



APR - 5 2019

*Administrator*  
Washington, DC 20201

Robert Gordon  
Director  
Michigan Department of Health and Human Services  
100 South Capitol Avenue  
Lansing, MI 48909

Dear Mr. Gordon:

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

For the reasons discussed below, the Centers for Medicare & Medicaid Services (CMS) is approving Michigan’s (the “state”) request for a new section 1115(a) demonstration titled, “Pathway to Integration” (Project Number 11-W-00305/5) (the “demonstration”), in accordance with section 1115(a) of the Act. With this approval, the Pathway to Integration demonstration will become effective from April 5, 2019 through September 30, 2024.

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

### **Objectives of the Medicaid Program**

As noted above, the Secretary may approve a demonstration project under section 1115 of the Act if, in his judgment, the demonstration is likely to assist in promoting the objectives of title XIX. The purposes of Medicaid include an authorization of appropriation of funds to “enabl[e] each state, as far as practicable under the conditions in such state, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical

services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care.” Act § 1901. This provision makes clear that an important objective of the Medicaid program is to furnish medical assistance and other services to vulnerable populations. But, there is little intrinsic value in paying for services if those services are not advancing the health and wellness of the individual receiving them, or otherwise helping the individual attain independence. Therefore, we believe an objective of the Medicaid program, in addition to furnishing services, is to advance the health and wellness needs of its beneficiaries, and that it is appropriate for the state to structure its demonstration project in a manner that prioritizes meeting those needs.

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

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

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<sup>1</sup> States have considerable flexibility in the design of their Medicaid programs, within federal guidelines. Certain benefits are mandatory under federal law, but many benefits may be provided at state option, such as prescription drug benefits, vision benefits, and dental benefits. Similarly, states have considerable latitude to determine whom their Medicaid programs will cover. Certain eligibility groups must be covered under a state’s program, but many states opt to cover additional eligibility groups that are optional under the Medicaid statute. The optional groups include a new, non-elderly adult population (ACA expansion population) that was added to the Act at section 1902(a)(10)(A)(i)(VIII) by the Patient Protection and Affordable Care Act (ACA). Coverage of the ACA expansion population became optional as a result of the Supreme Court’s decision in *NFIB v. Sebelius*, 567 U.S. 519 (2012). Accordingly, several months after the *NFIB* decision was issued, CMS informed the states that they “have flexibility to start or stop the expansion.” CMS, *Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid* at 11 (Dec. 10, 2012). In addition to expanding Medicaid coverage by covering optional eligibility groups and benefits beyond what the Medicaid statute requires, many states also choose to cover benefits beyond what is authorized by statute by using expenditure authority under section 1115(a)(2) of the Act. For example, recently, many states have

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

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

### **Background on Medicaid Coverage in Michigan**

Michigan's Medicaid and CHIP programs provide health coverage to over 2.3 million individuals. The Medicaid program in Michigan includes non-mandatory populations, such as the medically needy and optional targeted low income children, in addition to the mandatory eligibility groups. The state also covers several categories of non-mandatory services, including prescription drugs, dental services, and vision benefits, in addition to mandatory services. In addition, on April 1, 2014, Michigan expanded its Medicaid program to include the ACA expansion population (adults with income up to and including 133 percent of the federal poverty level).

### **Extent and Scope of Demonstration**

Approval of this demonstration will allow Michigan to broaden the crucial component of residential substance use disorder (SUD) services in the state's current SUD benefits to create a full continuum of care for beneficiaries with substance use disorders. This approval authorizes Michigan to receive federal financial participation (FFP) for the provision of all Medicaid state plan services, including a continuum of services to treat substance use disorder for Medicaid beneficiaries primarily diagnosed with opioid use disorder (OUD) and/or other SUD who are short-term residents in residential and inpatient treatment facilities that meet the definition of an Institution for Mental Diseases (IMD). Additionally, any beneficiary with a SUD who meets certain clinical guidelines will be able to access the enhanced SUD services.

This demonstration also will establish an integrated behavioral health delivery system that includes a flexible and comprehensive SUD benefit and the Michigan continuum of care, enhance provider competency related to the use of ASAM criteria or other nationally recognized criteria, SUD-specific program standards for patient assessment and placement in treatment, and within treatment programs, expand the treatment continuum of residential care including medically necessary use of qualified residential treatment facilities regardless of the size of the facility, expand withdrawal management programming and medication assisted treatment and recovery, expand the use of recovery coach delivered support services, and establish coordination of care models between SUD providers, primary care and other behavioral health providers.

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been relying on this authority to expand the scope of services they offer to address SUD beyond what the statute explicitly authorizes.

In addition, Michigan submitted its SUD Implementation Plan Protocol as required by the STCs. CMS has completed its review of the SUD Implementation Plan Protocol and determined that it is consistent with the requirements set forth in the STCs and is, therefore, concurrently approving the SUD Implementation Plan Protocol and incorporating it as Attachment D of the STCs. With this approval, the state may begin receiving FFP under the terms of the demonstration, effective as of the date of this letter. As set forth in the STCs, the SUD Health Information Technology (Health IT) Plan must be submitted within 90 calendar days of this letter. If the state fails to submit the SUD Health IT Plan within this timeframe, CMS will issue a funding deferral, as specified in STC 28. Once approved by CMS, the SUD Health IT Plan will be incorporated as an attachment to the STCs. CMS is available to provide technical assistance, if needed.

CMS intends to continue working 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 use of appropriate authorities.

### **Determination that the Demonstration Project is likely to Assist in Promoting Medicaid's Objectives**

For the reasons discussed below, the Secretary has determined that the Pathway to Integration demonstration is likely to assist in promoting the objectives of the Medicaid program. CMS has determined this because it gives the state expenditure authority to offer the SUD program. Under this initiative, all Medicaid beneficiaries will continue to have access to all current mental health and SUD benefits. In addition, all beneficiaries ages 21 through 64 will have access to covered services, authorized under section 1115(a)(2) of the Act, including SUD treatment services provided to individuals with SUD who are short-term residents in residential treatment facilities that meet the definition of an IMD. These services would otherwise be excluded from federal reimbursement.

CMS also expects that implementation of this demonstration in Michigan is likely to assist in promoting the objectives of the Medicaid program as it is expected to improve health outcomes for Medicaid beneficiaries by increasing access to high quality OUD/SUD care and expand the OUD/SUD provider networks available to serve Medicaid populations.

### **Consideration of Public Comments**

To increase the transparency of demonstration projects, sections 1115(d)(1) and (2) of 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, benefits, 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.

Section 1115(d)(2)(A) & (C) of the Act further specify that comment periods should be "sufficient to ensure a meaningful level of public input," but the statute imposes no additional requirement on the states or the Secretary 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 written responses to public comments.<sup>2</sup>

CMS did not receive any comments regarding the SUD component of the Pathways to Integration application.

The approval is also subject to your written acknowledgement of the award and acceptance of the enclosed STCs within 30 calendar days of the date of this letter—please send your written acceptance to your project officer, Mr. Ed Francell. Mr. Francell is available to answer any questions concerning your section 1115(a) demonstration and may be contacted 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  
Telephone: (410) 786-1342  
E-mail: [ed.francell@cms.hhs.gov](mailto:ed.francell@cms.hhs.gov)

Official communication regarding official matters should be simultaneously sent to Mr. Francell and Mr. James Scott, Director, Division of Medicaid Field Operations North. Mr. Scott's contact information is as follows:

Mr. James Scott - Director, Division of Medicaid Field Operations North  
Centers for Medicare & Medicaid Services  
Richard Bolling Federal Building  
601 East 12th Street, Room 355  
Kansas City, MO 64106-2808  
Telephone: (816)426-6417  
E-mail: [James.Scott1@cms.hhs.gov](mailto:James.Scott1@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,

A large black rectangular redaction box covers the signature area. A vertical line is drawn above the box, and a handwritten flourish is visible below it.

Enclosures

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<sup>2</sup> 42 CFR § 431.416(d)(2); see also Medicaid Program; Review and Approval Process for Section 1115 Demonstrations; Application, Review, and Reporting Process for Waivers for State Innovation; Final Rules, 77 Fed. Reg. 11678, 11685 (Feb. 27, 2012) (final rule).

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

**NUMBER: 11-W-00305/5**

**TITLE: Pathway to Integration Section 1115 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).

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

**NUMBER: 11-W-00305/5**

**TITLE: Pathway to Integration**

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

**I. PREFACE**

The following are the special terms and conditions (STCs) for the “Pathway to Integration” 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 waivers and expenditure authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state’s obligations to CMS related to this demonstration. These STCs neither grant additional waivers or 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. [Demonstration Programs and Benefits](#)
- VI. [Cost Sharing](#)
- VII. [Delivery System](#)
- VIII. [General Reporting Requirements](#)
- IX. [Monitoring](#)
- X. [Evaluation of the Demonstration](#)
- XI. [General Financial Requirements Under Title XIX](#)
- XII. [Monitoring Budget Neutrality for the Demonstration](#)
- XIII. [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](#)

## II. PROGRAM DESCRIPTION AND OBJECTIVES

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.

This demonstration seeks to accomplish these efforts by:

- Establishing an integrated behavioral health delivery system that includes 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.

## 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 waiver and 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 Waiver or Expenditure Authority.** CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waivers

or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX. CMS 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 a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

**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. The demonstration will allow Michigan Medicaid recipients ages 21-64 to receive opioid use disorder (OUD)/SUD treatment services 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. 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. DEMONSTRATION PROGRAMS AND BENEFITS

**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 SUD Monitoring Plan 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**

<b>SUD Benefit</b>	<b>Medicaid Authority</b>	<b>Expenditure Authority</b>
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. SUD Implementation Plan.** The state must submit a OUD/SUD Implementation Plan within 90 calendar days after approval of the 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 SUD Implementation Plan

concurrently with this demonstration. The approved SUD Implementation Plan appears as [Attachment D](#) and may be altered only with CMS approval. After approval of the 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 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 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. SUD Monitoring Protocol.** The state must submit a SUD Monitoring Protocol within 150 calendar days after approval of the SUD Demonstration. The SUD Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. Once approved, the 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 27 and STC 28 for each incident of insufficient progress or failure to report in each reporting quarter.

**22. 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 28. 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)<sup>1</sup>
  - 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.<sup>2</sup> 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.

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<sup>1</sup> 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.

<sup>2</sup> *Ibid.*

- 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.<sup>3</sup>
- g. In developing the SUD Health IT Plan, the state may use the following resources:
  - i. 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.”
  - ii. 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.medicare.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.
  - iii. 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.
- h. 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.
- i. 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 an addendum to its Annual Reports (STC 31).
- j. 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.

## VII. COST SHARING

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

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<sup>3</sup> 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.

## VII. DELIVERY SYSTEM

- 25. Delivery System.** Beneficiaries who are eligible for the Michigan Pathway to Integration demonstration will receive services through the same managed care and fee-for-service arrangements as currently authorized in the state.

## VIII. GENERAL REPORTING REQUIREMENTS

- 26. Submission of Post-approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.
- 27. 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.

**28. 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.

**29. 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.

**30. 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 27.

## IX. MONITORING

**31. 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.
- 32. 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 27.
- 33. 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.
- 34. 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.

## **X. EVALUATION OF THE DEMONSTRATION**

- 35. 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.

- 36. 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.
- 37. 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.
- 38. 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.
- 39. 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).
- 40. 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.
- 41. 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, April 5, 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.
- 42. 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.
- 43. 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.
- 44. 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.

## **XI. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX**

**45. Reporting Expenditures under the Demonstration.** The following describes the reporting of expenditures subject to the Budget Neutrality agreement:

- a. Tracking Expenditures. In order to track expenditures under this demonstration, the state must report demonstration expenditures through the Medicaid and Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in section 2500 of the State Medicaid Manual. All demonstration expenditures claimed under the authority of title XIX of the Act and subject to the BN expenditure limit must be reported each quarter on separate Forms CMS-64.9 Waiver and/or 64.9P Waiver, identified by the demonstration project number (11-W-00304/0) assigned by CMS, including the project number extension which indicates the Demonstration Year (DY) in which services were rendered.
- b. Cost Settlements. For monitoring purposes, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (Form CMS-64.9P Waiver) for the Summary Sheet Line 10B, in lieu of Lines 9 or 10C. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual.
- c. Pharmacy Rebates. Because pharmacy rebates are not reflected in the data used to determine the budget neutrality expenditure limit, 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. Use of Waiver Forms. For each demonstration year, separate Forms CMS-64.9 Waiver and/or 64.9P Waiver must be completed, using the waiver names listed below. Expenditures should be allocated to these forms based on the guidance which follows.
  - i. **SUD IMD-DAB:** 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 belonging to Disabled, Aged and Blind eligibility categories during a month in which the individual is a short-term resident in an IMD.
  - ii. **SUD IMD-HMP:** 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 belonging to Healthy Michigan Plan eligibility categories during a month in which the individual is a short-term resident in an IMD.
  - iii. **SUD IMD-TANF:** 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 belonging to TANF eligibility categories during a month in which the individual is a short-term resident in an IMD.

- 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.
- f. Demonstration Years. The demonstration years are as follows:

<i>Demonstration Year 1</i>	<i>October 1, 2019- September 30, 2020</i>	<i>12 Months</i>
<i>Demonstration Year 2</i>	<i>October 1, 2020 – September 30, 2021</i>	<i>12 Months</i>
<i>Demonstration Year 3</i>	<i>October 1, 2021 – September 30, 2022</i>	<i>12 Months</i>
<i>Demonstration Year 4</i>	<i>October 1, 2022 – September 30, 2023</i>	<i>12 Months</i>
<i>Demonstration Year 5</i>	<i>October 1 2023 – September 30, 2024</i>	<i>12 Months</i>

**46. Budget Neutrality Monitoring Tool.** The state and CMS will jointly develop a BN monitoring tool (using a mutually agreeable spreadsheet program) for the state to use for quarterly BN status updates including established baseline and member months data and other in situations when an analysis of BN is required. The tool will incorporate the “C Report” for monitoring actual expenditures subject to BN. A working version of the monitoring tool will be available for the state’s first Annual Report.

**47. Quarterly Expenditure Reports.** The state must provide quarterly expenditure reports using the Form CMS-64 to report total expenditures for services provided through this under the Medicaid program, including those provided through the demonstration under section 1115 authority that are subject to budget neutrality. This project is approved for expenditures applicable to services rendered during the demonstration period. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.

FFP will be provided for expenditures net of collections in the form of pharmacy rebates, cost sharing, or third party liability.

**48. Expenditures Subject to the Budget Neutrality Agreement.** For the purpose of this section, the term “expenditures subject to the budget neutrality agreement” means expenditures for the EGs outlined in Section XII, Monitoring Budget Neutrality for the Demonstration, except where specifically exempted. All expenditures that are subject to the budget neutrality agreement are considered demonstration expenditures and must be reported on Forms CMS-64.9 Waiver and/or 64.9P Waiver.

- 49. Administrative Costs.** Administrative costs will not be included in the budget neutrality limit, but the state must separately track and report additional administrative costs that are directly attributable to the demonstration, using separate CMS-64.10 waiver and 64.10 waiver forms, with waiver name “ADM”.
- 50. Claiming Period.** All claims for expenditures subject to the budget neutrality limit (including any cost settlements) must be made within two (2) years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including any cost settlements) must be made within two (2) years after the conclusion or termination of the demonstration. During the latter 2-year period, the state must continue to identify separately net expenditures related to dates of service during the operation of the section 1115 demonstration on the Form CMS-64 in order to properly account for these expenditures in determining budget neutrality.
- 51. Reporting Member Months.** The following describes the reporting of member months for demonstration populations.
- a. For the purpose of calculating the BN expenditure limit and for other purposes, the state must provide to CMS, as part of the BN Monitoring Tool required under STC 48, the actual number of eligible member months for each MEG described in subparagraph D below. The state must submit a statement accompanying the BN Monitoring Tool, which certifies the accuracy of this information. To permit full recognition of “in-process” eligibility, reported counts of member months may be subject to revision.
  - b. The term "eligible member/months" refers to the number of months in which persons are eligible to receive services. For example, a person who is eligible for 3 months contributes 3 eligible member months to the total. Two individuals who are eligible for 2 months each contribute 2 eligible member months to the total, for a total of 4 eligible member/months.
  - c. The state must report separate member month totals for individuals enrolled in the Pathway to Integration demonstration and the member months must be subtotaled according to the MEGs defined in STC 51 (d)(i).
  - d. The state must report member months according to following definitions:
    - i. **SUD IMD-DAB:** SUD IMD-DAB Member Months are months of Medicaid eligibility during which the individual belonging to the Disabled, Aged, and Blind 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-DAB MEG, as applicable. SUD IMD-DAB Member Months must not be duplicative of member months reported under any other Michigan section 1115 demonstration.
    - ii. **SUD IMD-HMP:** 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.

- iii. **SUD IMD-TANF:** 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.

**52. Standard Medicaid Funding Process.** The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable Medicaid expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report those expenditures by quarter for each FFY on the Form CMS-37 (narrative section) for both Medical Assistance Payments (MAP) and state and Local Administrative Costs (ADM). As a supplement to the Form CMS-37, the state will provide updated estimates of expenditures subject to the budget neutrality limit. CMS will make federal funds available based upon the state's estimate, as approved by CMS. Within 30 calendar days after the end of each quarter, the state must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter just ended. CMS 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.

**53. 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.

**54. 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. CMS may review at any time the sources of the non-federal share of funding for the demonstration. The state agrees that all funding sources deemed unacceptable by CMS must be addressed within the time frames set by CMS.
- b. 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.
- c. The state assures that all health care-related taxes comport with section 1903(w) of the Act and all other applicable federal statutory and regulatory provision, as well as the approved Medicaid state plan.

**55. 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.
- 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.

**56. 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.

## XII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

- 57. Limit on Title XIX Funding.** The state will be subject to a limit on the amount of federal title XIX funding that the state may receive on selected Medicaid expenditures during the period of approval of the demonstration. The limit is determined by using the per capita cost method described in STCs 59 and 61, and budget neutrality expenditure limits are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. Actual expenditures subject to the budget neutrality expenditure limit must be reported by the state using the procedures described in section XI. The data supplied by the state to CMS to set the annual caps is subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit. CMS' assessment of the state's compliance with these annual limits will be done using the Schedule C report from the CMS-64.
- 58. Risk.** The state will be at risk for the per capita cost (as determined by the method described below) for state plan and hypothetical populations, but not at risk 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.
- 59. Calculation of the Budget Neutrality Limit and How It Is Applied.** For the purpose of calculating the overall budget neutrality limit for the demonstration, separate annual budget limits will be calculated for each DY on a total computable basis, by multiplying the predetermined PMPM cost for each MEG (shown on the table in STC 61) by the corresponding actual member months total, and summing the results of those calculations. The PMPM reflects all expenditures from the entire month in which a member received a service of any length of stay in an SUD IMD. The expenditures reflect 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. 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 Composite Federal Share, which is defined in STC 63 below. The demonstration expenditures subject to the budget neutrality limit are those reported under the following Waiver Names: SUD IMD-DAB, SUD IMD-HMP, and SUD IMD-TANF.
- 60. Impermissible DSH, Taxes, or Donations.** CMS reserves the right to adjust the budget neutrality ceiling 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 (if necessary adjustments must be made). 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 Social Security Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

**61. Main Budget Neutrality Test: Substance Use Disorder Expenditures.** The trend rates and per capita cost estimates for the MEG for each year of the demonstration are listed in the table below.

<i>MEG</i>	<i>TREND</i>	<i>DY1 - PMPM</i>	<i>DY2 – PMPM</i>	<i>DY3 – PMPM</i>	<i>DY4 – PMPM</i>	<i>DY5 – PMPM</i>
SUD-IMD-DAB	4.4%	\$1,657.57	\$1,730.50	\$1,806.64	\$1,886.14	\$1,969.13
SUD-IMD-HMP	4.8%	\$842.81	\$883.27	\$925.66	\$970.09	\$1,016.66
SUD-IMD-TANF	4.9%	\$729.30	\$765.03	\$802.52	\$841.84	\$883.09

**62. Hypothetical Model.** As part of the SUD initiative, the state may receive FFP for the continuum of services to treat OUD and other SUDs, provided to Medicaid enrollees in an IMD. These are state plan services that would be eligible for reimbursement if not for the IMD exclusion. Therefore, they are being treated as hypothetical for the purposes of budget neutrality. Hypothetical services can be treated in budget neutrality in a way that is similar to how Medicaid state plan services are treated, by including them as a “pass through” in both the without-waiver and with-waiver calculations. However, the state will not be allowed to obtain budget neutrality “savings” from these services.

**63. 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.

**64. Exceeding Budget Neutrality.** The budget neutrality limits calculated in STCs 59 and 61 will apply to actual expenditures for demonstration services as reported by the state under section XI 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.

**65. Enforcement of Budget Neutrality.** CMS will enforce the budget neutrality agreement over the life of the demonstration, rather than on an annual basis. However, if the state exceeds the calculated cumulative target limit by the percentage identified below for any of the DYs, the state must submit a corrective action plan to CMS for approval.

<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>

### **XIII. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION**

<b>Date</b>	<b>Deliverable</b>	<b>STC</b>
30 days after approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
150 days after approval date	SUD Monitoring Plan	STC 19
90 days after SUD program approval	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 37
60 days after receipt of CMS comments	Revised Draft Evaluation Design	STC 38
30 days after CMS Approval	Approved Evaluation Design published to state's website	STC 38
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 40(c)
60 days after receipt of CMS comments	Final Interim Evaluation Report	STC 40(d)
18 months after the end of the demonstration	Draft Summative Evaluation Report	STC 41
60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	STC 41

30 calendar days after approval of CMS comments	Approved Final Summative Evaluation Report published to state's website	STC 41
Monthly Deliverables	Monitoring Calls	STC 33
Quarterly Deliverables Due 60 days after end of each quarter, except 4 <sup>th</sup> quarter	Quarterly Monitoring Reports	STC 31
Annual Deliverables -Due 90 days after end of each 4 <sup>th</sup> quarter	Annual Reports	STC 31
Within 120 calendar days after the expiration of the demonstration	Draft Close-out Operational Report	STC 32
30 calendar days after receipt of CMS comments	Final Close-out Operational Report	STC 32
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**

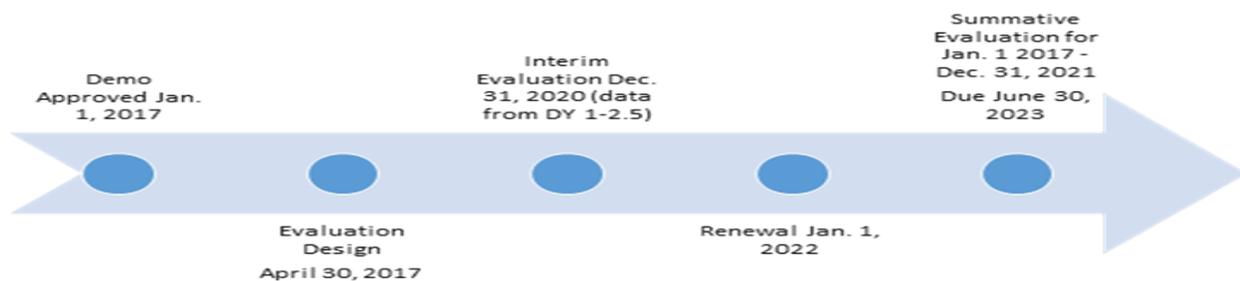
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, 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
<b>Hypothesis 1</b>				
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
<b>Hypothesis 2</b>				
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**

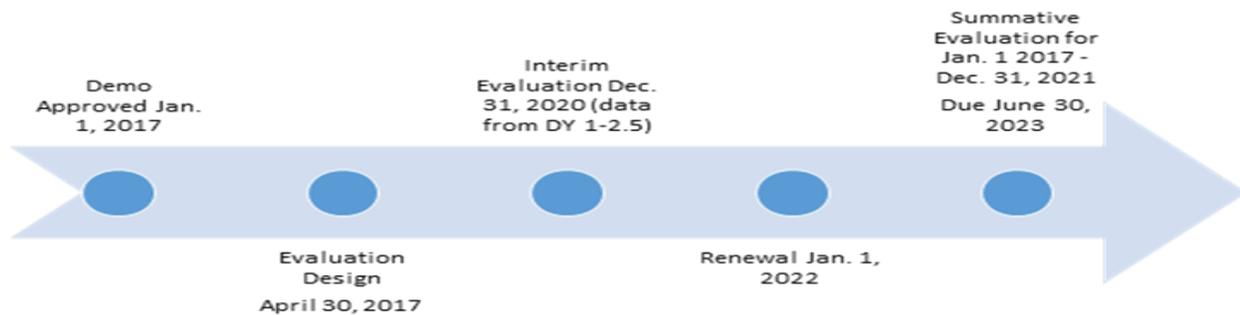
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved 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:  
2016 SUD Implementation Plan**

State of Michigan  
1115 Demonstration Waiver  
Substance Use Disorder Implementation Plan

November 1, 2016

## Comprehensive Benefit Design

Michigan provides coverage for an extensive array of Substance Use Disorder (SUD) treatment and recovery support services. Below we list all of the SUD services available under the waiver, including those newly covered under the 1115 waiver. SUD treatment services are arrayed by ASAM Level. Recovery Support Services are available to individuals regardless of ASAM care level. Unless otherwise noted, all services are available to adults and children/adolescents. For each service we also provide definitions and components for each service.

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits
SUD TREATMENT				
0.5 - Early Intervention				
	Screening, Brief Intervention, and Referral to Treatment (SBIRT)	Assessment and education for at-risk individuals. A face-to-face service for the purpose of identifying functional, treatment, and recovery needs and a basis for formulating the Individualized Treatment Plan.	Primary care providers payable under the state's managed care/fee for service physical health care system.	NA.
	Early intervention services	Includes stage-based interventions for individuals with substance use disorders and individuals who may not meet the threshold of abuse or dependence but are experiencing functional/social impairment as a result of use.	Provider agency licensed and accredited as substance abuse treatment program.  Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.	Services are not subdivided by the number of hours received during a week. The amount and type of services provided are based on individual needs based on the beneficiary's motivation to change and other risk factors that may be present.
Level 1 - Opioid Treatment Program (OTP)				

	Approved pharmacological support services	Oral medication administration, direct observation, physician evaluations, individual and person centered assessments, nursing assessments,	Services must be provided under the supervision of a physician licensed to practice medicine in Michigan. Programs must meet	Service limitations as indicated by state and federal requirements (e.g., physical
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ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits
		counseling and laboratory testing and access to primary care (approved for use of Methadone and/or Buprenorphine).	applicable state licensure, CSAT certification, DEA licensure and accreditation requirements.	examination, laboratory tests, etc.).
Level 1 - Outpatient Services				
	Psychiatric evaluation	Physician evaluation/exam	Psychiatrist or psychiatric mental health nurse practitioner.	Services provided as medically necessary.
	Assessment	A face-to-face service for the purpose of identifying functional, treatment, and recovery needs and a basis for formulating the Individualized Treatment Plan.	Provider agency licensed and accredited as substance abuse treatment program.  Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.	ASAM level 1 Services from one to eight hours during a week. Less than 9 hours of service/week (adults); less than 6 hours/week (adolescents) for recovery or motivational enhancement therapies/strategies.
	Treatment planning	Activities associated with the development and periodic review of the plan of service, including all aspects of the person-centered planning process, such as pre-meeting activities, and external facilitation of person-centered planning.  This includes writing goals, objectives, and outcomes; designing strategies to achieve outcomes (identifying amount, scope, and duration) and ways to measure achievement relative to the outcome methodologies; attending person-centered planning meetings per invitation; and documentation.	Provider agency licensed and accredited as substance abuse treatment program.  Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.	Services provided as medically necessary.

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits
		Monitoring of the individual plan of service including specific services, when not performed by the case manager or supports coordinator, is included in this coverage.		
	Therapy (Individual, Group, Family)	Individual - Face to face counseling services with the beneficiary; Group - Face-to-face counseling with three or more beneficiaries, and can include didactic lectures, therapeutic interventions/counseling, and other group activities; Family - Face-to-face counseling with the beneficiary and the significant other and/or traditional or nontraditional family members.	<p>Provider agency licensed and accredited as substance abuse treatment program.</p> <p>Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.</p>	Services provided as medically necessary.

	Counseling (Individual, Group)	An interpersonal helping relationship that begins with the client exploring the way they think, how they feel, and what they do, for the purpose of enhancing their life. The counselor helps the client set the goals that pave the way for positive change to occur.	<p>Provider agency licensed and accredited as substance abuse treatment program.</p> <p>Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.</p> <p>Services can be provided by appropriately trained staff when working under the supervision of a SATS or SATP. A recovery coach or SUD peer specialist must be certified through an MDHHS-approved training program.</p>	Services provided as medically necessary.
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ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits
	Didactics/education	Services that are designed or intended to teach information about addiction and/or recovery skills.	<p>Provider agency licensed and accredited as substance abuse treatment program.</p> <p>Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.</p> <p>Services can be provided by appropriately trained staff when working under the supervision of a SATS or SATP. A recovery coach or SUD peer specialist must be certified through an MDHHS-approved training program.</p>	Services provided as medically necessary.
	Crisis Intervention	A service for the purpose of addressing problems/issues that may arise during treatment and could result in the beneficiary requiring a higher level of care if intervention is not provided.	<p>Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.</p> <p>Services can be provided by appropriately trained staff when working under the supervision of a SATS or SATP. A recovery coach or SUD peer specialist must be certified through an MDHHS-approved training program.</p>	Services provided as medically necessary.

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits
	Medication review	Evaluating and monitoring medications, their effects, and the need for continuing or changing the medication regimen. Medication review includes the administration of screening tools for the presence of extra pyramidal symptoms and tardive dyskinesia secondary to untoward effects of neuroactive medications.	A physician, physician assistant, nurse practitioner, registered nurse, licensed pharmacist, or a licensed practical nurse assisting the physician may perform medication reviews. Only an MD or DO, or a licensed physician's assistant or nurse practitioner under the supervision of a physician may prescribe medications.	Services provided as medically necessary.
	Laboratory Tests	Laboratory analysis of specimens to detect presence of alcohol or drugs.	Medicaid eligible and enrolled laboratory services providers.	Services provided as medically necessary.
Level 2.1 – Intensive Outpatient Services				
	Intensive Outpatient Services (IOP)	Includes assessment, counseling, crisis intervention, and activity therapies or education.  Outpatient services can include any variety of the covered services and are dependent on the individual needs of the beneficiary. The assessment, treatment plan and recovery support preparations are the only components that are consistent throughout the outpatient levels of care as each beneficiary must have these as part of the authorized treatment services.	Provider agency licensed and accredited as substance abuse treatment program.  Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.	Provided as 9 to 19 hours of structured programming per week based on an individualized treatment plan. As a beneficiary's needs increase, more services and/or frequency/duration of services may be utilized if these are medically necessary.

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits
Level 2.5 – Partial Hospitalization Services				
	Partial hospitalization (Expanded Intensive Outpatient)	20 or more hours of service/week for multidimensional instability not requiring 24-hour care.	<p>Provider agency licensed and accredited as substance abuse treatment program.</p> <p>Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.</p>	<p>Authorization for the partial hospitalization admission and continued stay includes authorization for all services related to that admission/stay, including laboratory, pharmacy, and radiology services.</p>
Level 3.1 – Clinically Managed Low-intensity Residential Services				

	<p>Clinically Managed Low-Intensity Residential Services</p>	<p>The services are directed toward applying recovery skills, preventing relapse, improving emotional functioning, promoting personal responsibility, and reintegrating the individual in work, education, and family life. Treatment services are similar to low intensity outpatient services focused on improving the individual's functioning and coping skills in Dimension 5 and 6.</p> <p>Functional deficits found in this population may include problems in applying recovery skills to their everyday lives, lack of personal responsibility, or lack of connection to employment, education, or family life. The setting allows clients opportunity to develop and practice skills while reintegrating into the community.</p>	<p>Provider agency licensed and accredited as substance abuse treatment program.</p> <p>Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.</p> <p>Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this level of care.</p>	<p>At least 5 hours per week of clinical services (Assessment; Episode of Care Plan- addressing treatment, recovery, discharge and transition across episode; interaction/ teaching to process skills and information adapted to the individual needs; includes alternative therapies, individual, group and family counseling, anger management, coping skills, recovery skills, relapse triggers, and crisis intervention); coordination and referral;</p>
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ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits
		<p>Services are inclusive of structured supervision within the 24-hour program, provided by available trained personnel; at least 5 hours of clinical service/week in which services are preparing individual for outpatient treatment.</p>		<p>medical evaluation and linkage to services; connection to next provider and medical services; preparation for next step.</p> <p>At least 5 hours of life skills and self-care per week.</p>
Level 3.3 – Clinically Managed Population-specific High-Intensity Residential Services				
	<p>Clinically Managed Population-specific High-Intensity Residential Services (Adult only)</p>	<p>The program provides a structured recovery environment in combination with medium-intensity clinical services to support recovery. Services may be provided in a deliberately repetitive fashion to address the special needs of individuals who are often elderly, cognitively impaired, or developmentally delayed. Typically, they need a slower pace of treatment because of mental health problems or reduced cognitive functioning. Treatment services are directed to provision of simple interventions to increase awareness and understanding of dangerous consequences of behavior and improving functioning and coping in Dimensions 4 and 5.</p> <p>The deficits for clients at this level are primarily cognitive, either temporary or</p>	<p>Provider agency licensed and accredited as substance abuse treatment program.</p> <p>Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.</p> <p>Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this level of care.</p>	<p>Not less than 13 hours per week of core services (Assessment; Episode of Care Plan- addressing treatment, recovery, discharge and transition across episode; interaction/teaching to process skills and information adapted to the individual needs; includes alternative therapies, individual, group and family counseling, anger management, coping skills, recovery skills, relapse triggers, and crisis intervention); coordination and referral; medical evaluation and</p>

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits
		<p>permanent. Clients in this LOC have needs that are more intensive and to benefit effectively from services, they must be provided at a slower pace and over a longer period of time. The client's level of impairment is more severe at this level, requiring services be provided differently in order for maximum benefit to be received.</p> <p>Services are inclusive of structured supervision 24/7, provided by trained counselors to stabilize the multidimensional aspects of imminent danger. Services are offered within the less intense milieu and group treatment for those with cognitive or other impairments unable to use full active milieu or the therapeutic community as they prepare for outpatient treatment.</p>		<p>linkage to services; connection to next provider and medical services; preparation for next step.</p> <p>Not less than 13 hours per week of life skills and self-care services.</p>
Level 3.5 – Clinically Managed High-Intensity Residential Services				

	Clinically Managed High-Intensity Residential Services	<p>Services are inclusive of structured supervision within the 24-hour /7 day a week program, provided by available trained counselors who intervene to stabilize multidimensional aspects of imminent danger and other behaviors that are based in dysfunctional actions and require habilitation.</p> <p>Staff provide targeted interventions to rebuild social, psychological,</p>	<p>Provider agency licensed and accredited as substance abuse treatment program.</p> <p>Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.</p>	<p>Not less than 20 hours per week of core services (services (Assessment; Episode of Care Plan-addressing treatment, recovery, discharge and transition across episode); coordination and referral; medical evaluation and linkage to services; connection to next</p>
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ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits
		<p>educational/ vocational and employment limitations and support preparation and development for outpatient treatment.</p> <p>Clients must be able to tolerate and use full milieu or therapeutic community and began to address and make progress and improvements as they master life skills.</p>	<p>Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this level of care.</p>	<p>provider and medical services; preparation for next step.</p> <p>Not less than 20 hours per week of life skills and self-care services.</p>
Level 3.7 – Medically Monitored High-Intensity Inpatient Services				
	<p>Medically Monitored High-Intensity Inpatient Services</p>	<p>Services are inclusive of structured supervision within the 24-hour/7 day a week program, provided by available trained counselors who intervene to stabilize multidimensional aspects of imminent danger and other behaviors that are based in dysfunctional actions and require habilitation. Programs provide a planned and structured regimen of 24-hour professionally directed evaluation, observation, medical monitoring and addiction treatment.</p> <p>The service, when clinically indicated, is an alternative to acute medical care provided by licensed health care professionals in a hospital setting.</p> <p>The skills of the interdisciplinary team and the availability of support services can accommodate withdrawal management</p>	<p>Provider agency licensed and accredited as substance abuse treatment program.</p> <p>Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.</p> <p>Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this level of care.</p> <p>These services must be staffed 24-hours-per-day, seven-days-per-week by a licensed physician or by the designated representative of a licensed physician.</p>	<p>Not less than 20 hours per week of core services (services (Assessment; Episode of Care Plan-addressing treatment, recovery, discharge and transition across episode); coordination and referral; medical evaluation and linkage to services; connection to next provider and medical services; preparation for next step.</p> <p>Not less than 20 hours per week of life skills and self-care services.</p>

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits
4 – Medically Managed Intensive Inpatient Services				
	Medically Managed Intensive Inpatient Services	Organized service delivered in an acute care inpatient setting. It is for patients whose acute biomedical, emotional, behavioral and cognitive problems are so severe that they require primary medical and nursing care.	<p>A hospital providing medically managed intensive inpatient services is accredited and licensed and staffed 24/7 to provide licensed nursing and physician services to patients requiring access to a range of services including ancillary such as laboratory, x-ray, nutrition services) and specialty physician services.</p> <p>The staff are licensed and credentialed by the hospital and meet the accreditation standards related to practice within their licensures.</p>	Service provided as medically indicated and through established medical protocols.
Level 1-WM – Ambulatory Withdrawal Management without Extended On-site Monitoring (Outpatient Withdrawal Management)				
	Ambulatory Withdrawal Management without Extended On-site Monitoring (Outpatient Withdrawal Management)	<p>Ambulatory sub-acute detoxification without extended on-site monitoring for patients expected to demonstrate mild withdrawal with daily or less than daily outpatient supervision.</p> <p>Supervised monitoring of withdrawal occurs by personnel trained in SUD and withdrawal management during identified hours.</p>	<p>Provider agency licensed and accredited as substance abuse treatment program.</p> <p>Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.</p>	Initial length-of-stay authorizations may be for up to three days, with additional days authorized if there is clinical evidence that detoxification is not successful or complete and authorization requirements continue to be met.

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits
		<p>Services must have arrangements for access to licensed medical personnel as needed.</p>	<p>Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this level of care.</p>	
Level 2-WM– Ambulatory Withdrawal Management with Extended On-site Monitoring (Outpatient Withdrawal Management)				
	<p>Ambulatory Withdrawal Management with Extended On-site Monitoring (Outpatient Withdrawal Management)</p>	<p>Ambulatory sub-acute detoxification with extended on-site monitoring for patients expected to demonstrate moderate withdrawal with all day withdrawal management and support and supervision.</p> <p>Services must have arrangements for access to licensed medical personnel as needed.</p> <p>Patient has a supportive family or living situation at night.</p>	<p>Provider agency licensed and accredited as substance abuse treatment program.</p> <p>Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.</p> <p>Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this level of care.</p> <p>Ambulatory detoxification services must be monitored by appropriately credentialed and licensed nurses.</p>	<p>Initial length-of-stay authorizations may be for up to three days, with additional days authorized if there is clinical evidence that detoxification is not successful or complete and authorization requirements continue to be met.</p>

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits
Level 3.2-WM Clinically Managed Residential Withdrawal Management (Residential Withdrawal Management)				
	Clinically Managed Residential Withdrawal Management (Residential Withdrawal Management)	<p>Detoxification management and monitoring of services to client determined to need moderate withdrawal, and 24-hour support to complete withdrawal supervision and increase likelihood of continuing treatment or recovery. This residential setting for detoxification emphasizes peer and social support for persons who warrant 24-hour support. Sub-acute detoxification provides supervised care to manage the effects of withdrawal from alcohol and/or other drugs as part of a planned sequence of addiction treatment. Detoxification is limited to stabilization of the medical effects of withdrawal and referral to ongoing treatment and/or support services.</p> <p>Services must have arrangements for access to licensed medical personnel as needed.</p>	<p>Provider agency licensed and accredited as substance abuse treatment program. Licensure as a sub-acute detoxification program is required.</p> <p>Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.</p> <p>Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this level of care.</p>	Initial length-of-stay authorizations may be for up to three days, with additional days authorized if there is clinical evidence that detoxification is not successful or complete and authorization requirements continue to be met.
Level -3.7 WM – Medically Monitored Inpatient Withdrawal Management				

	Medically Monitored Inpatient Withdrawal Management	Services are inclusive of structured supervision within the 24-hour /7 day a week program, provided by available trained counselors who intervene to stabilize multidimensional aspects of imminent danger and other behaviors	Provider agency licensed and accredited as substance abuse treatment program.  Clinical service provided by Substance Abuse Treatment	Initial length-of-stay authorizations may be for up to three days, with additional days authorized if there is clinical evidence that
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ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits
		<p>that are based in dysfunctional actions and require habilitation.</p> <p>The service is limited to stabilization of the medical effects of the withdrawal, and referral to necessary ongoing treatment and/or support services.</p> <p>The service, when clinically indicated, is an alternative to acute medical care provided by licensed health care professionals in a hospital setting.</p>	<p>Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.</p> <p>Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this level of care.</p> <p>These services must be staffed 24-hours-per-day, seven-days-per-week by a licensed physician or by the designated representative of a licensed physician.</p>	<p>detoxification is not successful or complete and authorization requirements continue to be met.</p>
Level 4-WM – Medically Managed Intensive Inpatient				
	<p>Medically Monitored Inpatient Withdrawal Management</p>	<p>Severe, unstable withdrawal requiring 24-hour nursing care and daily physician visits.</p> <p>Inpatient medical acute detoxification services provided in a hospital setting must meet one of the following criteria as documented in the physician's orders and patient care plan: Vital signs, extreme and unstable; uncontrolled hypertension, extreme and unstable; delirium tremens, e.g., confusion, hallucinations, seizures or a documented history of delirium tremens requiring</p>	<p>A hospital providing medically managed intensive inpatient services is accredited and licensed and staffed 24/7 to provide licensed nursing and physician services to patients requiring access to a range of services including ancillary such as laboratory, x-ray, nutrition services) and specialty physician services.</p> <p>The staff are licensed and credentialed by the hospital and</p>	<p>Service provided as medically indicated and through established medical protocols.</p>

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits
		<p>treatment; convulsions or multiple convulsions within the last 72 hours; unconsciousness; occurrence of SUD; with pregnancy, monitoring the fetus is vital to the continued health of the fetus; severe/complex medical conditions including insulin-dependent diabetes complicated by diabetic ketoacidosis; suspected diagnosis of closed head injury based on trauma injury; congestive heart disease, ischemic heart disease, or significant arrhythmia as examples of active symptomatic heart disease; suicidal ideation and gestures necessitating suicidal precautions as part of treatment; blood alcohol level 350 mg/dl with a diagnosis of alcohol abuse; blood alcohol level 400 mg/dl with diagnosis of alcohol dependence; active presentation of psychotic symptoms reflecting an urgent/emergent condition.</p>	<p>meet the accreditation standards related to practice within their licensures.</p> <p>The inpatient unit must be staffed by a physician and nursing personnel.</p>	
SUD SUPPORT SERVICES				
	Recovery Supports	<p>To support and promote recovery and prevent relapse through supportive services that result in the knowledge and skills necessary for an individual's recovery. Recovery programs are designed and delivered to and offer social, emotional, and/or educational supportive services to help prevent relapse and promote recovery.</p>	<p>Services can be provided by appropriately trained staff when working under the supervision of a SATS or SATP. A recovery coach or SUD peer specialist must be certified through an MDHHS-approved training program.</p>	<p>Available as medically necessary and appropriate (i.e., one to eight hours during a week; 9 to 19 hours in a week; 20 or more hours in a week).</p>

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits
	Peer Supports	To support and promote recovery and prevent relapse through supportive services that result in the knowledge and skills necessary for an individual's recovery. Peer recovery support programs are designed and delivered primarily by individuals in recovery (Recovery Coach) and offer social, emotional, and/or educational supportive services to help prevent relapse and promote recovery.	Services can be provided by appropriately trained staff when working under the supervision of a SATS or SATP. A recovery coach or SUD peer specialist must be certified through an MDHHS-approved training program.	Available as medically necessary and appropriate (i.e., one to eight hours during a week; 9 to 19 hours in a week; 20 or more hours in a week).
	Case Management	Referral/linking/coordinating/management of services - For the purpose of ensuring follow-through with identified providers, providing additional support in the community if primary services are to be provided in an office setting, addressing other needs identified as part of the assessment and/or establishing the beneficiary with another provider and/or level of care. This service may be provided individually or in conjunction with other services based on the need of the beneficiary.	<p>Provider agency licensed and accredited as substance abuse treatment program.</p> <p>Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.</p> <p>Services can be provided by appropriately trained staff when working under the supervision of a SATS or SATP. A recovery coach or SUD peer specialist must be certified through an MDHHS-approved training program.</p>	Available as medically necessary.

## I. Standards of care

One of the critical expectations that CMS set forth in the State Medicaid Director Letter is a requirement that States use established standards of care in their design of the SUD benefit package, incorporating industry-standard benchmarks for defining medical necessity criteria, covered services, and provider qualifications. As indicated above, Michigan has developed the continuum of SUD services using the treatment and recovery services for adolescents and adults recommended by ASAM.

Providers are currently required to perform a psychosocial assessment, develop a diagnostic impression and collect other relevant information that will assist in determining the most appropriate level of care. The new waiver benefit will contain specific assessment guidelines on how ASAM criteria are to be used to ensure consistent practice in the assessment and treatment planning process. Specifically, the Six Dimensions of Multidimensional Assessment, part of the ASAM criteria, will be incorporated into the assessment process for any individual seeking SUD related services. These dimensions include a detailed review of the following areas:

1. Dimension 1 – Acute Intoxication and/or Withdrawal Potential
2. Dimension 2 – Biomedical Conditions and Complications
3. Dimension 3 – Emotional, Behavioral, or Cognitive Conditions and Complications
4. Dimension 4 – Readiness to Change
5. Dimension 5 – Relapse, Continued Use, or Continued Problem Potential
6. Dimension 6 – Recovery/Living Environment

The considerations that need to be addressed in each dimension are numerous and they fit within the established framework of the assessment process that is already required to take place. The ASAM dimensions will be incorporated so that each area is a standard part of the assessment and level of care determination process. We are projecting that all SUD providers in the network will have these dimensions as part of their assessment by July 1, 2017. The assessment procedures that are required through accreditation and licensing standards do not conflict with the information that is needed to make a level of care determination based on ASAM, therefore no barriers exist for the system to make this change.

The standardizing of the section of the assessment to include the ASAM dimensions will require training. Prior to July 1, 2017 there will be ongoing training and education on the application of the ASAM level of care criteria and use of the ASAM criteria in the assessment process. Michigan will be working directly with national experts, to provide training on the use of ASAM criteria. The PIHPs will be required to ensure that their providers and/or the intake agencies within their networks are all appropriately trained/educated in the application and use of ASAM. The frequency and duration of treatment services are expected to be guided by the ASAM criteria, not the designation of the provider program as being early intervention, outpatient, intensive outpatient, or partial hospitalization. PIHPs will provide evidence of initial training and ongoing training of providers during site reviews conducted by the state.

Additionally, as part of quality monitoring during site reviews, records will be reviewed to determine appropriate application and fidelity to the established assessment and early intervention processes. This quality monitoring will address the expectations that the assessment for all SUD services, level of care and length of stay recommendations has an independent third party reviewing and determining if the provider has the necessary competencies on the use of ASAM in the assessment process. If the PIHP

determines during this monitoring that the provider is not using ASAM to make the appropriate level of care and length of stay decisions and recommendations, the PIHP will take the necessary corrective action.

The PIHPs will continue to make authorization decisions regarding residential length of stay (including continued stay), change in Level of Care (LOC) and discharge based on the ASAM criteria. The PIHP will apply residential decisions for both adolescents and adults. No predetermined limits of care will be established for these services. Access and continued involvement in a level of care will be based on individual need as determined through medical necessity criteria. For residential services, PIHPS will use the six dimensions as follows:

Level of Care	Level 3.1	Level 3.3	Level 3.5	Level 3.7
Dimension 1 Withdrawal Potential	No withdrawal risk, or minimal/stable withdrawal; concurrently receiving Level 1-WM or Level 2-WM	Not at risk of severe withdrawal, or moderate withdrawal is manageable at Level 3.2-WM	At minimal risk of severe withdrawal. If withdrawal is present, manageable at Level 3.2-WM	At high risk of withdrawal, but manageable at level 3.7 WM and does not require the full resources of a licensed hospital
Dimension 2 Medical conditions and complications	None or very stable; or receiving concurrent medical monitoring	None or stable; or receiving concurrent medical monitoring	None or stable; or receiving concurrent medical monitoring	Requires 24-hour medical monitoring but not intensive treatment
Dimension 3 Emotional, behavioral, or cognitive conditions and complications	None or minimal; not distracting to recovery. If stable, a dual diagnosis capable program is appropriate. If not, a dual diagnosis-enhanced program is required	Mild to moderate severity; needs structure to focus on recovery. If stable, a dual diagnosis capable program is appropriate. If not, a dual diagnosis-enhanced program is required. Treatment should be designed to respond to any cognitive deficits	Demonstrates repeated inability to control impulses, or a personality disorder that requires structure to shape behavior. Other functional deficits require a 24-hour setting to teach coping skills. A dual diagnosis enhanced setting is required for the seriously mentally ill client	Moderate severity, needs a 24-hour structured setting. If co-occurring mental health disorder present, requires concurrent mental health services in a medically monitored setting

Dimension 4 Readiness to change	Open to recovery but needs a structured environment to maintain therapeutic gains	Has little awareness and needs interventions available only at Level 3.3 to engage and stay in treatment; or there	Has marked difficulty engaging in treatment, with dangerous consequences; or there is high severity in this dimension	Low interest in treatment and impulse control is poor, despite negative consequences; needs motivating
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Level of Care	Level 3.1	Level 3.3	Level 3.5	Level 3.7
		is high severity in this dimension but not in others. The client needs a Level I motivational enhancement program (Early Intervention)	but not in others. The client needs a Level I motivational enhancement program (Early Intervention)	strategies only safely available in a 24-hour structured setting
Dimension 5 Relapse, continued use, or continued problem potential	Understands relapse but needs structure to maintain therapeutic gains	Has little awareness and needs intervention only available at Level 3.3 to prevent continued use, with imminent dangerous consequences because of cognitive deficits or comparable dysfunction	Has no recognition of skills needed to prevent continued use, with imminent dangerous consequences	Unable to control use, with imminently dangerous consequences, despite active participation at less intensive levels of care
Dimension 6 Recovery/living environment	Environment is dangerous, but recovery achievable if Level 3.1 24-hour structure is available	Environment is dangerous and client needs 24-hour structure to cope	Environment is dangerous and client lacks skills to cope outside of a highly structured 24-hour setting	Environment is dangerous and the patient lacks skills to cope outside of a highly structured 24-hour setting

The second part of the standards of care expectation is that states implement a process to assess and demonstrate that residential providers meet ASAM criteria prior to participating in the Medicaid program. The State of Michigan will ensure that providers meet key program requirements set forth by ASAM for each of the residential levels of care. A projected 75-80 organizations provide the residential level of SUD treatment services.

Currently the State's laws and regulations that apply to organizations and practitioners rendering SUD services align with some of the ASAM program expectations. Michigan will maintain its robust process for ensuring the initial and ongoing qualification standards for individual providers of SUD treatment services. It utilizes state licensing, to ensure quality and competency of the provider network for publicly funded services based on educational and legal requirements for providing services as the initial standard.

State licensure has four general categories that apply to:

1. Outpatient
2. Residential

3. Withdrawal Management (called sub-acute detoxification)
4. Opioid Treatment Programs (Methadone)

Additionally, any organization that provides SUD services for Medicaid beneficiaries must also be accredited by a national body. The following accreditation bodies are recognized in Michigan:

- The Joint Commission;
- Commission on Accreditation of Rehabilitation Facilities (CARF);
- American Osteopathic Association (AOA);
- Council on Accreditation of Services for Families and Children (COA);
- National Committee on Quality Assurance (NCQA); or
- Accreditation Association for Ambulatory Health Care (AAAHC).

The next level is the credentialing of the individual clinical providers of services within each program. This includes the counselors, psychologists, social workers and medical staff along with their identified supervisors. In addition to having to meet professional licensing standards for education and experience to practice in the state, Michigan further delineates that an individual must also be certified through the state board for the International Certification and Reciprocity Consortium (IC&RC). This certification ensures that individuals providing services in the publicly funded SUD service system have received additional experience and education in SUD treatment. The ongoing educational requirements that must be met in order to maintain that credential keeps knowledge current.

In addition, Michigan has set forth various Treatment Policies that provide additional guidance to providers and PIHPs regarding expectations regarding the structure of specific services and qualifications of providers. The current treatment policies are available online at [http://www.michigan.gov/mdhhs/0,5885,7-339-71551\\_2945\\_42542\\_42543\\_42546\\_42553-188444--,00.html](http://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_42542_42543_42546_42553-188444--,00.html).

As part of the implementation of this waiver, the policies on outpatient and residential will be updated to reflect the appropriate ASAM criteria. A new policy on withdrawal management is also being developed to support ASAM use for this level of care. All policies will be effective for the start of the demonstration waiver.

While the combination of licensing and guidance provides a firm foundation for providers to meet the program requirements set forth by ASAM, the State is taking an additional step to review providers against these expectations. After licensure and accreditation are established, each organization that is seeking to provide SUD treatment services (for adults and adolescents) must apply to the state to have an ASAM level assigned to their program. An application, in which the provider describes their program and submits policy evidence of compliance with ASAM, must be submitted for review. Based on the information submitted, the state will assign the appropriate ASAM level or reject the application. An organization is only able to join a PIHP network after a level has been assigned. This determination from the state will be effective for two years and then a redetermination will be required. The state forecasts that all applications for residential services will be submitted to the state by providers by early December 2016. The state

projects to review these application and make a decision regarding a residential provider meeting the ASAM level of care by early to mid-January 2017. Only residential providers that have been reviewed and assigned a level of care will be allowed to participate in the Medicaid program. A copy of the residential assessment instrument is in Attachment A (*Michigan Department of Health and Human Services: American Society of Addiction Medicine (ASAM) Residential Level of Care Designation Questionnaire*).

An online application process is being developed by the state to manage this assignment process for use in demonstration year two and moving forward. The initial provider approval process, is a manual process and will focus on the residential level of care to ensure state approval is in place prior to waiver approval. The state will then move to approve withdrawal management providers within six months of approval and the remaining providers by the end of the first demonstration year. The approval timeline is outlined below:

Level of Care	Approval Deadline
Early Intervention	End of year one
Outpatient	End of year one
Residential, including Withdrawal Management	At approval
Other Withdrawal Management	Six months after approval
Opioid Treatment Program	End of year one

## II. Network development plan

While Michigan has historically maintained a robust network of SUD providers and services spanning from early intervention through inpatient withdrawal management services, the 1115 waiver authority will permit the state to broaden the array of treatment services available and provide Medicaid coverage for the full ASAM care continuum, including residential services in an IMD setting for adults age 21-64.

### 1. Current Capacity

In preparation for development of the 1115 waiver, Michigan conducted an assessment of the current SUD provider network and utilized self-reported data from the 2016 National Survey of Substance Abuse Treatment Services (N-SSATS). In the waiver application, Michigan also committed to utilizing state-level licensure and program data (e.g., BH Treatment Episode Data Set (TEDS)) to further understand current network capacity and development needs. While N-SSATS data confirmed that Michigan offers a breadth of services across all ASAM levels, the data also reaffirmed the state’s understanding that although all residential levels of care are available within the state, there remain opportunities to develop additional capacity (e.g., ASAM Level 3.7), particularly to ensure that time and distance requirements specified under newly promulgated Medicaid managed care regulations will be met by the October 1, 2018 effective date.

## 2. Assessing Future Capacity

In acknowledgement of the need to develop a strong SUD network capable of delivering a comprehensive benefit consistent with ASAM criteria, requirements, MDHHS is currently embarking on a process intended to enable the state to generate comprehensive and refreshable reports for future planning and decision-making. Through use of coaching and technical assistance resources available under the CMS Innovation Accelerator Program (IAP) SUD track, MDHHS is leading an interdisciplinary workgroup comprised of staff and leadership from the Medical Services Administration, the Behavioral Health and Developmental Disabilities Administration, the Licensing and Regulatory Affairs agency and Prepaid Inpatient Health Plans. Through the workgroup, MDHHS will develop a strategy to more effectively utilize existing state-specific and other publicly available data (e.g., the SAMHSA Treatment Locator) and establish processes to:

### Ensure a Comprehensive Evidence-Based Benefit SUD Benefit

- To guarantee a full continuum of evidence-based practices
- To ensure use of evidence-based practices including SBIRT, withdrawal management, medication assisted treatment, care coordination, long-term recovery supports and services
- To confirm service availability and use of services (e.g., short-term inpatient and short-term residential), including in IMDs

### Ensure that SUD providers meet ASAM Program and Service Requirements

- By establishing standards of care using ASAM criteria
- By using ASAM standards to develop residential or inpatient services and other care levels
- By ensuring residential providers meet ASAM prior to participating in

### Medicaid Ensure the Presence and Maintenance of a Strong SUD Provider

#### Network

- By developing and implementing a plan and strategy to ensure a sufficient network of providers across all ASAM levels
- By ensuring that providers have the ability to deliver services consistent with ASAM criteria and provide evidence-based SUD practices
- By ensuring that the provider network is robust in the event providers stop participating in Medicaid, are suspended or terminated

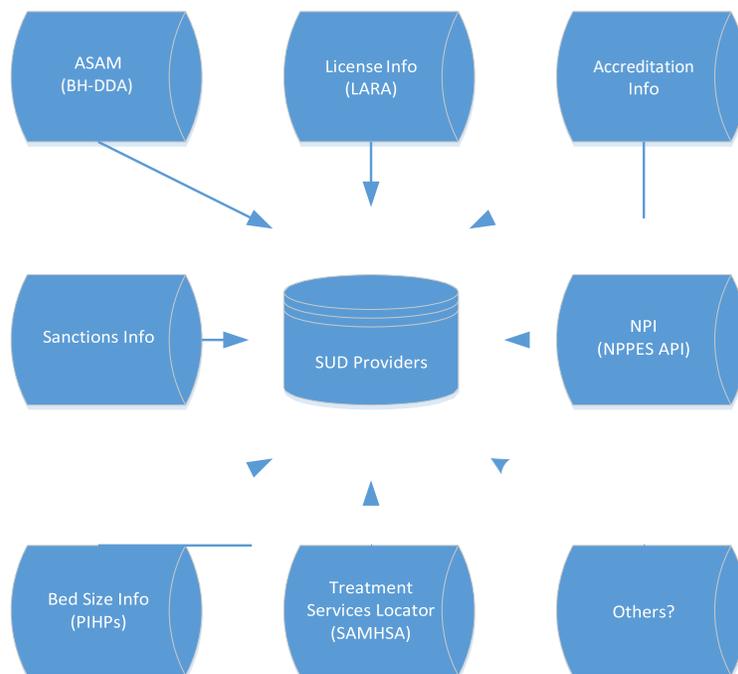
The workgroup began its work on October 1, 2016 and will continue through December 31, 2016. Current efforts of the workgroup center on understanding current processes for accessing multiple data sources about SUD providers to support MDHHS and PIHP business process requirements for:

- Service Authorization
- Credentialing
- Empaneling
- Procurement and contracting
- Utilization management and quality

The workgroup is now focused on documenting the requirements for an ideal solution to support business processes which may include the following features using a database populated from the multiple sources accessed by state and PIHP staff:

- A website portal through which users could input query parameters and obtain a result set of data about an individual provider or a set of providers (including licensure status/type, ASAM level, services provided)
- A Web-based service to which PIHPs subscribe and integrate with their systems in order to develop a comprehensive provider profile
- Batch Interface which would periodically provide a data file with specified data about all or a subset of providers

The graphic below attempts to capture the data sources that were discussed which are candidates for inclusion in such a database:



This workgroup process, slated for conclusion in December 2016, will enable the state to design and implement a strategy to conduct assessments to understand network capacity as well as ensure compliance with future Medicaid managed care network adequacy requirements.

### III. Care coordination

MDHHS is committed to integrating physical and behavioral health care services for beneficiaries with behavioral health conditions and has been implementing several solutions to improve care coordination and care transitions to ensure warm hand-offs and successful engagement in treatment and transitions across levels of care, particularly for high-risk cohorts with complex care needs. Michigan will work with stakeholders to develop a framework to evaluate successful care transitions to outpatient care, including

hand-offs between levels of care within the SUD care continuum as well as linkages with primary care upon discharge.

A description of selected activities intended to ensure improved coordination of care among individuals with SUD are below. Michigan continues to explore and plan for an increasing number of care coordination and care integration strategies as part of the state's ongoing Medicaid system transformation:

#### 1) Medicaid Health Plan (MHP) and Prepaid Inpatient Health Plan Coordination Agreement Requirements

In contracts with managed care entities, Michigan requires Medicaid Health Plans (MHP) and PIHPs to establish and implement coordination agreements with each other to better integrate services covered by MHPs and the PIHPs as well as provide incentives to support behavioral health integration. Managed care entities are also contractually required to collaborate and develop shared metrics to measure the quality of care provided to beneficiaries jointly served by MHPs and PIHPs.

In carrying out this requirement, MHPs and PIHPs have collaborated to work with MDHHS to establish a uniform process for identifying high-risk individuals and stratify populations as required under the MHP [contract](#), which state in part that MHPs must work collaboratively with PIHPs to:

- Identify and coordinate the provision of services to shared members who have significant behavioral health issues and complex physical co-morbidities.
- Jointly create and implement a method for stratifying shared members who have significant behavioral health issues and complex physical co-morbidities.
- Jointly develop care management standards for providing care management services to shared members with significant behavioral health issues and complex physical co-morbidities based on patient needs and goals.
- Jointly develop and implement processes for providing coordinated complex care management services for shared members with significant behavioral health issues and complex physical co-morbidities.
- Jointly create a care management tool used by staff from each organization to document a jointly created care plan and to track contacts, issues, and services regarding shared members with significant behavioral health issues and complex physical co-morbidities.
- Hold case reviews at least monthly during which the care managers and other team members, including community health workers, pharmacists, medical directors and behavioral health providers, must discuss shared members with significant behavioral health issues and complex physical co-morbidities, and develop shared care management interventions.
- Work collaboratively with PIHPs, primary care providers, and MDHHS to develop and implement performance improvement projects involving shared metrics and incentives for performance.

- Report to MDHHS the results of shared metric performance incentive programs in a manner determined by MDHHS.

2) **Health Information Exchange and Data Analytics** Michigan makes two important resources available to enable PIHPs and behavioral health providers to improve care coordination through use of health information: (1) The Michigan Health Information

Network (MiHIN) is the state authority for electronic health information exchange. MiHIN is currently being used by providers of mental health, SUD and intellectual and developmental disability (IDD) services to facilitate and initiate electronic exchange with physical health providers. PIHPs are also eligible to participate as data sharing organizations in the MiHIN network; (2) Data analytics and population health management have been aided by the state's creation of a web portal, CareConnect 360 (CC 360), which was created and launched as a care coordination tool. This tool makes information in the Data Warehouse, including behavioral and physical health claims, available to Medicaid Health Plans, PIHPs and CMHSPs. These resources assist PIHPs and providers to identify a range of health conditions in individual beneficiaries and support both PIHP and provider-level care coordination activities.

- 3) **Section 298 Initiative** The Section 298 Initiative is a statewide effort to improve the coordination of physical health services and behavioral health services in Michigan. This initiative is based upon Section 298 in the Public Act 268 of 2016, under which the Michigan Legislature directed the Department of Health and Human Services to develop a set of recommendations “regarding the most effective financing model and policies for behavioral health services in order to improve the coordination of behavioral and physical health services for individuals with mental illnesses, intellectual and developmental disabilities, and substance use disorders.” The state is currently working towards developing a set of recommendations which will be published and submitted to the Michigan Legislature by January 15, 2017.

Michigan intends to utilize the waiver of services comparability sought under the 1115 Demonstration Waiver to enable behavioral health providers and managed care entities to pilot test varying models of care integration that may emerge as a result of the 298 Workgroup.

- 4) **Certified Community Behavioral Health Clinics** Michigan was awarded a federal planning grant for development of requirements for certified community behavioral health clinics (CCBHCs), which must ensure a broad range of mental health and SUD treatment and support services for all populations with behavioral health needs. Care coordination and ensuring appropriate transitions of care within and across care settings is the centerpiece of the CCBHC program. If Michigan is awarded a Demonstration Grant to pilot CCBHCs throughout the state, selected providers will be required to organize and coordinate patient care across a broad array of providers and safety net systems. This demand will require our participating providers to develop contracts and/or partnership agreements that go beyond the traditional memorandum of understanding arrangements that many providers current have in place.

#### **IV. Care integration**

Michigan's contractual requirements for MHP/PIHP care coordination became effective January 1, 2016. In addition, the state has continued to support and encourage practice-level care integration efforts at the provider level, including impending pilots that will emerge from the 298 Workgroup. Our efforts will be further strengthened if Michigan is awarded status as a CCBHC Demonstration state in that providers will take on the responsibility of service provision to individuals with mild-to-moderate behavioral health conditions. Upon measuring the impact and preliminary results of MHP/PIHP coordination agreement efforts and 298 Workgroup pilot initiatives the state commits to identifying an approach to SUD care integration within twelve months after approval of the 1115 Waiver and also commits to producing a concept design within eighteen months after demonstration approval, with implementation of the concept design within two years after demonstration approval.

#### **V. Program integrity**

The PIHP, through its contract with the state, is required to ensure an ongoing validation and re-validation processes for credentials of all providers in their network. Records must be maintained that show that any applicable licensure and certification are being maintained in good standing, the person is not excluded from Medicaid or Medicare participation and that criminal background checks are being made every other year. In addition to this, the PIHP also has to ensure that any state licensing requirements surrounding scope of practice and supervision are being followed.

The contracts with the State require PIHPs to comply with the federal regulations to obtain, maintain, disclose, and furnish required information about ownership and control interests, business transactions, and criminal convictions as specified in 42 CFR 455.104-106. In addition, the contract requires all PIHP ensure that any and all contracts, agreements, purchase orders, or leases to obtain space, supplies, equipment or services provided under the Medicaid agreement require compliance with 42 C.F.R.

455.104-106.

At the time of provider enrollment or re-enrollment in the PIHP's provider network, the PIHP is required to search the Office of Inspector General's (OIG) exclusions database to ensure that the provider entity, and any individuals with ownership or control interests in the provider entity (direct or indirect ownership of five percent or more or a managing employee), have not been excluded from participating in federal health care programs. Because these search activities must include determining whether any individuals with ownership or control interests in the provider entity appear on the OIG's exclusions database, the PIHP mandates provider entity disclosure of ownership and control information at the time of provider enrollment, re-enrollment, or whenever a change in provider entity ownership or control takes place.

The PIHP must notify the Division of Program Development, Consultation and Contracts, Behavioral Health and Developmental Disabilities Administration in MDHHS immediately if

search results indicate that any of their network's provider entities, or individuals or entities with ownership or control interests in a provider entity are on the OIG exclusions database.

The MDHHS has responsibility and authority to make fraud and/or abuse referrals to the Office of the Attorney General, Health Care Fraud Division. Contractors who have any suspicion or knowledge of fraud and/or abuse within any of the MDHHS's programs must report directly to the MDHHS.

## VI. Benefit management

Benefit management for SUD services has been the responsibility of the PIHPs since 2014. The PIHP will employ its established utilization management system for prior authorization and continued stay reviews which will include applying the ASAM criteria to identify the more appropriate individual treatment and support needs. Eligibility to receive services is based on medical necessity criteria that are outlined through currently established guidelines. These criteria were created for both behavioral health and developmental disabilities services and read as follows:

### 3. Medical Necessity Criteria

Mental health, developmental disabilities, and substance use disorder services are supports, services, and treatment:

- Necessary for screening and assessing the presence of a mental illness, developmental disability or substance use disorder; and/or
- Required to identify and evaluate a mental illness, developmental disability or substance use disorder; and/or
- Intended to treat, ameliorate, diminish or stabilize the symptoms of mental illness, developmental disability or substance use disorder; and/or
- Expected to arrest or delay the progression of a mental illness, developmental disability, or substance use disorder; and/or
- Designed to assist the beneficiary to attain or maintain a sufficient level of functioning in order to achieve his goals of community inclusion and participation, independence, recovery, or productivity.

The policy then further delineates how the medical necessity criteria are to be applied when determining the needs of an individual:

### 4. Determination Criteria

The determination of a medically necessary support, service or treatment must be:

- Based on information provided by the beneficiary, beneficiary's family, and/or other individuals (e.g., friends, personal assistants/aides) who know the beneficiary;
- Based on clinical information from the beneficiary's primary care physician or health care professionals with relevant qualifications who have evaluated the beneficiary;
- For beneficiaries with mental illness or developmental disabilities, based on person-centered planning, and for beneficiaries with substance use disorders, individualized treatment planning;
- Made by appropriately trained mental health, developmental disabilities, or substance abuse professionals with sufficient clinical experience;
- Made within federal and state standards for timeliness;
- Sufficient in amount, scope and duration of the service(s) to reasonably achieve its/their

- purpose; and
- Documented in the individual plan of service.

Consistent with federal statutes and regulations that apply parity to the Medicaid program, the benefits available in this demonstration will not have preset limits placed on them. There will be individual

determination of medical and clinical necessity by qualified providers for each beneficiary for initial and ongoing care needs. The frequency and duration of treatment services are expected to be guided by the ASAM criteria, which is a standardized tool based on significant research evidence and application. As set forth in the Standards of Care discussion, PIHPs currently make authorization decisions (initial and continuing stay) regarding residential length of stay, change in LOC and discharge based on the ASAM criteria. PIHPs will continue to apply the ASAM criteria to ~~both outpatient and~~ residential services for adolescents and adults. In addition, PIHPs will make information regarding medical necessity and information regarding denials or changes in lengths of stay for residential services available to the client or the provider. The PIHP must disseminate all practice guidelines it uses to all affected providers and upon request to beneficiaries.

## **VII. HCBS**

Michigan has long required providers and PIHPs to adhere to requirements of person-centered planning. Person-centered planning requirements and principles for service planning and delivery are specified in the PIHP contract as part of the March 15, 2011 Michigan Department of Community Health Mental Health and Substance Abuse Administration [Person-Centered Planning Policy and Practice Guideline](#).

“Through the PCP process, an individual and those who support him or her:

- a. Focus on the individual’s life goals, interests, desires, preferences, strengths and abilities as the foundation for the planning process.
- b. Identify outcomes based on the individual’s life goals, interests, strengths, abilities, desires and preferences.
- c. Make plans for the individual to work toward and achieve identified outcomes.
- d. Determine the services and supports the individual needs to work toward or achieve outcomes including, but not limited to, services and supports available through the community mental health system.
- e. Develop an Individual Plan of Service (IPOS) that directs the provision of supports and services to be provided through the community mental health services program (CMHSP).”

## **VIII. Prescription Drug Abuse Strategy / Opioid Strategy**

Governor Rick Snyder created a task force in June 2015 to address the growing prescription drug and opioid problem in Michigan. The task force reported the following information the escalation of Michigan’s problem.

According to published raw data from the Michigan Automated Prescription System (MAPS), more than 21 million prescriptions for controlled substances were written in 2014. This is roughly four million more prescriptions than were written in 2007, despite the fact that Michigan’s population slightly decreased over the same time period.

Of the 21 million controlled substance prescriptions written last year, nearly 11 million (over half) were for schedule II drugs. Schedule II drugs are classified by the U.S. Drug Enforcement Agency (DEA) as having a high potential for abuse and dependence. This compares with just three million schedule II prescriptions in 2007. Thus, schedule II prescriptions have nearly quadrupled in Michigan over the past

seven years. Since the creation of MAPS, hydrocodone has been the most prescribed drug, accounting for 32.2% of all prescriptions written in Michigan in 2012. MAPS also tracks dosage units, or pill counts, of controlled substances. In 2007, prescribers wrote nearly 180 million individual dosage units of schedule II drugs. In 2014, this number was an astonishing 745 million. This represents a quadrupling of pill counts in just seven years.

The task force made recommendations under five areas: Prevention, Treatment, Regulation, Policy and Outcomes, and Enforcement. Many of the recommendations addressed the three critical areas set forth by the Secretary of Health and Human Services: provider education, increased access to Naloxone and strategies to increase Medication Assisted Treatment.

## **5. Prevention**

1. Require additional training for all professionals who will be prescribing controlled substances, including training on the new CDC prescribing guidelines.
2. Development and maintenance of relationships among state and local agencies to provide necessary information regarding prescription drug abuse, prevention and treatment.
3. Collaboration among local coalitions, pharmacies, health profession boards, state agencies and the DEA to increase the availability of prescription drop off bins.
4. Review programs and parameters established within the Medicaid system as well as actions taken by other states to determine the best route forward to eliminate doctor and pharmacy shopping. Recommend looking at programs already in use in Tennessee and Washington.
5. Public awareness campaign to inform the public of the dangers of abuse, how to safeguard and properly dispose of medicines, publicize improper prescribing practices, and reduce the stigma of addiction.

## **6. Treatment**

1. Pharmacists should be allowed to dispense Naloxone to the public in similar fashion to how pseudoephedrine is currently dispensed.
2. Pursue increased public awareness regarding the laws that limit civil and criminal liabilities for administering Naloxone.
3. Explore the possibility of limited statutory immunity for low-level offenses involved in reporting an overdose and seeking medical assistance.
4. Explore ways for the State to increase access to care, including wraparound services and MAT, as indicated by national and state guidelines for treatment. In addition, the Task Force recommends that insurance companies consider providing health plans that cover the costs of MAT with reasonable quantity limits on medication used.
5. Explore ways to increase the number of addiction specialists practicing in Michigan.
6. Additional training for law enforcement in the area of recognizing and dealing with addiction for those officers who do not deal directly with narcotics regularly. The Task Force also recommends expansion of treatment courts as called for by Gov. Rick Snyder in his 2015 Criminal Justice Message, as well as expanding the courts'

- ability to create pilot programs for the use of Medication Assisted Treatment.
7. Require a bona-fide physician-patient relationship as defined in Michigan law prior to prescribing controlled substances.

8. The State should review current best practice guidelines for reducing the development of neonatal abstinence syndrome (NAS) and consider pilot programs for the development of testing of pregnant women to reduce the risk of NAS caused by prescription drug and opioid abuse.

#### **7. Regulation**

1. Consider legislation to better define and identify pain management practice for the purposes of licensing.
2. Update regulations to delineate licensing for clinics (methadone) based on the population being treated. The State should consider a tiered system of licensing that regulates the functions and prescription capabilities of the clinics and their staff.
3. Recommend the establishment of an exemption from civil liability when a pharmacist is acting in good faith and has reasonable doubt regarding the authenticity of the prescription or believes the prescription is being filled for non-medical purposes.
4. Review the Michigan College of Emergency Physicians policy and then endorse a best practices policy that hospitals and doctors could use as a model.
5. Review the limitation of the sale of pseudoephedrine by pharmacies only.

#### **8. Policy and Outcomes**

1. Create an ongoing Prescription Drug and Opioid Task Force or Commission to evaluate the efficacy of current proposals and continually develop new solutions to address societal changes.
2. Add outcomes to the State Dashboard to track the success of efforts.
3. The State should consider mechanisms to ensure patient continuity of care during an abrupt closure of a medical practice to ensure that necessary treatments can continue without interruption.
4. Document law enforcement efforts with local coalitions and focus groups that have resulted in a reduction of prescription overdose deaths to determine if replication and expansion are possible and warranted.

#### **9. Enforcement**

1. Review the budgetary requirements for updating or replacing the Michigan Automated Prescription System (MAPS.) There should be mandatory registration in MAPS by all licensed prescribers to ensure all are registered when the updated or new system is brought online.
2. Allow broader access to MAPS for law enforcement purposes when investigating questionable business practices by prescribers.
3. Require enhanced licensing sanctions for health professionals that violate proper prescribing and dispensing practices.

The Department of Licensing and Regulatory Affairs which oversees all healthcare professional and healthcare organization licensure is actively involved in providing education about the use of opiate medications and pain management. Information regarding the activities, groups and educational materials can be found at the following website: [http://www.michigan.gov/lara/0,4601,7-154-72600\\_72603\\_45947---,00.html](http://www.michigan.gov/lara/0,4601,7-154-72600_72603_45947---,00.html) .

MDHHS is actively involved in statewide efforts to address the increasing use of both illegal and prescription opiates in conjunction with recommendations made by the Task Force. In addition to ensuring that a variety of treatment and recovery support services are available, MDHHS, under the direction of the Single State Authority, is actively involved in supporting prevention activities around the state that are aimed at decreasing opiate use and providing education on the impacts of use. Some of these efforts include:

- Increase multi-system collaboration at state and community levels
  - Assure and monitor PIHPs to develop and implement action plans for the prevention of prescription and over-the-counter drugs to prevent unintentional deaths from drug overdoses.
  - Provide training to strengthen infrastructure to enhance substance use disorder prevention and mental health promotion at the community/coalition level.
  - Promote to develop leadership structure combining MDHHS, Licensing and Regulatory Affairs, Law Enforcement and other stakeholders to oversee surveillance, intervention, education and enforcement to prevent illegal distribution and use of controlled substances.
- Broaden statewide media messages
  - Promote the use of statewide media campaign entitled: Do Your Part: Be the Solution to Prevent Prescription Drug Abuse ([www.michigan.gov/doyourpart](http://www.michigan.gov/doyourpart)), that includes information portals for parents, physicians, youth, educators and the general public interested in learning about prescription drug and opioid abuse.
- Broaden Rx/OTC drug abuse education and use of brief screenings in behavioral and primary health care settings
  - Ensure that public health approached to the delivery of early intervention such as SBIRT are implemented in behavioral and primary health care settings by providing funding and training
  - Ensure on-going surveillance to monitor data relevant to drug overdoses and deaths from drug overdoses

Michigan has developed new Medication Assisted Treatment guidelines that are consistent with the new federal guidelines and contain detailed statewide guidelines for treating people addicted to heroin and other opiates. The guidelines define mild, moderate and severe levels of addiction and then apply medication and behavioral therapy that research has shown to be most effective for that level of addiction. These guidelines will be incorporated into policy and practice and will lead efforts on changing how treatment will be delivered and viewed in Michigan during the implementation of the waiver. The MAT guidelines can be found at <https://macmhb.org/sites/default/files/attachments/files/Waller%20-%20Opioid%20Tx%20Guidelines.pdf>.

Recent legislation has allowed Naloxone to be made available to first responders and law enforcement and it is being used in communities around the state. Additional legislation is being passed to allow family members of those with opioid prescriptions to receive Naloxone as an additional way to prevent death from overdose.

## IX. Adolescent services

Statewide, an estimated 127,000 (14%) youth aged 16-21 had a substance use disorder (SUD). Thirty-seven percent of those youth also had identified mental health concerns. 4% of adolescents (12-16) used pain relievers for nonmedical reasons. In 2013, a total of 6,749 substance abuse treatment admissions for youth were reported by publicly funded SUD programs.

Adolescents require different models of service than adults. As indicated in the Continuum of Care section, adolescents that are enrolled in the Medicaid program and have or are at risk of an SUD will have access to early intervention, treatment and recovery services. Specifically, adolescents will have access to the following services:

- Early Intervention Services, including, but not limited to Screening, Brief Intervention, and Referral to Treatment (SBIRT).
- Outpatient Services including initiation services (assessment and treatment planning), individual, group and family therapy, crisis intervention services
- Intensive Outpatient Program and Partial Hospitalization
- Residential Services (3.1, 3.5 and 3.7)
- Inpatient Services (4.0)

Adolescents will also have access to the various Withdrawal Management Services set forth in the Continuum of Care Sections. When appropriate, older adolescents will also have access to SUD medications as part of the State's Medication Assisted Treatment approach.

While the current continuum reflects services that can be effective for treating adolescents with SUD, the state is aware that the current system of care reflects poor penetration rates for the treatment of adolescents and transitional youth age. Only approximately 8% of those with an identified need, receiving substance use disorder (SUD) treatment services

In response, the state has developed the Michigan Youth Treatment Infrastructure Enhancement (MYTIE) initiative. This two-year project (beginning in October of 2015) will guide the state in the development of an effective continuum of care for transitional aged youth 16-21 years of age and their caregivers, with the goal of increased access to and improved quality of treatment and recovery support services. MYTIE has several goals, including:

- Establish state infrastructure that will increase service access, treatment and recovery support service use and quality for transitional youth aged 16-21;
- Establish partnerships with key stakeholders for the purpose of developing policies, expanding workforce capacity, disseminating evidence-based practices, and implementing financial mechanisms;
- Identify issues and barriers that affect access and treatment of SUD and co-occurring

disorders;

- Identify disparities that effect access to treatment;
- Promote the development of statewide family and youth support organizations;

- Develop a strategic plan to guide needed changes to the service delivery system.

Information regarding the MYTIE program and a description of current activities regarding the needs assessment and workforce development can be found at:

[http://www.michigan.gov/mdhhs/0,5885,7-339-71550\\_2941\\_4871\\_4877\\_77211---,00.html](http://www.michigan.gov/mdhhs/0,5885,7-339-71550_2941_4871_4877_77211---,00.html).

Information from the gaps analysis in the MYTIE program will assist the State and PIHPs in their network development strategies, including age- appropriate recovery support services for adolescents.

## X. Quality measures

### 10. Reporting of Quality Measures

Michigan intends to develop a rigorous evaluation design that will utilize valid and reliable data, standardized measures and specifications, and robust methodology.

- 5) **Measures** Michigan will use the following measures to assess quality and access to care throughout the demonstration. Where nationally-recognized specifications for these measures exist, they will be utilized. Michigan will look for guidance from CMS on state-specific measures.

Measure	Steward	Data Source	Notes
Initiation and Engagement of Alcohol and Other Drug Dependence Treatment	NQF #0004	Data Warehouse (encounter data)	Admin data only (have baseline data)
SUB-3 Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge	NQF # 1664	To be determined	Admin and medical records
Follow-up after Discharge from the Emergency Department for Mental Health or Alcohol or Other Drug Dependence	NQF # 2605	Data warehouse (encounter data)	Admin data only (have baseline data)
Readmission rates (Plan All Cause Readmission)	NQF # 1768	Data Warehouse (encounter data)	May currently be available in Symmetry
Emergency Department Utilization	Need to determine a specific measure	Data Warehouse (encounter data)	Admin data only
Inpatient Utilization (IPU)	NCQA	Data Warehouse (encounter data)	May currently be available in Symmetry
Number of People Engaged in Recovery Support	State-specific	Data Warehouse (encounter data)	Need to determine exactly what they're asking
Length of Time in Formal Treatment	State-specific	Data Warehouse (encounter data)	Need to determine exactly what they're asking

Improvement in Overall Health	State-specific	Survey	Need to determine exactly what they're asking
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Measure	Steward	Data Source	Notes
Adult Access to Preventive/Ambulatory Services	NCQA	Data Warehouse (encounter data)	May currently be available in Symmetry
Rate of completed follow up appointments with Specialty Service System providers	State-specific	Data Warehouse (encounter data)	Need to determine the best way to measure

6) **Methodology** Baselines for two of the measures (Initiation and Engagement of Alcohol and Other Drug Dependence Treatment and Follow-up after Discharge from the Emergency Department for Mental

Health or Alcohol or Other Drug Dependence) have already been established and the state will continue to report on these data at least annually, including by December 31, 2016. For the remaining measures, we expect to establish baselines by the end of demonstration year 1. Data will be extracted for these measures for each PIHP and Michigan will allow the opportunity for stakeholder review and feedback on the methodology and results. Performance standards will be set using baseline data. Payment of bonus dollars will be contingent upon meeting quality thresholds. Reports will be published at intervals to be determined. Michigan’s complete pay-for-performance strategy is outlined in Section 8.4.2 (Contract Withholds) and Section 8.4.2.1 (2016 2016 Performance Bonus Integration of Behavioral Health and Physical Health Services) of the Medicaid Managed Specialty Supports and Services Concurrent 1915(b)/(c) Waiver Program FY 16 Contract, Amendment #1, available at <http://www.midstatehealthnetwork.org/docs/AmendmentNo-1ToFY16MSHN-MDHHSContract.pdf>.

7) **Improving partnerships** Building on work already done in Michigan, the demonstration will enhance the ability of Specialty Service System payers and providers to work with Medicaid Health Plans to improve service delivery by jointly developing processes, procedures, and methods for population identification and intervention.

**Addressing Social Determinants of Health** The demonstration will afford Michigan the opportunity to develop meaningful linkages to community- based resources that can assist providers in address social determinants (including housing) to their patients.

9) **Evaluation** The goal of the evaluation is to determine whether the waiver program impacts services utilization, cost, and health outcomes of SUD treatment. Michigan will work with an independent evaluator to ensure the highest rigor and adherence to evaluation methodology.

Because the demonstration is statewide, encompassing all patients who are eligible for the program Michigan will employ a time trend analysis evaluation design to validate the following hypotheses:

1. The demonstration increases access to services for patients in the intervention group.
2. The demonstration increases quality of care and enhances health outcomes for patients in the intervention versus the control group.
  - a. There are no differences in quality or outcomes by region, race/ethnicity, or other demographic factors.
3. The demonstration reduces overall utilization of emergency department visits, inpatient stays, and inpatient readmissions for patients in the intervention versus control group.
4. The demonstration reduces costs associated with utilization of emergency department visits, inpatient stays, and inpatient readmissions for patients in the intervention vs. control group.

Michigan will implement a formative evaluation design. In addition to the required mid-point evaluation report, the evaluator will develop interim reports on demonstration progress at intervals to be determined. The reports may be used to drive discussion, stakeholder engagement, and program/policy change at the state or provider level. A final evaluation report will be submitted as required.

#### **XI. Single state agency**

The single state agency for SUD is the Michigan Department of Health and Human Services (MDHHS), Behavioral Health and Developmental Disabilities Administration (BHDDA).

**Attachment A**

**MDHHS ASAM Residential Level of Care Designation Questionnaire**

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10) The Michigan Department of Health and Human Services (MDHHS) is required to designate the ASAM level of care for all licensed residential treatment facilities. In order to make this determination, the following questionnaire is required to be filled out for each licensed facility seeking to provide publicly funded services. The information provided and submitted with this questionnaire will allow MDHHS to assign an ASAM level for the program.

Program/Facility Name: [Click here to enter text.](#)

Facility Address: [Click here to enter text.](#)

City/State/Zip: [Click here to enter text.](#)

License Number: [Click here to enter text.](#)

Treatment Capacity: [Click here to enter text.](#)

Please indicate the ASAM Level being applied for:

- 3.1 Clinically Managed Low Intensity
- 3.3 Clinically Managed Population Specific High Intensity
- 3.5 Clinically Managed High Intensity
- 3.7 Medically Monitored Intensive Inpatient Services

Please indicate the population served by the program:

- Adolescent
- Adult

### SERVICE DELIVERY and SETTING

Please indicate the type of setting where services are provided.

- 1)  Freestanding community setting.
- 2)  Unit within a licensed health care facility.
- 3)  Secure community setting in the criminal justice system.
- 4) On average, over the past 90 days, what percentage of residents were treated for moderate or severe substance use disorders: (Total must equal 100%)
  - a. Without a co-occurring mental health disorder – %
  - b. Combined with a co-occurring mental health disorder – %
  - c. Combined with functional limitations that were primarily cognitive in

nature? (For example: Traumatic Brain Injury, Dementia, Memory Problems) – %

## SUPPORT SYSTEMS

11) Please select “yes” or “no” for each of the following questions:

- 1) Telephone or in-person consultation with physician and emergency services available 24/7?  
 Yes       No
- 2) Direct affiliations with other levels of care and/or close coordination for referrals to other services?       Yes       No
- 3) Ability to conduct and/or arrange for laboratory/toxicology tests or other needed procedures.       Yes       No
- 4) Ability to arrange for pharmacotherapy for psychiatric or anti-addiction medications.       Yes       No
- 5) Psychiatric/psychological consultation available as needed.  
 Yes       No

## STAFF

Please select “yes” or “no” for each of the following questions:

- 1) Professional staff available on-site 24 hours a day.  
 Yes       No
- 2) Treatment team consists of medical, addiction and mental health professionals.  
 Yes       No
- 3) One or more clinicians available on site or by telephone 24 hours a day.  
 Yes       No
- 4) Please indicate program staff conducting each service.

Check all that apply on the following table:

License or Certification/Registration	Individual Counseling Sessions	Group Counseling Sessions	Didactic/Educational Sessions	COD Treatment Services	Medical RX Services
MD/DO	<input type="checkbox"/>				
LP/LLP/TLLP	<input type="checkbox"/>				
LMFT/LLMFT	<input type="checkbox"/>				
LPC/LLPC	<input type="checkbox"/>				
RN,NP,LPN	<input type="checkbox"/>				
PA	<input type="checkbox"/>				
LMSW/LLMSW	<input type="checkbox"/>				
LBSW/LLBSW	<input type="checkbox"/>				
CADC-M/CADC	<input type="checkbox"/>				
CAADC	<input type="checkbox"/>				
CCJP-R	<input type="checkbox"/>				
CCDP	<input type="checkbox"/>				
CCDP-D	<input type="checkbox"/>				
CCS-M	<input type="checkbox"/>				
CCS-R	<input type="checkbox"/>				
DP-S	<input type="checkbox"/>				
DP-C	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**THERAPIES**

Please describe the therapy services that are available:

- 1) Planned clinical program activities (professionally directed) hours perweek:
- 2) Focus of counseling and clinical program activities: [Click here to enter text.](#)
- 3) Recovery support services available: [Click here to enter text.](#)

**4) Involvement of family members and significant others?**  
Yes      No

5) Medication assisted treatment available?  
Yes      No

6) Monitoring of medication adherence (for behavioral health and physical health)?  
Yes      No

7) Use of random drug screens to monitor compliance?

Yes

No

8) Please attach a weekly schedule of services with the individual, group,

educational and/or other treatment services labeled, in order to validate the service hours listed above. Please attach other programmatic documentation that will support the ASAM Level for which approval is being sought.

**ASSESSMENT/ TREATMENT PLAN REVIEW**

Does the program’s assessment & treatment plan review include:

- 1) Individualized, comprehensive bio-psychosocial assessment  
 utilized?  Yes  No
  
- 2) Individualized treatment plan, developed in collaboration with client and reflects client’s personal goals?  
 Yes       No
  
- 3) Daily assessment of progress and treatment  
 changes?  Yes  No
  
- 4) Physical examination by (MD/DO, PA, NP) performed as part of initial assessment/admission process?  
 Yes       No
  
- 5) Ongoing transition/continuing care  
 planning?  Yes  No

**I CERTIFY THAT THE INFORMATION PROVIDED REGARDING THE OPERATION OF THIS PROGRAM IS ACCURATE, TRUE, AND COMPLETE IN ALL MATERIAL ASPECTS. (Electronic signatures are acceptable)**

AUTHORIZED INDIVIDUAL	TITLE	SIGNATURE	DATE
Click here to enter text.			

**ENTER THE CONTACT INFORMATION OF THE PERSON THAT CAN BE REACHED FOR FOLLOW-UP IF NEEDED.**

<b>NAME</b>	<b>TITLE</b>	<b>EMAIL</b>	<b>TELEPHONE</b>
Click here to enter text.			

**ATTACHMENT E:  
Reserved for SUD Monitoring Protocol**