include in its SUD Monitoring Protocol (STC 19) an approach to monitoring its SUD Health IT Plan which will include performance metrics provided by CMS or State defined metrics to be approved in advance by CMS.
- l. The state must monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in in an addendum to its Annual Reports (STC 31).
- m. As applicable, the state must 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.
 - i. 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 must use the federally-recognized standards, barring another compelling state interest.
 - ii. 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 must use the federally-recognized ISA standards, barring no other compelling state interest.

VI. COST SHARING

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

VII. DELIVERY SYSTEM

25. General. The state must comply with the managed care regulations published under 42 CFR 438 unless explicitly waived.

26. Type of Managed Care. The state is authorized to operate a risk based Prepaid Inpatient Health Plan (PIHP) as defined under 42 CFR 438.2. One PIHP will operate in each geographical region designated by the state.

27. Contracts. No FFP is available for activities covered under contracts and/or modifications to existing contracts that are subject to 42 CFR 438 requirements prior to CMS approval of such contracts and/or contract amendments. The State will provide CMS with a minimum of 60 days to review and approve changes.

28. Enrollment. The State will mandatorily and passively enroll the following groups of beneficiaries into a PIHP:

- a. Section 1931 Children and Related Populations are children including those eligible under Section 1931, poverty-level related groups and optional groups of older children;
- b. Section 1931 Adults and Related Populations are adults including those eligible under Section 1931, poverty-level pregnant women and optional group of caretaker relatives;
- c. Blind/Disabled Adults and Related Populations are beneficiaries, age 18 or older, who are eligible for Medicaid due to blindness or disability. Report Blind/Disabled Adults who are age 65 or older in this category, not in Aged;
- d. Blind/Disabled Children and Related Populations are beneficiaries, generally under age 18, who are eligible for Medicaid due to blindness or disability;
- e. Aged and Related Populations are those Medicaid beneficiaries who are age 65 or older and not members of the Blind/Disabled population or members of the Section 1931 Adult population;
- f. Foster Care Children are Medicaid beneficiaries who are receiving foster care or adoption assistance (Title IV-E), are in foster-care, or are otherwise in an out-of-home placement; and
- g. New adults.

29. Disenrollment and choice of providers. Beneficiaries cannot disenroll from the PIHP in their area. However, for specific services within the PIHP network, the beneficiary may choose from among a range of available network providers, and may change providers within the PIHP at any time. In addition, in some special circumstances, a beneficiary may wish to receive services from a provider that is part of another PIHP's provider network. In these situations, the PIHP may make arrangements to contract with that provider.

30. Transition Plan for Care Coordination. The state must develop a transition of care policy consistent with 438.62(b)(1). In the event the State intends to transition beneficiaries to an alternative delivery system, the State will timely inform CMS how the transition will comply with their transition of care policy.

VIII. TRANSITIONAL ELIGIBILITY FOR HCBS REQUIREMENTS

In order to come into compliance with CMS policy with regard to HCBS services covered under the State plan pursuant to section 1915(i), the state must meet the established transitional eligibility requirements as follows:

31. By November 1, 2019, the State will phase in the proposed tool to assess and evaluate beneficiaries against the 1915(i) HCBS State plan benefit needs-based eligibility criteria.
32. From June 1, 2020 through September 30, 2020, the State will provide technical assistance to all PIHPs on the 1915(i) HCBS State plan benefit needs-based eligibility packets and tools developed to assure individuals meet all the eligibility requirements.
33. From October 1, 2020 through January 1, 2021, the State will do the joint Application and Design (JAD) Sessions for requirements/design.
34. From January 1, 2021 through September 30, 2022, the State will phase in enrolled beneficiaries information packets to the online system with the state testing the eligibility capabilities and notifications.
35. From June 1, 2021 through July 1, 2021, the State will analyze the adequacy of administration needed to process information and to make eligibility determinations.
36. From September 1, 2021 through September 30, 2022, the State will finalize the process and requirements via manual revisions and training to all PIHP users.
37. From October 1, 2022 forward, the State will demonstrate full compliance in executing eligibility determinations for all individuals currently enrolled in or seeking 1915(i) HCBS State plan benefits to ensure all individuals receiving services will be determined eligible by the state on or before October 1, 2023. NOTE: PIHPs will no longer be responsible for determining needs-based criteria and eligibility for initial or re-evaluations.
38. The state will adhere to all of the requirements, including quality monitoring and reporting, in accordance with the information specified in the approved 1915(i) HCBS State plan benefit which will become effective as of October 1, 2023.

IX. GENERAL REPORTING REQUIREMENTS

39. **Submission of Post-approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.
40. **Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, 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 are 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) Thirty (30) days after the deliverable was 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) Thirty days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable 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 to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state's written extension request.
- c. If CMS agrees to an interim corrective plan in accordance with subsection (b), 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) with all required contents in satisfaction of 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 with respect to required deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified 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.

41. 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 the 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. The state is expected to meet the milestones by the end of the first two years of the SMI demonstration.

42. Compliance with Federal Systems Updates. As federal systems continue to evolve and incorporate additional 1115 demonstration 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, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
- c. Submit deliverables to the appropriate system as directed by CMS.

43. Cooperation with Federal Evaluators. 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. 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 40.

X. MONITORING

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

- a. Operational Updates - Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key 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 issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends;

legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

- b. Performance Metrics – Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.
- c. Budget Neutrality and Financial Reporting Requirements - 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 should be reported separately.
- d. Evaluation Activities and Interim Findings - 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.
- e. SUD Health IT - The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 23.

45. Close-Out 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. 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 30 calendar 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 21.

46. 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. Examples include implementation activities, enrollment and access, budget neutrality, and progress on the evaluation.
- 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.

47. Post Award Forum. Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 30 calendar 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 quarter in which the forum was held, as well as in its compiled Annual Report.

XI. EVALUATION OF THE DEMONSTRATION

48. Independent Evaluator. Upon approval of the demonstration, the state must begin 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 state must require the independent party to sign an agreement to conduct the demonstration evaluation in an independent manner 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.

49. Evaluation Budget. A budget for the evaluation must 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 or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.

50. Draft Evaluation Design. The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, 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.

51. 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 to the state's website 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 Monitoring Reports, including any required Rapid Cycle Assessments specified in these STCs. 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.

52. Evaluation Questions and Hypotheses. Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) 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. 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).

53. Interim Evaluation Report. 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.

- 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 and 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 60 calendar 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.

54. Summative Evaluation Report. The draft Summative Evaluation Report must be developed in accordance with Attachment B of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period, October 1 2019 to September 30, 2024, within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

- a. Unless otherwise agreed upon in writing by CMS, the state must submit the final Summative Evaluation Report within 60 calendar 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 30 calendar days of approval by CMS.

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

56. Public Access. The state shall post the final documents (e.g., Monitoring Reports, Close Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 days of approval by CMS.

57. Additional Publications and Presentations. For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business 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.

XII. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

58. Standard Medicaid Funding Process. The standard Medicaid funding process must be used during the demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this 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 those

expenditures by quarter for each federal fiscal year on the Form CMS-37 (narrative section) for both the medical assistance payments (MAP) and state and local administrative costs (ADM). CMS will make federal funds available based upon the state's estimate, as approved by CMS. Within thirty (30) calendar days after the end of each quarter, the state shall submit the 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 will reconcile expenditures reported on the Form CMS-64 quarterly with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

59. 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 demonstration as a whole for the following, subject to the limits described in Section XII:

- 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.

60. Sources of Non-Federal Share. The state certifies that the matching non-federal share of funds for the demonstration is state/local monies. The state further certifies that such funds must 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. The state acknowledges that CMS has authority to review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS must be addressed within the time frames set by CMS.
- b. The state acknowledges that any amendments that impact the financial status of the program must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

61. 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 monies have been expended as the non-federal share of funds under the demonstration.

- b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, 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 expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR 433.51(c). 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 (IGT) to the extent that such funds are derived from state or local monies 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.
- e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state 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.

62. Program Integrity. The state must have a process in place to ensure that 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.

63. Medicaid Expenditure Groups (MEG). MEGs 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	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description
DAB	Hypo 1	X		X	Includes non-dual and dual eligible members who are enrolled in the disabled, aged, or blind (DAB) eligibility categories.
TANF	Hypo 1	X		X	Includes non-dual and dual eligible members who are enrolled in the Temporary Assistance for Needy Families (TANF) eligibility categories.
HMP	Hypo 1	X		X	Includes non-dual and dual eligible members who are enrolled in the Healthy Michigan Plan (HMP) eligibility categories.
HSW	Hypo 1	X		X	Includes members who are enrolled in the 1915 (c) Habilitation Supports Waiver (HSW) program.
SED	Hypo 1	X		X	Includes members who are enrolled in the 1915(c) Serious Emotional Disturbances (SED) Waiver program.
CWP	Hypo 1	X		X	Includes members who are enrolled in the 1915(c) Children’s Waiver Program (CWP)
SUD IMD- DAB	Hypo 1	X		X	All expenditures for costs of medical assistance that could be covered, were it not for the IMD prohibition under the state plan, provided to individuals in the DAB eligibility category during a month in which the

					individual is a short-term resident in an IMD.
SUD IMD- TANF	Hypo 1	X		X	All expenditures for costs of medical assistance that could be covered, were it not for the IMD prohibition under the state plan, provided to individuals in the TANF eligibility category during a month in which the individual is a short-term resident in an IMD.
SUD IMD- HMP	Hypo 1	X		X	All expenditures for costs of medical assistance that could be covered, were it not for the IMD prohibition under the state plan, provided to individuals in the HMP eligibility category during a month in which the individual is a short-term resident in an IMD.

64. 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-00305/5). 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 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. 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 DY 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 not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.
- 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 the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the Master MEG Chart table, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

Member Months. As part of the Quarterly and Annual Monitoring Reports described in section IX, 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, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.

Table 3: MEG Detail for Expenditure and Member Month Reporting								
MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date

DAB	See Brief Description above	N/A	Standard lines by type of service	Date of service	MAP	Yes ⁴	Oct. 1, 2019	Sep. 30, 2024
TANF	See Brief Description above	N/A	Standard lines by type of service	Date of service	MAP	Yes ⁵	Oct. 1, 2019	Sep. 30, 2024
HMP	See Brief Description above	N/A	Standard lines by type of service	Date of service	MAP	Yes	Oct. 1, 2019	Sep. 30, 2024
HSW	See Brief Description above	N/A	Standard lines by type of service	Date of service	MAP	Yes	Oct. 1, 2019	Sep. 30, 2024
SED	See Brief Description above	N/A	Standard lines by type of service	Date of service	MAP	Yes	Oct. 1, 2019	Sep. 30, 2024
CWP	See Brief Description above	N/A	Standard lines by type of service	Date of service	MAP	Yes	Oct. 1, 2019	Sep. 30, 2024
SUD IMD-DAB	See Brief Description above	N/A	Standard lines by type of service	Date of service	MAP	Yes	Oct. 1, 2019	Sep. 30, 2024
SUD IMD-TANF	See Brief Description above	N/A	Standard lines by type of service	Date of service	MAP	Yes	Oct. 1, 2019	Sep. 30, 2024
SUD IMD-HMP	See Brief Description above	N/A	Standard lines by	Date of service	MAP	Yes	Oct. 1, 2019	Sep. 30, 2024

⁴ SUD IMD-HMP Member Months are months of Medicaid eligibility during which the individual belonging to the Healthy Michigan Plan MEG is an inpatient in an IMD under terms of the demonstration for any day during the month and must be reported separately for each SUD IMD-HMP MEG, as applicable. SUD IMD-HMP Member Months must not be duplicative of member months reported under any other Michigan section 1115 demonstration

⁵ SUD IMD-TANF Member Months are months of Medicaid eligibility during which the individual belonging to the TANF MEG is an inpatient in an IMD under terms of the demonstration for any day during the month and must be reported separately for each SUD IMD-TANF MEG, as applicable. SUD IMD-TANF Member Months must not be duplicative of member months reported under any other Michigan section 1115 demonstration.

			type of service					
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- e. 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.

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

Table 4: Demonstration Years		
Demonstration Year 1	October 1, 2019- September 30, 2020	12 months
Demonstration Year 2	October 1, 2020- September 30, 2021	12 months
Demonstration Year 3	October 1, 2021- September 30, 2022	12 months
Demonstration Year 4	October 1, 2022- September 30, 2023	12 months
Demonstration Year 5	October 1, 2023 - September 30, 2024	12 months

66. 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 demonstration’s actual expenditures to the budget neutrality expenditure limits described in section XI. CMS will provide technical assistance, upon request.⁶

⁶ 42 CFR §431.420(a)(2) provides that 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 in states agree to use the tool as a condition of demonstration approval.

67. Claiming Period. The state will report all claims for expenditures subject to the budget neutrality agreement (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 demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.

68. 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 letters, 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 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.

XIII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

69. Limit on Title XIX Funding. The state will be subject to limits on the amount of federal Medicaid funding 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 may consist of a Main Budget Neutrality Test, and one or more Hypothetical Budget Neutrality Tests, as described below. CMS’ 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.

70. Risk. The budget neutrality expenditure limits are determined on either a per capita or aggregate basis. 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 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.

71. Calculation of the Budget Neutrality Limit and How It Is 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 will then be 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 limit by appropriate Composite Federal Share.

72. Main Budget Neutrality Test. The Main Budget Neutrality Test allows the state to show that demonstration expenditure authorities granted have not resulted in increased costs to Medicaid, and that federal Medicaid “savings” have been achieved sufficient to offset the additional projected federal costs resulting from expenditure authority. The table below identifies the MEGs that are used for the Main Budget Neutrality Test. MEGs designated as “WOW Only” or “Both” are components used to calculate the budget neutrality expenditure limit. MEGs that are indicated as “WW Only” or “Both” are counted as expenditures against the budget neutrality expenditure limit. In addition, any expenditures in excess of limit from Hypothetical Budget Neutrality Tests count as expenditures under the Main Budget Neutrality Test. The Composite Federal Share for this test is calculated based on all MEGs indicated as “Both.”

MEG	PC or Agg*	WOW Only, WW Only, or Both	TREND	DY1 - PMPM	DY2 – PMPM	DY3 – PMPM	DY4 – PMPM	DY5 – PMPM
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DAB	PC	Both	4.2%	\$318.29	\$331.50	\$345.26	\$359.59	\$374.51
TANF	PC	Both	4.5%	\$27.27	\$28.50	\$29.78	\$31.12	\$32.52
HMP	PC	Both	4.5%	\$53.51	\$55.92	\$58.44	\$61.07	\$63.82
HSW	PC	Both	2.0%	\$5,004.36	\$5,104.45	\$5,206.54	\$5,310.67	\$5,416.88
SED	PC	Both	0.0%	\$2,117.84	\$2,117.84	\$2,117.84	\$2,117.84	\$2,117.84
CWP	PC	Both	0.0%	\$3,547.20	\$3,547.20	\$3,547.20	\$3,547.20	\$3,547.20
SUD- IMD- DAB	PC	Both	4.4%	\$1,657.57	\$1,730.50	\$1,806.64	\$1,886.14	\$1,969.13
SUD- IMD- TANF	PC	Both	4.8%	\$842.82	\$883.27	\$925.66	\$970.09	\$1016.66
SUD- IMD- HMP	PC	Both	4.9%	\$729.30	\$765.03	\$802.52	\$841.84	\$883.09

73. 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), CMS considers these expenditures to be “hypothetical;” that is, the expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. 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 otherwise allowable services. This approach reflects CMS’s current view that states should not have to “pay for,” with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, 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 a 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 supplemental test’s expenditure limit, the state agrees (as a condition of CMS approval) to refund the FFP to CMS.

74. Hypothetical Budget Neutrality Test 1: Substance Use Disorder Expenditures. 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 are counted as WW expenditures under the Main Budget Neutrality Test.

75. Composite Federal Share Ratios. 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 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 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 Main or Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

76. Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from October 1, 2019 to September 30, 2024. The budget neutrality limits calculated in STC 72 will apply to actual expenditures for demonstration services as reported by the state under section XIII of these STCs. Actual expenditures are from a state and federal basis, including managed care capitation payments for members enrolled in managed care programs and fee-for-service (FFS) claims for services or members carved out of MDHHS’ managed care programs. If at the end of the demonstration period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

77. Mid- Course Correction. 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 for CMS review and approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

Table 9: Main Budget Neutrality Test Mid-Course Correction Calculations		
<i>Demonstration Year</i>	<i>Cumulative Target</i>	<i>Percentage</i>
<i>DY 1</i>	<i>Cumulative budget neutrality cap plus:</i>	<i>0.25 percent</i>
<i>DY 2</i>	<i>Cumulative budget neutrality cap plus:</i>	<i>0.25 percent</i>
<i>DY 3,4, and 5</i>	<i>Cumulative budget neutrality cap plus:</i>	<i>0 percent</i>

Table 10: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations

<i>Demonstration Year</i>	<i>Cumulative Target</i>	<i>Percentage</i>
<i>DY 1</i>	<i>Cumulative budget neutrality cap plus:</i>	<i>0.25 percent</i>
<i>DY 2</i>	<i>Cumulative budget neutrality cap plus:</i>	<i>0.25 percent</i>
<i>DY 3,4, and 5</i>	<i>Cumulative budget neutrality cap plus:</i>	<i>0 percent</i>

XIV. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

Date	Deliverable	STC
30 days after approval date	State acceptance of demonstration STCs and Expenditure Authorities	Approval letter
150 days after approval date	OUD/SUD Monitoring Plan	STC 19
90 days after SUD program approval	OUD/SUD Implementation Plan	STC 18
90 days after SUD program approval	SUD Health IT Plan	STC 23
180 days after approval date	Draft Evaluation Design	STC 22
60 days after receipt of CMS comments	Revised Draft Evaluation Design	STC 22
30 days after CMS Approval	Approved Evaluation Design published to state's website	STC 22
December 31, 2022	Mid-Point Assessment	STC 20
One year prior to the end of the demonstration, or with renewal application	Draft Interim Evaluation Report	STC 53
60 days after receipt of CMS comments	Final Interim Evaluation Report	STC 53
18 months after the end of the demonstration	Draft Summative Evaluation Report	STC 54
60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	STC 54

30 calendar days after approval of CMS comments	Approved Final Summative Evaluation Report published to state's website	STC 54
Monthly Deliverables	Monitoring Calls	STC 46
Quarterly Deliverables Due 60 days after end of each quarter, except 4 th quarter	Quarterly Monitoring Reports	STC 44
Annual Deliverables -Due 90 days after end of each 4 th quarter	Annual Reports	STC 44
30 calendar days after receipt of CMS comments	Final Close-out Operational Report	STC 45
60 calendar days after receipt of CMS comments	Final SUD Mid-point assessment	STC 20

ATTACHMENT A

Developing the Evaluation Design

Introduction

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

Expectations for Evaluation Designs

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

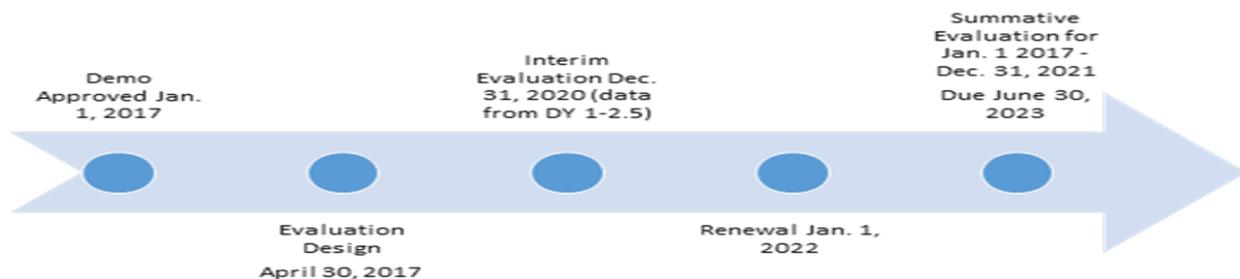
The format for the Evaluation Design is as follows:

General Background Information;
Evaluation Questions and Hypotheses;
Methodology;
Methodological Limitations;
Attachments.

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Design and Reports. (The

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



Required Core Components of All Evaluation Designs

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

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

- 1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).
- 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
- 3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;
- 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.
- 5) Describe the population groups impacted by the demonstration.

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

- 1) Describe how the state’s demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.
- 2) Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams:
<https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf>
- 3) Identify the state’s hypotheses about the outcomes of the demonstration:
- 4) Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
- 5) Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

C. Methodology – In this section, the state is to describe in detail the proposed research methodology.

The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

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

- 1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?
- 2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling

methodology for the populations, as well as support that a statistically reliable sample size is available.

- 3) *Evaluation Period* – Describe the time periods for which data will be included.
- 4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by “owning”, defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:
 - a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
 - b. Qualitative analysis methods may be used, and must be described in detail.
 - c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
 - d. Proposed health measures could include CMS’s Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
 - f. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
 - g. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.
- 5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

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

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

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

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

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

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

- 1) When the state demonstration is:
 - a. Long-standing, non-complex, unchanged, or
 - b. Has previously been rigorously evaluated and found to be successful, or
 - c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)
- 2) When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
 - a. Operating smoothly without administrative changes; and
 - b. No or minimal appeals and grievances; and
 - c. No state issues with CMS-64 reporting or budget neutrality; and
 - d. No Corrective Action Plans (CAP) for the demonstration.

E. Attachments

- 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, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include “No Conflict of Interest” 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 cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.
- 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 an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

ATTACHMENT B

Preparing the Interim and Summative Evaluation Reports

Introduction

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

Expectations for Evaluation Reports

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

Intent of this Guidance

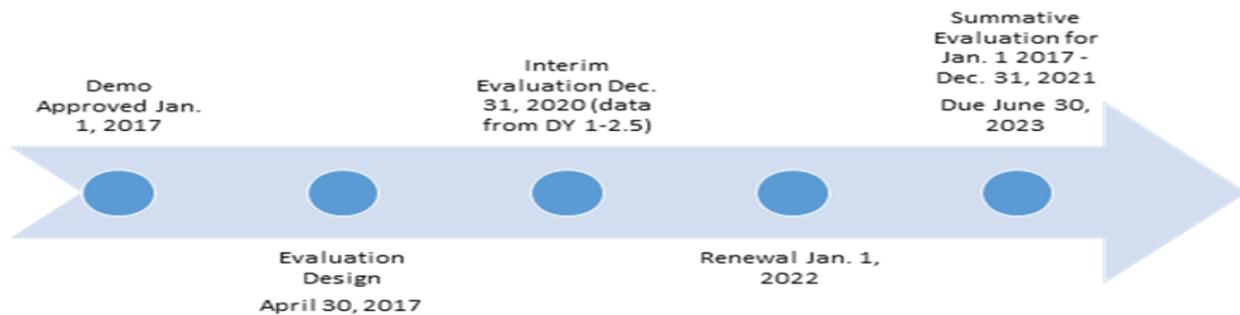
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved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

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

- A. Executive Summary;
- B. General Background Information;
- C. Evaluation Questions and Hypotheses;
- D. Methodology;
- E. Methodological Limitations;
- F. Results;
- G. Conclusions;
- H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
- I. Lessons Learned and Recommendations; and
- J. Attachment(s).

Submission Timelines

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



Required Core Components of Interim and Summative Evaluation Reports

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

- A. Executive Summary** – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.
- B. General Background Information about the Demonstration** – In this section, the state should include basic information about the demonstration, such as:
 - 1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
 - 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
 - 3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
 - 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
 - 5) Describe the population groups impacted by the demonstration.
- C. Evaluation Questions and Hypotheses** – In this section, the state should:
 - 1) Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.

- 2) Identify the state’s hypotheses about the outcomes of the demonstration;
 - a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
 - b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
 - c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

D. Methodology – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design.

The evaluation design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

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

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

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

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

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

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

- 1) In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
- 2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:
 - a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

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

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

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

F. Attachment - Evaluation Design: Provide the CMS-approved Evaluation Design

**ATTACHMENT C:
Reserved for Evaluation Design**

**ATTACHMENT D:
OUD/SUD Implementation Plan**

**ATTACHMENT E:
 OUD/SUD Monitoring Protocol**

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

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

a. State	<i>Michigan</i>
b. Demonstration name	<i>Michigan’s 1115 Behavioral Health Demonstration</i>
c. Approval date for demonstration	<i>04/05/2019</i>
d. Approval period for SUD	<i>10/01/2019 – 09/30/2024</i>
e. Approval date for SUD, if different from above	<i>N/A</i>
f. Implementation date of SUD, if different from above	<i>N/A</i>
g. SUD (or if broader demonstration, then SUD - related) demonstration goals and objectives	<i>This demonstration will allow Michigan to broaden the crucial component of residential substance disorder services in the state’s existing network of SUD providers and SUD benefits to provide a broader continuum of care for beneficiaries seeking help with a SUD, including withdrawal management services in residential treatment facilities that meet the definition of an IMD. The benefits will continue to be provided through a managed care delivery system. The state and CMS expect that offering a full continuum of SUD treatment and recovery supports based on American Society of Addiction Medicine (ASAM) criteria or other nationally recognized, SUD-specific program standards, will result in improved health outcomes and sustained recovery for this population.</i>

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

Summary of proposed modification	Related metric (if any)	Justification for modification
1. Assessment of Need and Qualification for SUD Services		
N/A	3, 4, 5,	<i>Michigan has no modification expectations for this topic.</i>
<input type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
<input checked="" type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
2. Access to Critical Levels of Care for OUD and other SUDs (Milestone 1)		
N/A	6, 7, 8, 9, 10, 11, 12, 36	<i>Michigan has no modification expectations for Milestone 1.</i>
<input type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
<input checked="" type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
3. Use of Evidence-based, SUD-specific Patient Placement Criteria (Milestone 2)		
N/A		<i>There are no CMS-provided metrics related to Milestone 2.</i>
<input type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
<input checked="" type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
4. Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities (Milestone 3)		
N/A		<i>There are no CMS-provided metrics related to Milestone 3.</i>
<input type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
<input checked="" type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
5. Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment for OUD (Milestone 4)		
N/A	13, 14	<i>Michigan has no modification expectations for Milestone 4.</i>

Summary of proposed modification	Related metric (if any)	Justification for modification
<input type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
<input checked="" type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
6. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD (Milestone 5)		
N/A	15, 18, 19, 20, 21, 22	<i>Michigan has no modification expectations for Milestone 5.</i>
<input type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
<input checked="" type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
7. Improved Care Coordination and Transitions between Levels of Care (Milestone 6)		
N/A	17	<i>Michigan has no modification expectations for Milestone 6.</i>
<input type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
<input checked="" type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
8. SUD Health Information Technology (Health IT)		
Please see detailed outline in part A	Q1, Q2, Q3	
<input type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
<input checked="" type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
9. Other SUD-related Metrics		
N/A	23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35	<i>Michigan has no modifications for other SUD-related metrics.</i>

Summary of proposed modification	Related metric (if any)	Justification for modification
<input type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
<input checked="" type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
10. Budget Neutrality		
N/A		<i>Michigan has no modifications for the budget neutrality.</i>
<input type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
<input checked="" type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
11. SUD-Related Demonstration Operations and Policy		
N/A		<i>Michigan has no modifications for SUD-related demonstration operations and policy.</i>
<input type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
<input checked="" type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
12. SUD Demonstration Evaluation Update		
N/A		<i>Michigan has no modifications for SUD demonstration evaluation.</i>
<input type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
<input checked="" type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
13. Other Demonstration Reporting		
N/A		<i>Michigan has no modifications for other demonstration reporting.</i>
<input type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
<input checked="" type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
14. Notable State Achievements and/or Innovations		
N/A		

Summary of proposed modification	Related metric (if any)	Justification for modification
<input type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
<input checked="" type="checkbox"/> The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		

3. Acknowledgement of Budget Neutrality Reporting-

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

4. Retrospective reporting

If a state's monitoring protocol is approved after its first quarterly monitoring report submission date, the state should report data to CMS retrospectively for any prior quarters of SUD demonstration implementation. States are expected to submit retrospective metrics data in the state's second monitoring report submission after monitoring protocol approval, or propose an alternative plan for reporting retrospectively on its SUD demonstration.

In the monitoring report submission containing retrospective metrics data, the state should also provide a general assessment of metrics trends from the start of the state's demonstration through the end of the current reporting period. The state should report this information in Part B of its report submission (Table 3: Narrative Information on Implementation, by Milestone and Reporting Topic). This general assessment is not intended to be a comprehensive description of every trend observed in metrics data (for example, unlike other monitoring report submissions, the state is not required to describe all metrics changes (+ or - greater than 2 percent). Rather, the assessment is an opportunity for states to provide context for its retrospective metrics data, to support CMS's review and interpretation. For example, consider a state that submits data showing an increase in the number of medication assisted treatment (MAT) providers (Metric #14) over the course of the retrospective reporting period. The state may decide to highlight this trend to CMS in Part B of its report (under Milestone 4) by briefly summarizing the trend and providing context that during this period, the state implemented a grant that supported training for new MAT providers throughout the state.

The state will report retrospectively for any quarters prior to monitoring protocol approval as described above, in the state's second monitoring report submission after protocol approval.

The state proposes an alternative plan to report retrospectively for any quarters prior to monitoring protocol approval: *Based upon MI's Covid-19 Declaration of Emergency we are requesting an alternative reporting plan for retrospectively to accomplish the response to help the epidemic. We are requesting to report all first-year data by 12/30/2020. The following reports will be reported together in 12/30/2020: Narrative information for SUD DY1 Q1; Narrative information for SUD DY1 Q2; Other monthly and quarterly metrics for SUD DY1 Q1; Narrative information for SUD DY1 Q3; Other monthly and quarterly metrics for SUD DY1 Q2; Narrative and information for SUD DY1 Q4; Other monthly and quarterly metrics for SUD DY1 Q3.*

5. Reporting SUD Demonstration Metrics and Narrative Information

The state should review the guidance in Appendix A of the instructions document in order to attest it will follow CMS's guidance on reporting metrics and narrative information, or propose any deviations. The state should complete Table A below to reflect its proposed reporting schedule for the duration of its SUD demonstration approval period.

The state has completed the table below according to the guidance in Appendix A of the instructions document and attests to reporting metrics and narrative information in its quarterly and annual reports according as described.

The state has reviewed Appendix A of the instructions document and completed the table below with the following deviations: *Michigan seeks CMS approval to submit all annual metrics in the first quarter of the subsequent demonstration year (e.g., for DY1, the annual metrics will be reported in DY2Q1). Michigan seeks this deviation to comport with its data run schedule for annual metrics calculated on a fiscal year measurement period. This aligns with Michigan's overarching performance monitoring reporting and defined data calculation schedules. Michigan also seeks to report the last demonstration year's annual metrics on February 28, 2025.*

Table A. Michigan’s reporting in quarterly and annual monitoring reports

Dates of reporting quarter	Broader 1115 DY (if applicable) *	SUD DY	Report due (per STCs schedule)	Measurement period associated with SUD information in report, by reporting category
October 1, 2019- December 31, 2019	N/A	DY1 Q1	12/31/2020	<ul style="list-style-type: none"> • Narrative information for SUD DY1 Q1
January 1, 2020- March 31, 2020	N/A	DY1 Q2	12/31/2020	<ul style="list-style-type: none"> • Narrative information for SUD DY1 Q2 • Other monthly and quarterly metrics for SUD DY1 Q1
April 1, 2020- June 30, 2020	N/A	DY1 Q3	12/31/2020	<ul style="list-style-type: none"> • Narrative information for SUD DY1 Q3 • Other monthly and quarterly metrics for SUD DY1 Q2
July 1, 2020- September 30, 2020	N/A	DY1 Q4	12/31/2020	<ul style="list-style-type: none"> • Narrative information for SUD DY1 Q4 • Other monthly and quarterly metrics for SUD DY1 Q3
October 1, 2020- December 31, 2020	N/A	DY2 Q1	2/28/2021	<ul style="list-style-type: none"> • Narrative information for SUD DY2 Q1 • Other monthly and quarterly metrics for SUD DY1 Q4 • Annual metrics that are established quality measures for CY 2019 • Other annual metrics for SUD DY1
January 1, 2021- March 31, 2021	N/A	DY2 Q2	5/30/2021	<ul style="list-style-type: none"> • Narrative information for SUD DY2 Q2 • Other monthly and quarterly metrics for SUD DY2 Q1

Dates of reporting quarter	Broader 1115 DY (if applicable) *	SUD DY	Report due (per STCs schedule)	Measurement period associated with SUD information in report, by reporting category
April 1, 2021- June 30, 2021	N/A	DY2 Q3	8/31/2021	<ul style="list-style-type: none"> • Narrative information for SUD DY2 Q3 • Other monthly and quarterly metrics for SUD DY2 Q2
July 1, 2021- September 30, 2021	N/A	DY2 Q4	12/31/2021	<ul style="list-style-type: none"> • Narrative information for SUD DY2 Q4 • Other monthly and quarterly metrics for SUD DY2 Q3
October 1, 2021- December 31, 2021	N/A	DY3 Q1	2/28/2022	<ul style="list-style-type: none"> • Narrative information for SUD DY3 Q1 • Other monthly and quarterly metrics for SUD DY2 Q4 • Annual metrics that are established quality measures for CY 2020 • Other annual metrics for SUD DY2
January 1, 2022- March 31, 2022	N/A	DY3 Q2	5/30/2022	<ul style="list-style-type: none"> • Narrative information for SUD DY3 Q2 • Other monthly and quarterly metrics for SUD DY3 Q1
April 1, 2022- June 30, 2022	N/A	DY3 Q3	8/31/2022	<ul style="list-style-type: none"> • Narrative information for SUD DY3 Q3 • Other monthly and quarterly metrics for SUD DY3 Q2
July 1, 2022- September 30, 2022	N/A	DY3 Q4	12/31/2022	<ul style="list-style-type: none"> • Narrative information for SUD DY3 Q4 • Other monthly and quarterly metrics for SUD DY3 Q3
October 1, 2022-	N/A	DY4 Q1	2/28/2023	<ul style="list-style-type: none"> • Narrative information for SUD DY4 Q1 • Other monthly and quarterly metrics for SUD DY3 Q4

Dates of reporting quarter	Broader 1115 DY (if applicable) *	SUD DY	Report due (per STCs schedule)	Measurement period associated with SUD information in report, by reporting category
December 31, 2022				<ul style="list-style-type: none"> Annual metrics that are established quality measures for CY 2021 Other annual metrics for SUD DY3
January 1, 2023- March 31, 2023	N/A	DY4 Q2	5/30/2023	<ul style="list-style-type: none"> Narrative information for SUD DY4 Q2 Other monthly and quarterly metrics for SUD DY4 Q1
April 1, 2023- June 30, 2023	N/A	DY4 Q3	8/31/2023	<ul style="list-style-type: none"> Narrative information for SUD DY4 Q3 Other monthly and quarterly metrics for SUD DY4 Q2
July 1, 2023- September 30, 2023	N/A	DY4 Q4	12/31/2023	<ul style="list-style-type: none"> Narrative information for SUD DY4 Q4 Other monthly and quarterly metrics for SUD DY4 Q3
October 1, 2023- December 31, 2023	N/A	DY5 Q1	2/28/2024	<ul style="list-style-type: none"> Narrative information for SUD DY5 Q1 Other monthly and quarterly metrics for SUD DY4 Q4 Annual metrics that are established quality measures for CY 2022 Other annual metrics for SUD DY4
January 1, 2024- March 31, 2024	N/A	DY5 Q2	5/30/2024	<ul style="list-style-type: none"> Narrative information for SUD DY5 Q2 Other monthly and quarterly metrics for SUD DY5 Q1
April 1, 2024- June 30, 2024	N/A	DY5 Q3	8/31/2024	<ul style="list-style-type: none"> Narrative information for SUD DY5 Q3 Other monthly and quarterly metrics for SUD DY5 Q2

Dates of reporting quarter	Broader 1115 DY (if applicable) *	SUD DY	Report due (per STCs schedule)	Measurement period associated with SUD information in report, by reporting category
July 1, 2024-September 30, 2024	N/A	DY5 Q4	12/31/2024	<ul style="list-style-type: none"> • Narrative information for SUD DY5 Q4 • Other monthly and quarterly metrics for SUD DY5 Q3
July 1, 2024-September 30, 2024	N/A	N/A	2/28/2025	<ul style="list-style-type: none"> • Annual metrics that are established quality measures for CY 2022 • Other annual metrics for SUD DY4

*In this example, the state’s SUD demonstration was added to its broader 1115 demonstration by amendment at the start of the broader 1115 demonstration’s third demonstration year. States that do not have a broader 1115 demonstration (i.e., that have a SUD demonstration only) should delete this column.

**In this example, the state reports its established quality measures in the second quarterly report following the annual report because its demonstration year ends on 12/31; this lag allows adequate time for claims runout and other data completeness issues, as well as time to incorporate annual measure steward updates to specifications. States with demonstration years that end January 31 or February 28 should instead report established quality measures in the first quarterly report following the annual report. All other states should report established quality measures in the annual report.