DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop: S2-25-26 Baltimore, Maryland 21244-1850



State Demonstrations Group

June 25, 2025

Meghan Groen
Senior Deputy Director
Behavioral and Physical Health and Aging Services Administration
Michigan Department of Health and Human Services
400 South Pine Street 7th Floor
Lansing, MI 48933-2250

Dear Director Groen:

The Centers for Medicare & Medicaid Services (CMS) is updating the section 1115 demonstration monitoring approach to reduce state burden, promote effective and efficient information sharing, and enhance CMS's oversight of program integrity by reducing variation in information reported to CMS.

Federal section 1115 demonstration monitoring and evaluation requirements are set forth in section 1115(d)(2)(D)-(E) of the Social Security Act (the Act), in CMS regulations in 42 CFR 431.428 and 431.420, and in individual demonstration special terms and conditions (STCs). Monitoring provides insight into progress with initial and ongoing demonstration implementation and performance, which can detect risks and vulnerabilities to inform possible course corrections and identify best practices. Monitoring is a complementary effort to evaluation. Evaluation activities assess the demonstration's success in achieving its stated goals and objectives.

Key changes of this monitoring redesign initiative include introducing a structured template for monitoring reporting, updating the frequency and timing of submission of monitoring reports, and standardizing the cadence and content of the demonstration monitoring calls.

Updates to Demonstration Monitoring

Below are the updated aspects of demonstration monitoring for the Michigan 1115 Behavioral Health Demonstration (Project Number 11-W-00305/5).

Reporting Cadence and Due Date

CMS determined that, when combined with monitoring calls, an annual monitoring reporting cadence will generally be sufficient to monitor potential risks and vulnerabilities in demonstration implementation, performance, and progress toward stipulated goals. Thus, pursuant to CMS's authority under 42 CFR 431.420(b)(1) and 42 CFR 431.428, CMS is

updating the cadence for this demonstration to annual monitoring reporting (see also section 1115(d)(2)(D)-(E) of the Act). This transition to annual monitoring reporting is expected to alleviate administrative burden for both the state and CMS. In addition, CMS is extending the due date of the annual monitoring report from 90 days to 180 days after the end of each demonstration year to balance Medicaid claims completeness with the state's work to draft, review, and submit the report timely.

CMS might increase the frequency of monitoring reporting if CMS determines that doing so would be appropriate. The standard for determining the frequency of monitoring reporting will ultimately be included in each demonstration's STCs. CMS expects that this standard will permit CMS to make on-going determinations about reporting frequency under each demonstration by assessing the risk that the state might materially fail to comply with the terms of the approved demonstration during its implementation and/or the risk that the state might implement the demonstration in a manner unlikely to achieve the statutory purposes of Medicaid. *See* 42 CFR 431.420(d)(1)-(2).

The Michigan 1115 Behavioral Health demonstration will transition to annual monitoring reporting effective June 25, 2025. The next annual monitoring report will be due on March 30, 2026, which reflects the first business day following 180 calendar days after the end of the current demonstration year. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect the new reporting cadence and due date.

Structured Monitoring Report Template

As noted in STC 44, "Monitoring Reports," 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." Pursuant to that STC, CMS is introducing a structured monitoring report template to minimize variation in content of reports across states, which will facilitate drawing conclusions over time and across demonstrations with broadly similar section 1115 waivers or expenditure authorities. The structured reporting framework will also provide CMS and the state opportunities for more comprehensive and instructive engagement on the report's content to identify potential risks and vulnerabilities and associated mitigation efforts as well as best practices, thus strengthening the overall integrity of demonstration monitoring.

This structured template will include a set of base metrics for all demonstrations. For demonstrations with certain waiver and expenditure authorities, there are additional policy-specific metrics that will be collected through the structured reporting template.

Some of the metrics currently required for Substance Use Disorder (SUD) and Serious Mental Illness (SMI)/Serious Emotional Disturbance (SED) demonstrations will no longer be required.

CMS is also removing the requirement for a Monitoring Protocol deliverable, which has been required under certain types of section 1115 demonstration, including but not limited to the SUD, SMI/SED, Health-Related Social Needs (HRSN), and reentry demonstrations. Removal of the

Monitoring Protocol requirement simplifies and streamlines demonstration monitoring activities for states and CMS.

Demonstration Monitoring Calls

As STC 46 "Monitoring Calls" describes, CMS may "convene periodic conference calls with the state," and the calls are intended "to discuss ongoing demonstration operation, including (but not limited to) any significant actual or anticipated developments affecting the demonstration." Going forward, CMS envisions implementing a structured format for monitoring calls to provide consistency in content and frequency of demonstration monitoring calls across demonstrations. CMS also envisions convening quarterly monitoring calls with the state and will follow the structure and topics in the monitoring report template. We anticipate that standardizing the expectations for and content of the calls will result in more meaningful discussion and timely assessment of demonstration risks, vulnerabilities, and opportunities for intervention. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect that monitoring calls will be held no less frequently than quarterly.

CMS will continue to be available for additional calls as necessary to provide technical assistance or to discuss demonstration applications, pending actions, or requests for changes to demonstrations. CMS recognizes that frequent and regular calls are appropriate for certain demonstrations and at specific points in a demonstration's lifecycle.

In the coming weeks, CMS will reach out to schedule a transition meeting to review templates and timelines outlined above. As noted above, the pertinent Michigan 1115 Behavioral Health demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect these updates.

If you have any questions regarding these updates, please contact Danielle Daly, Director of the Division of Demonstration Monitoring and Evaluation, at Danielle.Daly@cms.hhs.gov.

Sincerely,

Karen LLanos
Acting Director

Enclosure

cc: Christine Davidson, State Monitoring Lead, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES EXPENDITURE AUTHORITY

NUMBER: 11-W-00305/5

TITLE: Michigan 1115 Behavioral Health Demonstration

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

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

- 1. Residential Treatment for Individuals with Substance Use Disorder (SUD). Expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD).
- 2. Time-Limited Expenditure Authority for 1915(i)-Like Services. Expenditures for 1915(i)-like home and community based (HCBS) services provided to individuals starting October 1, 2019, and ending September 30, 2023. During this period, the state will develop and implement a framework for performing independent assessments of financial and functional eligibility. As of October 1, 2023, all individuals will receive 1915(i) services in the State Plan Amendment effective on that date.
- 3. PrePaid Inpatient Health Plan (PIHP) Services. Expenditures for all PIHP services including case management and health education services that are not available to other Medicaid beneficiaries to the extent that not all services for categorically needy individuals will be equal in amount, duration, and scope. The state will be required to ensure that all beneficiaries use a specific regional PIHP plan and to restrict disenrollment from them. The state is also granted the authority to restrict freedom of choice of provider for the demonstration eligible population.

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

NUMBER: 11-W-00305/5

TITLE: Michigan 1115 Behavioral Health Demonstration

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

I. PREFACE

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

The STCs have been arranged into the following subject areas:

- I. <u>Preface</u>
- II. Program Description and Objectives
- III. General Program Requirements
- IV. Eligibility and Enrollment
- V. <u>Substance Use Disorder (SUD) Program</u>
- VI. Cost Sharing
- VII. Delivery System
- VIII. Eligibility Transition for HCBS State Plan Benefit
 - IX. General Reporting Requirements
 - X. Monitoring
 - XI. Evaluation of the Demonstration
- XII. General Financial Requirements Under Title XIX
- XIII. Monitoring Budget Neutrality for the Demonstration
- XIV. Schedule of Deliverables for the Demonstration

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

Attachment A: Developing the Evaluation Design

Attachment B: Preparing the Interim and Summative Evaluation Reports

Attachment C: Reserved for Evaluation Design Attachment D: OUD/SUD Implementation Plan

Attachment E: Reserved for OUD/SUD Monitoring Protocol

II. PROGRAM DESCRIPTION AND OBJECTIVES

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

This demonstration sought to accomplish these efforts by:

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

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

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

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

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

III. GENERAL PROGRAM REQUIREMENTS

- 1. Compliance with Federal Non-Discrimination Laws. The state must comply with applicable federal civil rights laws relating to non-discrimination in services and benefits in its programs and activities. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and Section 1557 of the Affordable Care Act (Section 1557). Such compliance includes providing reasonable modifications to individuals with disabilities under the ADA, Section 504, and Section 1557 in eligibility and documentation requirements, to ensure they understand program rules and notices, in establishing eligibility for an exemption from community engagement requirements on the basis of disability, and to enable them to meet and document community engagement requirements, as well as meeting other program requirements necessary to obtain and maintain benefits.
- 2. Compliance with Medicaid Law, Regulation, and Policy. All requirements of the Medicaid program, expressed in federal law, regulation, and written policy, not expressly waived or identified as not applicable in the expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

3. Changes in Medicaid Law, Regulation, and Policy. The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes of an operational nature without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 calendar days in advance of the expected approval date of the amended STCs to allow the state to provide comment.

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

- a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
- b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under federal law, whichever is sooner.
- **5. State Plan Amendments.** The state will not be required to submit title XIX state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan may be required, except as otherwise noted in these STCs. In all such instances, the Medicaid state plan governs.
- **6.** Changes Subject to the Amendment Process. If not otherwise specified in these STCs, changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7, except as provided in STC 3.
- **7. Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the

change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit reports required in the approved STCs and other deliverables in a timely fashion according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:

- a. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
- b. A data analysis worksheet which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detail projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
- c. An explanation of the public process used by the state consistent with the requirements of STC 13; and,
- d. If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.
- **8. Extension of the Demonstration.** States that intend to request a demonstration extension under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in statute. Otherwise, no later than twelve (12) months prior to the expiration date of the demonstration, the Governor or Chief Executive Officer of the state must submit to CMS either a demonstration extension request that meets federal requirements at 42 CFR 431.412(c) or a transition and phase-out plan consistent with the requirements of STC 9.
- **9. Demonstration Phase Out.** The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements:
 - a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six (6) months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 13, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

- b. <u>Transition and Phase-out Plan Requirements</u>. 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. <u>Transition and Phase-out Plan Approval</u>. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.
- d. Transition and Phase-out Procedures. The state must 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. <u>Exemption from Public Notice Procedures 42 CFR Section 431.416(g)</u>. 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. <u>Federal Financial Participation (FFP)</u>. 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. <u>Expiration Requirements</u>. 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. <u>Federal Public Notice</u>. 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. <u>Federal Financial Participation (FFP)</u>. FFP will be limited to normal closeout costs associated with the expiration of the demonstration authority including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.
- 11. Withdrawal of Expenditure Authority. CMS reserves the right to withdraw expenditure authorities at any time it determines that continuing the expenditure authorities would no longer be in the public interest or promote the objectives of title XIX. CMS must promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the expenditure authority,

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

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

The state must also comply with tribal and Indian Health Program/Urban Indian Health Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 7 or extension, are proposed by the state.

The state must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

- **14. Federal Financial Participation (FFP).** No federal matching for state expenditures under this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.
- 15. Common Rule Exemption. The state shall ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid program including procedures for obtaining Medicaid benefits or services, possible changes in or alternatives to Medicaid programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. The Secretary has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.101(b)(5).

IV. ELIGIBILITY AND ENROLLMENT

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

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

V. SUBSTANCE USE DISORDER (SUD) PROGRAM

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

The coverage of OUD/SUD treatment services and withdrawal management services during short-term residential and inpatient stays in IMDs will expand Michigan's current SUD benefit package available to all Michigan Medicaid recipients as outlined in Table 1. OUD/SUD treatment services and withdrawal management services approved through the state plan as well as expenditure authority to cover and provide FFP for such services for individuals residing in an IMD approved through this demonstration will be available to all Michigan Medicaid recipients who meet medical necessity criteria for services. Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

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

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

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 (Individual services covered)	Services provided to individuals in IMDs
Medically Supervised Withdrawal Management	State plan	Services provided to individuals in IMDs
Inpatient Services	State plan (Individual Services covered)	Services provided to individuals in IMDs
SUD Support Services	State plan (Individual services covered)	Services provided to individuals in IMDs

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

- 18. OUD/SUD Implementation Plan. The state must submit a OUD/SUD Implementation Plan within 90 calendar days after approval of the OUD/SUD program under this demonstration. The state may not claim FFP for services provided in IMDs until CMS has approved the SUD Implementation Plan. CMS is approving the OUD/SUD Implementation Plan concurrently with this demonstration. The approved OUD/SUD Implementation Plan appears as Attachment D and may be altered only with CMS approval. After approval of the OUD/SUD Implementation Plan, FFP will be available prospectively, not retrospectively. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral. At a minimum, the OUD/SUD Implementation Plan will describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives of the OUD/SUD component of this demonstration program:
 - a. Access to Critical Levels of Care for OUD and other SUDs: Service delivery for new benefits, including residential treatment and withdrawal management, within 12-24 months of OUD/SUD program demonstration approval;

- b. Use of Evidence-based SUD-specific Patient Placement Criteria:

 Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other patient placement assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of OUD/SUD program demonstration approval;
- c. **Patient Placement:** Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of SUD program demonstration approval;
- d. Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities: Currently, residential treatment service providers must be a licensed organization, pursuant to the residential service provider qualifications described in the *State Administrative Rules for the Licensure of Substance Use Disorder Programs*. The state will establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of OUD/SUD program demonstration approval;
- e. **Standards of Care:** Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of SUD program demonstration approval;
- f. **Standards of Care:** Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of SUD program demonstration approval;
- g. Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for OUD: An assessment of the availability of providers in the key levels of care throughout the state, or in the regions of the state participating under this demonstration, including those that offer MAT within 12 months of SUD program demonstration approval;
- h. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD: Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;

- i. Improved Care Coordination and Transitions between levels of care: Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of SUD program demonstration approval.
- 19. OUD/SUD Monitoring Protocol. The state must submit a OUD/SUD Monitoring Protocol within 150 calendar days after approval of the OUD/SUD Demonstration. The OUD/SUD Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. Once approved, the OUD/SUD Monitoring Protocol will be incorporated into the STCs, as Attachment E. At a minimum, the SUD Monitoring Plan Protocol must include reporting relevant to each of the program implementation areas listed in STC 18. The SUD Monitoring Protocol must specify the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in Section VIII of the demonstration. In addition, the SUD Monitoring Protocol must identify a baseline, and a target to be achieved by the end of the demonstration. Where possible, baselines must be informed by state data, and targets will be benchmarked against performance in best practice settings. CMS will closely monitor demonstration spending on services in IMDs to ensure adherence to budget neutrality requirements. Progress on the performance measures identified in the Monitoring Protocol must be reported via the quarterly and annual monitoring reports.
- 20. Mid-Point Assessment. The state must conduct an independent mid-point assessment by December 31, 2022. The state must require that the assessor must collaborate with key stakeholders, including representatives of MCOs, SUD treatment providers, beneficiaries, and other key partners in the design, planning and conducting of the mid-point assessment. The state must require that the assessment will include an examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plan, and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol. The state must require that the assessment include a determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date, and a determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and about the risk of possibly missing those milestones and performance targets. The state must require that the mid-point assessment also provide a status update of budget neutrality requirements. For each milestone or measure target at medium to high risk of not being met, the state must require that the assessor provide, for consideration by the state, recommendations for adjustments in the state's implementation plan or to pertinent factors that the state can influence that will support improvement. The state must require that the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS. The state must brief CMS on the report. For milestones and measure targets at medium to high risk of not being achieved, the state will

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

- **21. Deferral for Insufficient Progress Towards Milestones and Failure to Report Measurement Data.** If the state does not demonstrate sufficient progress on milestones, as specified in the Implementation Protocol, as determined by CMS, or fails to report data as approved in the Monitoring Protocol Monitoring Protocol, CMS will defer funds in the amounts specified in STC 40 and STC 41 for each incident of insufficient progress or failure to report in each reporting quarter.
- **22. OUD/SUD Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, the Evaluation Design to including the SUD program with implementation timeline, no later than one hundred eighty (180) days after the effective date of these STCs. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state must use an independent evaluator to develop the draft Evaluation Design.
 - a. Evaluation Design Approval and Updates. The state must submit a revised draft Evaluation Design within sixty (60) days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the Quarterly and Annual Reports, including any required Rapid Cycle Assessments specified in these STCs. Once CMS approves the evaluation design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.
 - b. Evaluation Questions and Hypotheses Specific to the OUD/SUD Program.

 Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component must have at least one evaluation question and hypothesis. The hypothesis testing must include, where possible, assessment of both process and outcome measures. Proposed measures must be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
- **23. SUD Health Information Technology (Health IT).** The state must provide CMS with an assurance that it has a sufficient health IT infrastructure/"ecosystem" at every appropriate

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

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

¹ Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance prescriptions in states. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the "opioid" epidemic and facilitate a nimble and targeted response.
² Ibid.

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

- h. The state may use resources at Health IT.Gov (https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/) in "Section 4: Opioid Epidemic and Health IT."
- i. The state may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. The state must review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing its SUD Health IT Plan.
- j. The state may request from CMS technical assistance to conduct an assessment and develop plans to ensure it has the specific health IT infrastructure with regards to PDMP plans and, more generally, to meet the goals of the demonstration.
- k. The state must include in its SUD Monitoring Protocol (STC 19) an approach to monitoring its SUD Health IT Plan which will include performance metrics provided by CMS or State defined metrics to be approved in advance by CMS.
- l. The state must monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in in an addendum to its Annual Reports (STC 31).
- m. As applicable, the state must advance the standards identified in the 'Interoperability Standards Advisory—Best Available Standards and Implementation Specifications' (ISA) in developing and implementing the state's SUD Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.
 - i. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state must use the federally-recognized standards, barring another compelling state interest.
 - ii. Where there are opportunities at the state and provider level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state must use the federally-recognized ISA standards, barring no other compelling state interest.

VI. COST SHARING

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

VII. DELIVERY SYSTEM

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

- **26. Type of Managed Care.** The state is authorized to operate a risk based Prepaid Inpatient Health Plan (PIHP) as defined under 42 CFR 438.2. One PIHP will operate in each geographical region designated by the state.
- **27. Contracts**. No FFP is available for activities covered under contracts and/or modifications to existing contracts that are subject to 42 CFR 438 requirements prior to CMS approval of such contracts and/or contract amendments. The State will provide CMS with a minimum of 60 days to review and approve changes.
- **28. Enrollment**. The State will mandatorily and passively enroll the following groups of beneficiaries into a PIHP:
 - a. Section 1931 Children and Related Populations are children including those eligible under Section 1931, poverty-level related groups and optional groups of older children;
 - b. Section 1931 Adults and Related Populations are adults including those eligible under Section 1931, poverty-level pregnant women and optional group of caretaker relatives;
 - c. Blind/Disabled Adults and Related Populations are beneficiaries, age 18 or older, who are eligible for Medicaid due to blindness or disability. Report Blind/Disabled Adults who are age 65 or older in this category, not in Aged;
 - d. Blind/Disabled Children and Related Populations are beneficiaries, generally under age 18, who are eligible for Medicaid due to blindness or disability;
 - e. Aged and Related Populations are those Medicaid beneficiaries who are age 65 or older and not members of the Blind/Disabled population or members of the Section 1931 Adult population;
 - f. Foster Care Children are Medicaid beneficiaries who are receiving foster care or adoption assistance (Title IV-E), are in foster-care, or are otherwise in an out-of-home placement: and
 - g. New adults.
- **29. Disenrollment and choice of providers**. Beneficiaries cannot disenroll from the PIHP in their area. However, for specific services within the PIHP network, the beneficiary may choose from among a range of available network providers, and may change providers within the PIHP at any time. In addition, in some special circumstances, a beneficiary may wish to receive services from a provider that is part of another PIHP's provider network. In these situations, the PIHP may make arrangements to contract with that provider.
- **30. Transition Plan for Care Coordination**. The state must develop a transition of care policy consistent with 438.62(b)(1). In the event the State intends to transition beneficiaries to an alternative delivery system, the State will timely inform CMS how the transition will comply with their transition of care policy.

VIII. TRANSITIONAL ELIGIBILITY FOR HCBS REQUIREMENTS

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

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

IX. GENERAL REPORTING REQUIREMENTS

- **39. Submission of Post-approval Deliverables.** The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.
- **40. Deferral for Failure to Submit Timely Demonstration Deliverables.** CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of \$5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to

CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

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

- a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
- b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state's written extension request.
- c. If CMS agrees to an interim corrective plan in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.
- d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement with respect to required deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified in these STCs, the deferral(s) will be released.
- e. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.
- **41. Deferral of Federal Financial Participation (FFP) from IMD claiming for Insufficient Progress toward Milestones.** Up to \$5,000,000 in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones and goals as evidenced by reporting on the milestones in the Implementation Plan and the required performance measures in the Monitoring Protocol agreed upon by the state and CMS. Once CMS determines the state has not made adequate progress, up to \$5,000,000 will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined

sufficient progress has been made. The state is expected to meet the milestones by the end of the first two years of the SMI demonstration.

- **42. Compliance with Federal Systems Updates.** As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state will work with CMS to:
 - a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
 - b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
 - c. Submit deliverables to the appropriate system as directed by CMS.
- 43. Cooperation with Federal Evaluators. As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors' in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 40.

X. MONITORING

- 44. Monitoring Reports. The state must submit three (3) Quarterly Reports and one (1) compiled Annual Report each DY. The information for the fourth quarter should be reported as distinct information within the Annual Report. The Quarterly Reports are due no later than sixty (60 calendar days) following the end of each demonstration quarter. The compiled Annual Report is due no later than ninety (90 calendar days) following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.
 - a. Operational Updates Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends;

- legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
- b. Performance Metrics Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.
- c. <u>Budget Neutrality and Financial Reporting Requirements</u> Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately.
- d. <u>Evaluation Activities and Interim Findings</u> Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.
- e. <u>SUD Health IT -</u> The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 23.
- **45. Close-Out Report**. Within 120 calendar days after the expiration of the demonstration, the state must submit a Draft Close-Out Report to CMS for comments.
 - a. The draft close-out report must comply with the most current Guidance from CMS
 - b. The state will present to and participate in a discussion with CMS on the close-out report.
 - c. The state must take into consideration CMS' comments for incorporation into the final close-out report.
 - d. The final close-out report is due to CMS no later than 30 calendar days after receipt of CMS' comments.
 - e. A delay in submitting the draft or final version of the close-out report may subject the state to penalties described in STC 21.
- **46. Monitoring Calls.** CMS will convene periodic conference calls with the state.

- a. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, enrollment and access, budget neutrality, and progress on the evaluation.
- b. CMS will provide updates on any amendments or concept papers under review, as well as federal policies and issues that may affect any aspect of the demonstration.
- c. The state and CMS will jointly develop the agenda for the calls.
- **47. Post Award Forum.** Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 30 calendar days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state must also post the most recent annual report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Report.

XI. EVALUATION OF THE DEMONSTRATION

- **48. Independent Evaluator.** Upon approval of the demonstration, the state must begin arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party to sign an agreement to conduct the demonstration evaluation in an independent manner in accord with the CMS-approved, Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.
- **49. Evaluation Budget.** A budget for the evaluation must be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluation such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.
- **50. Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after the effective date of these STCs. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable.

- **51.** Evaluation Design Approval and Updates. The state must submit a revised draft Evaluation Design within sixty (60) days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design to the state's website within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in theses STCs. Once CMS approves the evaluation design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.
- 52. Evaluation Questions and Hypotheses. Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
- **53. Interim Evaluation Report.** The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Report should be posted to the state's website with the application for public comment.
 - a. The interim evaluation report will discuss evaluation progress and present findings to date as per the approved evaluation design.
 - b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
 - c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses, and how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.

- d. The state must submit the final Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.
- e. The Interim Evaluation Report must comply with Attachment B of these STCs.
- **54. Summative Evaluation Report.** The draft Summative Evaluation Report must be developed in accordance with Attachment B of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period, October 1 2019 to September 30, 2024, within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.
 - a. Unless otherwise agreed upon in writing by CMS, the state must submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.
 - b. The final Summative Evaluation Report must be posted to the state's Medicaid website within 30 calendar days of approval by CMS.
- **55. State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the interim evaluation, and/or the summative evaluation.
- **56. Public Access**. The state shall post the final documents (e.g., Monitoring Reports, Close Out Report, approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's Medicaid website within 30 days of approval by CMS.
- 57. Additional Publications and Presentations. For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10 business days to review and comment on publications before they are released. CMS may choose to decline to comment or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

XII. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

58. Standard Medicaid Funding Process. The standard Medicaid funding process must be used during the demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report those

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

- **59.** Extent of Federal Financial Participation for the Demonstration. Subject to CMS approval of the source(s) of the non-federal share of funding. CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole for the following, subject to the limits described in Section XII:
 - a. Administrative costs, including those associated with the administration of the demonstration;
 - b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
 - c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.
- **60. Sources of Non-Federal Share.** The state certifies that the matching non-federal share of funds for the demonstration is state/local monies. The state further certifies that such funds must not be used as the match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.
 - a. The state acknowledges that CMS has authority to review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS must be addressed within the time frames set by CMS.
 - b. The state acknowledges that any amendments that impact the financial status of the program must require the state to provide information to CMS regarding all sources of the non-federal share of funding.
- **61. State Certification of Funding Conditions.** The state must certify that the following conditions for non-federal share of demonstration expenditures are met:
 - a. Units of government, including governmentally operated health care providers, may certify that state or local monies have been expended as the non-federal share of funds under the demonstration.

- b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
- c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR 433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match;
- d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments.
- e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.
- **62. Program Integrity.** The state must have a process in place to ensure that there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.
- **63. Medicaid Expenditure Groups (MEG).** MEGs are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The Master MEG Chart table provides a master list of MEGs defined for this demonstration.

Table 2: Master MEG Chart							
MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description		
DAB	Нуро 1	X		X	Includes non-dual and dual eligible members who are enrolled in the disabled, aged, or blind (DAB) eligibility categories.		
TANF	Нуро 1	X		X	Includes non-dual and dual eligible members who are enrolled in the Temporary Assistance for Needy Families (TANF) eligibility categories.		
НМР	Нуро 1	X		X	Includes non-dual and dual eligible members who are enrolled in the Healthy Michigan Plan (HMP) eligibility categories.		
HSW	Нуро 1	X		X	Includes members who are enrolled in the 1915 (c) Habilitation Supports Waiver (HSW) program.		
SED	Нуро 1	X		X	Includes members who are enrolled in the 1915(c) Serious Emotional Disturbances (SED) Waiver program.		
CWP	Нуро 1	X		X	Includes members who are enrolled in the 1915(c) Children's Waiver Program (CWP)		
SUD IMD- DAB	Нуро 1	X		X	All expenditures for costs of medical assistance that could be covered, were it not for the IMD prohibition under the state plan, provided to individuals in the DAB eligibility category during a month in which the		

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

- **64. Reporting Expenditures and Member Months.** The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00305/5). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.
 - a. <u>Cost Settlements</u>. The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b, in lieu of lines 9 or 10c. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.
 - b. <u>Premiums and Cost Sharing Collected by the State.</u> The state will report any premium contributions collected by the state from demonstration enrollees

quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by DY on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.

- c. <u>Pharmacy Rebates.</u> Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.
- d. <u>Administrative Costs.</u> The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the Master MEG Chart table, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

Member Months. As part of the Quarterly and Annual Monitoring Reports described in section IX, the state must report the actual number of "eligible member months" for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. The term "eligible member months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.

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

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

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

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

	type of			
	service			

- e. <u>Budget Neutrality Specifications Manual.</u> The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state's Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.
- **65. Demonstration Years.** Demonstration Years (DY) for this demonstration are defined in the Demonstration Years table below.

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

66. Budget Neutrality Monitoring Tool. The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the Performance Metrics Database and Analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing demonstration's actual expenditures to the budget neutrality expenditure limits described in section XI. CMS will provide technical assistance, upon request. ⁶

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

- 67. Claiming Period. The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.
- **68. Future Adjustments to Budget Neutrality.** CMS reserves the right to adjust the budget neutrality expenditure limit:
 - a. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments, CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.
 - b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.
 - c. The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

XIII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

69. Limit on Title XIX Funding. The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the

state would likely have received in the absence of the demonstration. The limit may consist of a Main Budget Neutrality Test, and one or more Hypothetical Budget Neutrality Tests, as described below. CMS' assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.

- **70. Risk.** The budget neutrality expenditure limits are determined on either a per capita or aggregate basis. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the for all demonstration populations, CMS will not place the state at risk for changing economic conditions. However, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration.
- 71. Calculation of the Budget Neutrality Limit and How It Is Applied. To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits will then be added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality limit by appropriate Composite Federal Share.
- 72. Main Budget Neutrality Test. The Main Budget Neutrality Test allows the state to show that demonstration expenditure authorities granted have not resulted in increased costs to Medicaid, and that federal Medicaid "savings" have been achieved sufficient to offset the additional projected federal costs resulting from expenditure authority. The table below identifies the MEGs that are used for the Main Budget Neutrality Test. MEGs designated as "WOW Only" or "Both" are components used to calculate the budget neutrality expenditure limit. MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against the budget neutrality expenditure limit. In addition, any expenditures in excess of limit from Hypothetical Budget Neutrality Tests count as expenditures under the Main Budget Neutrality Test. The Composite Federal Share for this test is calculated based on all MEGs indicated as "Both."

MEG	PC or Agg*	WOW Only, WW Only, or Both	TREND	DY1 - PMPM	DY2 – PMPM	DY3 – PMPM	DY4 – PMPM	DY5 – PMPM
-----	---------------	--	-------	---------------	---------------	---------------	---------------	---------------

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

- 73. Hypothetical Budget Neutrality. When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be "hypothetical;" that is, the expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS's current view that states should not have to "pay for," with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state's WW hypothetical spending exceeds the supplemental test's expenditure limit, the state agrees (as a condition of CMS approval) to refund the FFP to CMS.
- 74. Hypothetical Budget Neutrality Test 1: Substance Use Disorder Expenditures. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical

Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

- 75. Composite Federal Share Ratios. The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Main or Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.
- 76. Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from October 1, 2019 to September 30, 2024. The budget neutrality limits calculated in STC 72 will apply to actual expenditures for demonstration services as reported by the state under section XIII of these STCs. Actual expenditures are from a state and federal basis, including managed care capitation payments for members enrolled in managed care programs and fee-for-service (FFS) claims for services or members carved out of MDHHS' managed care programs. If at the end of the demonstration period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.
- 77. Mid- Course Correction. If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

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

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

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

XIV. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

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

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

ATTACHMENT A Developing the Evaluation Design

Introduction

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

Expectations for Evaluation Designs

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

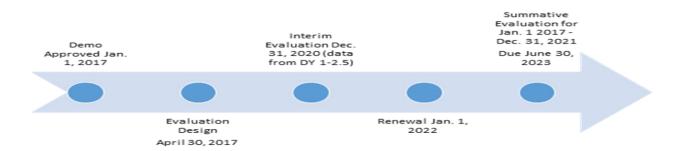
The format for the Evaluation Design is as follows:

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

Submission Timelines

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

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



Required Core Components of All Evaluation Designs

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

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

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

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

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

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

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

- methodology for the populations, as well as support that a statistically reliable sample size is available.
- 3) Evaluation Period Describe the time periods for which data will be included.
- 4) Evaluation Measures List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:
 - a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
 - b. Qualitative analysis methods may be used, and must be described in detail.
 - c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
 - d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
 - f. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
 - g. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.
- 5) *Data Sources* Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.
 - If primary data (data collected specifically for the evaluation) The methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection. (Copies of any proposed surveys must be reviewed with CMS for approval before implementation).
- 6) Analytic Methods This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:

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

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

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

D. Methodological Limitations – This section provides 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

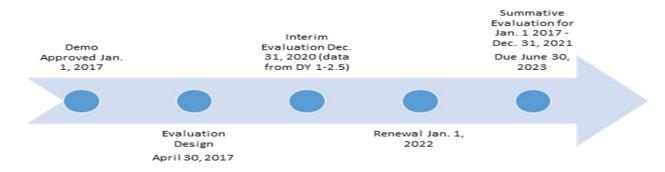
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved 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. Attachmen Design	t - Evaluation Desig	gn: Provide the C	CMS-approved E	valuation

University of Michigan Institute for Healthcare Policy and Innovation (IHPI)

Proposed Evaluation of Michigan's 1115 Behavioral Health Demonstration Waiver

Pursuant to Special Terms and Conditions 50-52 of Michigan's Approved 1115 Behavioral Health Demonstration Waiver

Table of Contents

A.	Background	1
	A.1 Overview of Michigan's behavioral health system	1
	A.2 SUD/OUD burden and inadequate treatment options in Michigan	2
	A.3 Other relevant contextual factors	4
	A.4 Goals of Michigan's Behavioral Health Demonstration Waiver	4
	A.5 Population served by the demonstration	6
В.	Evaluation Overview and Driver Diagram	7
C.	Methodology	8
	C.1 Evaluation design summary	8
	C.2 Data sources, evaluation measures, and analytic approach	. 20
	C.2.1 State administrative data	. 20
	C.2.2 Beneficiary surveys	. 23
	C.2.3 State monitoring reports and audit data	. 27
	C.2.4 Key informant interviews	. 28
	C.2.5 Program administrative cost data	. 30
	C.3 Evaluation period, timeline, and budget	. 31
D.	Methodological Limitations	. 31
Ε.	Evaluation Team	. 33
Tal	bles	
	Table 1. Anticipated Timing of Implementation	6
	Table 2. Hypotheses & Research Questions	. 10
	Table 3. Major evaluation reporting deliverables	. 31
Ар	pendix	
	Evaluation budget	. 35
	Evaluation timeline	. 36
	MODRN Measures and Patriating States	37

Michigan's Behavioral Health Demonstration Waiver - Evaluation Plan

Submitted to the Michigan Department of Health and Human Services from the University of Michigan Institute for Healthcare Policy and Innovation (IHPI) February 6, 2020

A. Background

The Centers for Medicare & Medicaid Services (CMS) approved Michigan's 1115 Demonstration Waiver amendment entitled: *Michigan's 1115 Behavioral Health Demonstration Waiver* (Project No I I-W-00305/5) on April 5, 2019, for the period of October 1, 2019, through September 30, 2024. As noted in the Special Terms and Conditions (STCs), the demonstration will allow Michigan to broaden the crucial component of residential substance disorder services (SUD) in the state's existing network of SUD providers and SUD benefits to provide a broader continuum of care for beneficiaries seeking help with a SUD, including withdrawal management services in residential treatment facilities that meet the definition of an Institution for Mental Disease (IMD). 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.

A.1 Overview of Michigan's behavioral health system

The Michigan Department of Health and Human Services' (MDHHS) Behavioral Health and Developmental Disabilities Administration (BHDDA), serves as the single state agency for mental health and SUD services. Through that designation, it is primarily responsible for the administration of behavioral health prevention, early identification, treatment, and recovery support services. BHDDA provides oversight to contracted Prepaid Inpatient Health Plans (PIHPs) and Community Mental Health Services Programs (CMHSPs) for the provision of specialty behavioral health supports and services. BHDDA's sister state agency, the Medical Services Administration (MSA), is also located within MDHHS, and functions as the State Medicaid Agency. MSA's primary responsibility is oversight of Michigan's Medicaid program. MSA manages comprehensive physical health services through Medicaid Health Plans (MHPs) including outpatient mental health services for individuals with mild to moderate behavioral health needs. MSA also oversees a fee-for-service benefit for office based opioid treatment providers outside the PIHP and MHP delivery systems.

In conjunction with MSA, BHDDA provides oversight of Medicaid-funded SUD services via the PIHP delivery system. BHDDA also oversees SUD appropriations, the Substance Abuse and Mental Health Services Administration's (SAMHSA) Substance Abuse Prevention and Treatment Block Grant, the SAMHSA Mental Health Block Grant, discretionary SAMHSA SUD grants, and other Medicaid-funded specialty supports and services. BHDDA carries out responsibilities specified in the Michigan Mental Health Code and the Michigan Public Health Code.

To achieve its charge, BHDDA contracts with regional PIHPs and local CMHSPs. PIHPs are public regional entities that serve as the state's publicly operated managed behavioral health plans for Medicaid-funded behavioral health specialty services and supports. PIHPs also serve as the department designated community mental health entity for substance use disorder prevention and treatment per the Mental Health Code. Ten regionalized PIHPs operate throughout the state and contract directly with MDHHS. All enrolled Medicaid beneficiaries are enrolled in a PIHP based on their county of residence. PIHPs, in turn, contract with SUD providers and CMHSPs to deliver public behavioral health services in Michigan. CMHSPs are publicly funded entities, created by county governments, that provide a comprehensive array of mental health services to meet local needs, regardless of an individual's ability to pay. CMHSPs provide Medicaid, state, block grant, and locally funded services to children with serious emotional disturbances, adults with serious mental illness, and children and adults with intellectual/developmental disabilities. CMHSPs provide these services either directly or through contracts with community-based providers. Some CMHSPs also contract to provide outpatient and other substance use disorder treatment services (residential, detoxification, and inpatient rehabilitation).

A.2 SUD/OUD burden and inadequate treatment options in Michigan

Michigan is experiencing a public health crisis related to SUD and OUD. The National Survey on Drug Use and Health (NSDUH) reported approximately 62,000 Michiganders had a past year pain reliever use disorder in 2017. According to published raw data from the Michigan Automated Prescription System (MAPS), more than 11.4 million prescriptions for controlled substances were written in 2016 – an increase of roughly one million additional prescriptions from 2011, despite a slight decrease in Michigan's population over the same period.

The negative impact of SUD/OUD is evident in the substantial increase in hospitalization linked to opioids: from 2000 to 2011 Michigan's hospitalization rate increased from 9.2 to 20.4 per 10,000 residents. Drug-related overdose deaths in Michigan increased from roughly 985 in 2005 to nearly 2,700 in 2017. The 2017 overdose rate for Michigan was 27 deaths per 100,000, substantially higher than the national average of 21.6 per 100,000.

Several efforts have occurred to identify policy approaches to addressing SUD/OUD treatment needs. In August 2019, Governor Gretchen Whitmer created the Michigan Opioids Task Force, chaired by Dr. Joneigh Khaldun, chief medical executive for the State of Michigan.⁴ The task force is charged with identifying the root causes of the opioid epidemic and implementing response actions to help Michiganders struggling with opioid addiction access the recovery services they need. The task force will also work to raise public awareness about the opioid

¹ SAMHSA National Survey on Drug Use and Health. 2016-2017 NSDUH State-Specific Tables. https://www.samhsa.gov/data/report/2016-2017-nsduh-state-specific-tables.

² Michigan Department of Community Health. Opioid-Related Hospitalizations in Michigan, 2000-2011. https://www.michigan.gov/documents/mdch/Opioid-Related_Hospit_2000-2011_05-31-13_427136_7_431273_7.pdf

³ Centers for Disease Control and Prevention. National Center for Health Statistics: Drug Overdose Mortality by State. https://www.cdc.gov/nchs/pressroom/sosmap/drug poisoning mortality/drug poisoning.htm

⁴ Michigan Executive Order No. 2019-18. https://www.michigan.gov/whitmer/0,9309,7-387-90499 90705-505270--,00.html

epidemic and the resources available to those impacted by it. Task force membership includes representatives from key state agencies and departments. The work of this group will complement and extend the efforts of Former Governor Rick Snyder's Prescription Drug and Opioid Task Force that worked to address the state's burgeoning opioid crisis across five areas: prevention, treatment, regulation, policy and outcomes, and enforcement. In 2013, CMS awarded Michigan a State Innovation Model (SIM) Design award that resulted in Michigan's "Blueprint for Health Innovation," which identified that lack of access to services for individuals with SUD and other behavioral health needs was a major driver of unnecessary hospital and emergency department utilization. More recently, MDHHS's engagement in the CMS Innovation Accelerator Program (IAP) for SUD aims to extend the state's comprehensive array of SUD/OUD and behavioral health treatment and, and to ensure more consistent use of industry-standard benchmarks to promote the use of evidence-based SUD services and strengthen SUD/OUD provider qualifications. MDHHS has also leveraged enhanced Medicaid authorities via the federal SUPPORT Act of 2018, including the Opioid Health Home currently implemented in PIHP Region 2. Even more recently, MDHHS applied for the Section 1003 SUD Demonstration Project with CMS to conduct a robust needs assessment and subsequent remediation initiatives to help increase SUD treatment capacity in Michigan.

These efforts also have identified several problems with the availability of SUD/OUD services in the state. Although Michigan maintains a robust network of SUD providers and services, spanning from early intervention through inpatient withdrawal management services, the prohibition against Medicaid reimbursement for services provided to certain adults in an IMD setting creates a disjointed benefit package, particularly for withdrawal management services. Successfully treating Medicaid beneficiaries with severe SUD/OUDs requires access to these critical levels of care. Many beneficiaries will also require medication assisted treatment (MAT) to recover from addiction; these services are both clinically effective and cost effective, and they reduce the need for inpatient and detoxification services.⁶ However, MAT is not currently consistently available in all regions of Michigan.

Residential treatment and withdrawal management for SUD/OUD also remains underutilized. A recent study found that individuals receiving residential treatment were three times more to complete treatment that those who received only outpatient treatment. Withdrawal management is a critical component of early recovery from SUD/OUD. It serves several key purposes including helping patients initiate abstinence, reducing withdrawal symptoms and preventing severe complications, and retaining the patient in treatment. Ongoing treatment is needed thereafter to maintain abstinence. Withdrawal management can take place in residential or outpatient settings depending on the substances used, the severity of

٠

⁵ Michigan Prescription Drug and Opioid Abuse Task Force. Report of Findings and Recommendations for Action. https://www.michigan.gov/documents/snyder/Presciption Drug and Opioid Task Force Report 504140 7.pdf

⁶ Baser O, Chalk M, Fiellin DA, Gastfriend DR. Cost and utilization outcomes of opioid-dependence treatments. Am J Mgd Care 2011;17 Suppl 8: S235-48.

⁷ Stahler GJ, Mennis J, DuCette JP. Residential and outpatient treatment completion for substance use disorders in the U.S.: Moderation analysis by demographics and drug of choice. Addictive Behaviors 2016; 58:129-35.

dependence, and the presence of co-morbid conditions. Withdrawal management is vital to support and monitor patients in early stages of abstinence and is critical to preventing severe withdrawal symptoms including sometimes fatal complications. ⁸ However, residential SUD/OUD treatment and withdrawal management are not consistently offered/available across all regions of Michigan.

A.3. Other relevant contextual factors

The demonstration builds on the success of Michigan's Medicaid expansion program, the Healthy Michigan Plan (HMP). HMP provides full coverage, including behavioral health care, to adults with incomes at or below 133% of the Federal Poverty Level. The University of Michigan's HMP evaluation found that the number of uninsured adults has decreased substantially, and that individuals enrolled in HMP report increased access to SUD-relevant services including primary care, behavioral health services, and prescription medication. 10

A.4. Goals of the Medicaid 1115 substance use demonstration

As noted in the Special Terms and Conditions (STCs), the demonstration seeks to improve health outcomes and sustained recovery for beneficiaries with SUD/OUD 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, withdrawal management programming,
 and medication assisted treatment (MAT);
- 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.

Michigan's revised implementation plan proposes specific strategies to accomplish the goals of the demonstration waiver. The implementation plan notes the current availability of services at all ASAM levels, but that efforts are needed to ensure that beneficiaries are assessed and recommended for treatment services according to evidence-based criteria. To this end, the state has established the expectation that all providers use an assessment tool that utilizes ASAM criteria. Initially, the state planned to require use of the GAIN-I (Global Assessment of Individual Needs - Initial)¹¹ as the standard for comprehensive assessment that supports clinical diagnosis, level of care placement, and treatment planning. However, the revised plan allows

⁸ Kosten TR, O'Connor PG. Management of drug and alcohol withdrawal. New Engl J Med 2003; 348:1786-95.

⁹ Levy H, Buchmueller T. Healthy Michigan Plan Evaluation. Domain II – Reduction in the Number of Uninsured. https://www.michigan.gov/documents/mdhhs/Domain_II_-_Reduction_in_Number_of_Uninsured_647135_7.pdf ¹⁰ Goold SD, Kullgren J, et al. Report on the 2016 Healthy Michigan Voices Enrollee Survey.

 $https://www.michigan.gov/documents/mdhhs/2016_Healthy_Michigan_Voices_Enrollee_Survey_-linear_Noices_Enrollee_Survey_-line$

Report Appendices 1.17.18 final 618161 7.pdf

¹¹ Dennis, M., Titus, J., White, M., Unsicker, J. & Hodkgins, D. (2002). Global Appraisal of Individual Needs (GAIN): Administration Guide for the GAIN and Related Measures. Bloomington, IL: Chestnut Health Systems.

PIHPs to choose any assessment tool that utilizes ASAM criteria, such as the Level of Care Index (LOCI). ¹² In addition, the state will establish and monitor the expectation that PIHPs will utilize the results of ASAM-based assessments and ASAM criteria to make authorization decisions for treatment services regarding length of stay, change in level of care, and discharge. For residential and withdrawal management services, PIHPs will be expected to use the six ASAM dimensions to guide decision-making for needed level of care, transitions in care, and discharge planning. The tentative timeline for implementation is for PIHPs to select their ASAM-based tools by September 30, 2020 (FY2020), and fully implement the ASAM-based assessment and treatment recommendations by October 1, 2021 (FY2022). The revised implementation plan offers the opportunity to compare outcomes for different ASAM-based tools, and to establish baseline rates prior to implementation of this strategy.

In addition, the state seeks to ensure all ASAM levels of care are available across PIHP regions and consistently offered and delivered. To this end, the state will validate the initial and ongoing qualifications of SUD providers to document their appropriate level of ASAM services and will use this information to assess availability across ASAM levels throughout the state. The implementation plan outlines several potential strategies that will be attempted to address deficiencies in availability.

Finally, the implementation plan proposes specific strategies to improve the coordination of care across levels of service and across settings.

The state's updated health information technology plan includes five key strategies.

- 1. The state will expand the cross-program use of the Master Person Index to enable greater precision in identifying high-need beneficiaries; the target implementation date is October 1, 2021.
- 2. The state will modify the existing care coordination platform, Care Connect 360, to allow expanded access to SUD claim/encounter information, including ADT messaging; the target implementation date for this modification is October 1, 2020.
- 3. The state will implement an electronic consent management system for data sharing. This system will be pilot tested in one region starting FY2021 and rolled out statewide by the end of the demonstration period.
- 4. The state will implement a SUD residential bed registry within the context of a broader integrated crisis and access system. The registry will be pilot tested in one region starting FY2021 and rolled out statewide by the end of the demonstration period.
- 5. The state will develop a customer relationship management database to facilitate and track access to needed SUD treatment across providers and designated contractors; this database is currently in development and is expected to begin pilot testing in FY2021, and rolled out statewide by the end of the demonstration period.

The revised implementation plan clarifies that the evaluation will have an opportunity to establish baseline rates of health IT-focused outcomes prior to implementation of these strategies (See Table 1).

¹² The LOCI is published by The Change Companies, www.changecompanies.net.

Table 1. Anticipated Timing of Implementation

·	FY2019	FY2020	FY2021	FY2022	FY2023
ASAM-based tools for assessment & treatment recommendations		PIHP selection of assessment tools by the end of FY2020 Sept. 30 2020	Training and integration Oct. 1 2020-Sept.30 2021	Full implementation will take place by the beginning. of FY2022 Oct. 1. 2021- Sept. 30 2022	Oct. 1 2022- Sept. 30 2023
Health IT		Expansion of Care Connect 360	Master Person Index in place; Pilot test of electronic consent, bed registry, customer relationship management database	Full implementation	
EVALUATION PERIOD	Pre	Transitional	Transitional	Post	Post

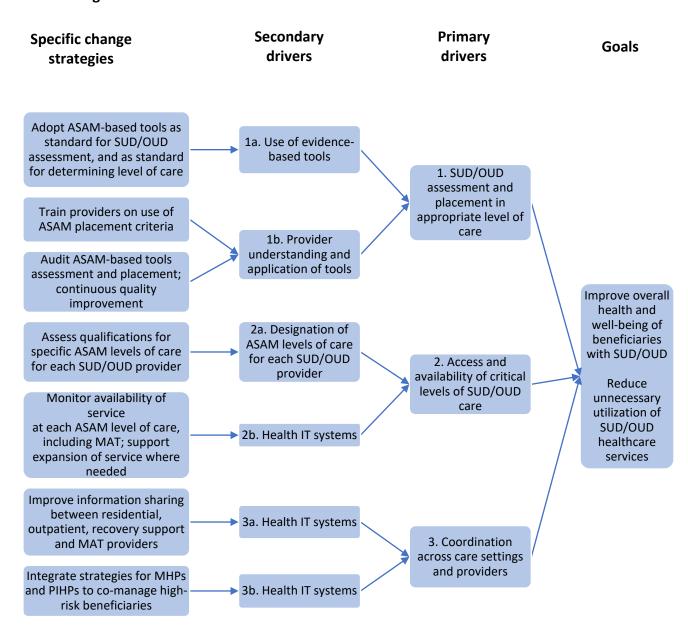
A.5. Population served by the demonstration

Medicaid eligibility will not change under the demonstration; standards for eligibility remain set per the state plan. The demonstration will also allow Medicaid beneficiaries ages 21-64 to receive SUD/OUD treatment services in residential and inpatient treatment settings that qualify as an Institution for Mental Diseases (IMD).

B. Evaluation Overview

The driver diagram represents the broad goals of the demonstration and the key pathways through which the state will achieve those goals. Primary drivers are the broad mechanisms, while secondary drivers highlight key elements that support those broad mechanisms. The specific change strategies represent the key processes that the state will use to drive change.

Driver Diagram



C. Methodology

C.1. Evaluation design summary

This evaluation design responds to the requirements outlined in the Special Terms and Conditions (STCs) Section X. Evaluation of the Demonstration and related guidance in Attachment A: Developing the Evaluation Design. The evaluation design also reflects CMS's March 2019 guidance for Substance Use Disorder (SUD) Section 1115 demonstration projects.

We organize the hypotheses and key research questions for the evaluation into five sections that correspond to the main outcomes of interest highlighted in the STCs: (1) use of evidence-based standards to support SUD/OUD assessment and placement for care, (2) availability of and access to critical levels of SUD/OUD care, (3) coordination of care across settings, (4) overall impact on health and health services utilization, and (5) cost.

Table 2 outlines specific hypotheses, research questions, and evaluation methods. The mixed methods design incorporates both quantitative and qualitative data collection and analysis to answer key research questions and test hypotheses. We will use five sources of evaluation data:

- 1) MDHHS administrative data
- 2) Beneficiary surveys
- 3) State monitoring reports and PIHP audit data
- 4) Key informant interviews
- 5) Medicaid cost reports

We will employ a quasi-experimental evaluation design that is based on the expected timing of implementation for key waiver strategies (selection and adoption of ASAM-based tools; implementation of new health IT mechanisms) outlined in the state's revised implementation plan. For annual measures, we will use descriptive comparisons over time. For quarterly measured based on administrative data, we will use interrupted time series analysis to assess changes from pre-implementation (FY2017-FY2020) to transitional implementation (FY2021-FY2022)) to full implementation (FY2023-FY2024). For measures based on beneficiary surveys, the evaluation will compare pre-implementation results from Cohort 1 (those who receive SUD/OUD services in demonstration Year 1-2) against post- implementation results from Cohort 2 (those who receive SUD/OUD services in Year 4-5-). Specific measures, data sources, and analytic methods are outlined in Table 2.

CMS technical advisory guidance¹³ on selection of comparison groups include: 1) a preintervention comparison group which would require prospectively collected data from prior to the start of the waiver intervention and/or 2) a Medicaid population from another state. Specifically, a SUD population with similar demographic characteristics, in another state without those waiver flexibilities interventions described in Michigan. However, an external state comparison group is not feasible, since comparable datasets are not shared outside of the

¹³ https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/smi-sed-sud-1115-eval-guide.pdf

state due to the sensitivity of SUD privacy concerns as it relates to data sharing. Thus, an external comparison group from another state is outside the scope of the evaluation.

We will incorporate geographic comparisons in all evaluation analyses. This includes stratifying key results by PIHP region, adjusting for PIHP region in multivariate models, and establishing minimum participation targets for beneficiary surveys. These regional analyses will allow us to assess the consistency of outcomes across the diverse PIHP regions, compare outcomes related to PIHP-specific features (e.g., choice of ASAM-based assessment tool; participation in health IT pilot test), and to identify any differential impacts of the demonstration for specific regions.

Table 2. Table of Hypotheses & Research Questions for Evaluation of Michigan's Behavioral Health Demonstration Waiver

Evidence-Based Standards for Assessment and Placement

Hypothesis 1. Implementation of Michigan's Behavioral Health Demonstration Waiver will increase utilization of evidence-based standards for patient assessment and treatment placement. (Driver 1)

Linked Demonstration Goal:

Goal 2: Enhancing provider competency related to the use of ASAM criteria or other nationally recognized, SUD-specific program standards, for patient assessment and treatment

Primary research question 1: Does the proportion of beneficiaries assessed and recommended for placement using evidence-based standards increase over the demonstration period?

Subsidiary research question 1a: Are there differences by PIHP and by assessment tool (e.g., GAIN-I, LOCI) in provider utilization of evidence-based standards for assessment and treatment placement?

Subsidiary research question 1b: What are key barriers and facilitators to evidence-based SUD/OUD assessment and placement?

Measure Description	Steward	Numerator	Denominator	Data sources	Measurement	Analytic approach
					Frequency	
OUTCOME: Proportion of	N/A	Number of beneficiaries	Number of	PIHP site visits and	Annual	Descriptive comparison
beneficiaries with ASAM-consistent		deemed to have ASAM-	beneficiary records	audits		over time, across PIHPs
assessment		consistent assessment	audited			(frequencies, graphs)
OUTCOME: Proportion of	N/A	Number of beneficiaries	Number of	PIHP site visits and	Annual	Descriptive comparison
beneficiaries with ASAM-consistent		deemed to have ASAM-	beneficiary records	audits		over time, across PIHPs
recommendation for treatment		consistent recommendation	audited			(frequencies, graphs)
placement		for treatment placement				
PROCESS: Number of providers	N/A	Number of providers engaged	N/A	PIHP site visits and	Annual	Descriptive comparison
trained on selected assessment tool		in training on ASAM-based		audits		over time, across PIHPs
		tools				(frequencies, graphs)
PROCESS: Experiences of PIHP	N/A	N/A	N/A	Key informant		Qualitative analysis
administrators and SUD providers				interviews		
with implementation of ASAM-						
consistent tools						

Expanding Availability and Access to SUD/OUD Levels of Care

Hypothesis 2: Implementation of Michigan's Behavioral Health Demonstration Waiver will expand availability of critical levels of SUD/OUD treatment, including residential treatment, withdrawal management, and MAT. (Driver 2)

Linked Demonstration Goal:

Goal 1: Establishing an integrated behavioral health delivery system that includes a flexible and comprehensive SUD benefit and the Michigan continuum of care.

Primary research question 2: Does the number of qualified SUD providers increase over the demonstration period?

Subsidiary research question 2a: Are there differences by PIHP region in the number of qualified SUDD providers?

Subsidiary research question 2b: What strategies are successful, and what are key barriers, to hiring and retaining SUD/OUD providers?

Measure Description	Steward	Numerator	Denominator	Data sources	Measurement	Analytic approach
					Frequency	
OUTCOME: SUD provider availability	N/A	Number of Medicaid-enrolled	N/A	Provider	Annual	Descriptive comparison
(all SUD; MAT)		providers qualified to deliver		enrollment		over time, across PIHPs
		SUD services;		database / state		(frequencies, graphs)
				monitoring		
		Subset who meet standards		reports		
		to provide buprenorphine or				
		methadone as part of MAT				
OUTCOME: rate of SUD provider	N/A	Number of Medicaid-enrolled	A) Total number of	Provider	Annual	Descriptive comparison
availability (all SUD; MAT)		providers qualified to deliver	Medicaid	enrollment		over time, across PIHPs
, , , , ,		SUD services;	beneficiaries	database/		(frequencies, graphs)
		,	B) Number of	administrative		, , , , ,
		Subset who meet standards	Medicaid	claims		
		to provide buprenorphine or	beneficiaries with			
		methadone as part of MAT	SUD diagnosis			
OUTCOME: Primary care provider	N/A	Number of primary care	N/A	Administrative	Annual	Descriptive comparison
engagement in MAT		providers with at least one		claims		over time, across PIHPs
		claim as rendering provider				(frequencies, graphs)
		for MAT				, , , , ,
OUTCOME: Number of residential	N/A	Number of beds licensed for	N/A	State licensing	Annual	Descriptive comparison of
treatment beds for SUD		SUD residential treatment		data		annual number over time
						(frequencies, graphs)
PROCESS: Experiences with hiring and	N/A	N/A	N/A	Key informant		Qualitative analysis
retaining SUD providers				interviews		

Hypothesis 3: Implementation of Michigan's Behavioral Health Demonstration Waiver will increase utilization of SUD treatment. (Driver 2 &3)

Linked Demonstration Goal:

Goal 1: Establishing an integrated behavioral health delivery system that includes a flexible and comprehensive SUD benefit and the Michigan continuum of care.

Goal 3: Expanding the treatment continuum of residential care including medically necessary use of qualified residential treatment facilities, withdrawal management programming, and medication assisted treatment (MAT).

Primary research question 3: Does utilization of SUD treatment increase over the demonstration period?

Subsidiary research question 3a: Are there differences by PIHP region in utilization of SUD treatment?

Subsidiary research question 3b: What are key barriers and facilitators to beneficiary utilization of recommended SUD treatment?

Measure Description	Steward	Numerator	Denominator	Data sources	Measurement	Analytic approach
					Frequency	
OUTCOME: Initiation of alcohol and	NQF	Number of beneficiaries who	Number of	Administrative	Quarterly	Interrupted time series;
other drug abuse or dependence	#0004	initiated treatment through	beneficiaries with a	claims		multivariable logistic
(AOD) treatment		an inpatient AOD admission,	new episode of AOD			regression models
-All AOD		outpatient visit, intensive				adjusting for PIHP region,

-Alcohol abuse or dependence -Opioid abuse or dependence -Other drug abuse or dependence		outpatient encounter, or partial hospitalization within 14 days of the diagnosis				beneficiary demographic and utilization characteristics
OUTCOME: Engagement of alcohol and other drug abuse or dependence (AOD) treatment -All AOD -Alcohol abuse or dependence -Opioid abuse or dependence -Other drug abuse or dependence	NQF #0004	Number of beneficiaries who initiated treatment who had two or more additional services with a diagnosis of AOD within 30 days of the initiation visit	Number of beneficiaries with a new episode of AOD	Administrative claims	Quarterly	Interrupted time series; multivariable logistic regression models adjusting for PIHP region, beneficiary demographic and utilization characteristics
OUTCOME: Any SUD treatment	N/A	Number of beneficiaries receiving any SUD treatment service, facility claim, or pharmacy claim	Total number of Medicaid beneficiaries	Administrative claims	Quarterly	Interrupted time series; multivariable logistic regression models adjusting for PIHP region, beneficiary demographic and utilization characteristics
OUTCOME: Residential SUD treatment	N/A	Number of beneficiaries receiving residential or inpatient SUD treatment	A) Total number of Medicaid beneficiaries B) Number of Medicaid beneficiaries with SUD diagnosis	Administrative claims	Quarterly	Interrupted time series; multivariable logistic regression models adjusting for PIHP region, beneficiary demographic and utilization characteristics
OUTCOME: Average length of residential SUD treatment	N/A	Total number of days of residential or inpatient SUD treatment	Number of residential or inpatient stays for SUD treatment	Administrative claims	Annual	Descriptive comparison over time, across PIHPs (frequencies, graphs)
OUTCOME: Withdrawal management	N/A	Number of beneficiaries receiving SUD withdrawal management services	A) Total number of Medicaid beneficiaries B) Number of Medicaid beneficiaries with SUD diagnosis	Administrative claims	Quarterly	Interrupted time series; multivariable logistic regression models adjusting for PIHP region, beneficiary demographic and utilization characteristics
OUTCOME: Medication assisted treatment (MAT)	N/A	Number of beneficiaries with a claim for MAT	A) Total number of Medicaid beneficiaries	Administrative claims	Quarterly	Interrupted time series; multivariable logistic regression models

			B) Number of Medicaid beneficiaries with SUD diagnosis			adjusting for PIHP region, beneficiary demographic and utilization characteristics
PROCESS: Experiences of providers and PIHP administrators with facilitating residential treatment and withdrawal management	N/A	N/A	N/A	Key informant interviews	Qualitative analysis	Qualitative analysis
PROCESS: Access to Treatment	ECHO/ CAHPS	Number of beneficiaries reporting they always or usually got counseling or treatment as soon as they wanted.	Number of beneficiaries surveyed	Beneficiary surveys (initial, follow-up)		Comparison of Cohort 1 vs Cohort 2 (chi-square tests; multivariable logistic regression)
PROCESS: Barriers to Treatment	ECHO/ CAHPS	Number of beneficiaries reporting delays in counseling or treatment were a big problem	Number of beneficiaries surveyed	Beneficiary surveys (initial, follow-up)		Comparison of Cohort 1 vs Cohort 2 (chi-square tests; multivariable logistic regression)

Care Coordination and Transitions in Care

Hypothesis 4: Implementation of Michigan's Behavioral Health Demonstration Waiver will improve care coordination and transitions in care for beneficiaries with SUD/OUD. (Driver 3)

Linked Demonstration Goal:

Goal 4: Expanding the use of recovery coach-delivered support services

Goal 5: Establishing coordination of care models between SUD providers, primary care and other behavioral health providers.

Primary research question 4: Does care coordination for beneficiaries with SUD increase over the demonstration period?

Subsidiary research question 4a: Are there differences by PIHP region in care coordination?

Subsidiary research question 4b: What strategies are successful to engage providers and beneficiaries in care coordination? What are key barriers?

Measure Description	Steward	Numerator	Denominator	Data sources	Measurement	Analytic approach
					Frequency	
OUTCOME: Follow-up after emergency department visit for alcohol or another drug dependence (FUA-AD)	NQF #2605	Number of beneficiaries who had a follow-up visit with a corresponding primary diagnosis for AOD within 7 days of the ED visit Number of beneficiaries who	Number of ED visits with a primary diagnosis of AOD abuse or dependent	Administrative claims	Quarterly	Interrupted time series; multivariable logistic regression models adjusting for PIHP region, beneficiary demographic and utilization characteristics
		had a follow-up visit with a corresponding primary				

		diagnosis for AOD within 30 days of the ED visit				
OUTCOME: Access to peer support	ECHO/ CAHPS	Number of beneficiaries who report being told about SUD treatment support options (e.g., peer support, 12-step programs)	Number of beneficiaries surveyed	Beneficiary surveys (follow- up)		Comparison of Cohort 1 vs Cohort 2 (chi-square tests; multivariable logistic regression)
OUTCOME: Access to assistance with arranging care	N/A	Number of beneficiaries who report getting as much help as they needed with arranging SUD care	Number of beneficiaries surveyed	Beneficiary surveys (follow- up)		Comparison of Cohort 1 vs Cohort 2 (chi-square tests; multivariable logistic regression)
OUTCOME: Adequate information sharing	N/A	Number of beneficiaries who report their outpatient providers always or usually know important information about their medical history	Number of beneficiaries surveyed	Beneficiary surveys (follow- up)		Comparison of Cohort 1 vs Cohort 2 (chi-square tests; multivariable logistic regression)
PROCESS: Number of unique users of Care Connect 360	N/A	Number of active users of Care Connect 360 in PIHPs, Medicaid Health Plans, and other settings	N/A	State health IT office	Annual	Descriptive comparison over time (frequencies, graphs)
PROCESS: Experiences of PIHP administrators and SUD providers with new health IT tools	N/A	N/A	N/A	Key informant interviews		Qualitative analysis
PROCESS: Experiences of primary care providers and ED staff with new health IT tools	N/A	N/A	N/A	Key informant interviews		Qualitative analysis

Hypothesis 5: Implementation of strategies to improve care coordination and transitions in care will result in increased duration of SUD/OUD treatment. (Driver 3)

Linked Demonstration Goal:

Goal 4: Expanding the use of recovery coach-delivered support services

Goal 5: Establishing coordination of care models between SUD providers, primary care and other behavioral health providers.

Primary research question 5: Does the duration of SUD/OUD treatment increase over the demonstration period?

Subsidiary research question 5a: Are there region differences by PIHP in SUD/OUD treatment duration?

Measure Description	Steward	Numerator	Denominator	Data sources	Measurement	Analytic approach
					Frequency	
OUTCOME: Continuity of	NQF	Number of beneficiaries with	Number of	Administrative	Quarterly	Interrupted time series;
pharmacotherapy for OUD	#3175	at least 90 days of continuous	beneficiaries with a	claims		multivariable logistic
(short-term, medium-term, long-		pharmacotherapy without a	diagnosis of OUD			regression models
term)		gap of more than 7 days	and at least one			adjusting for PIHP region,

7 titadrinierit G						
		Number of beneficiaries with at least 180 days of continuous pharmacotherapy without a gap of more than 7 days Number of beneficiaries with at least 270 days of continuous pharmacotherapy without a gap of more than 7 days	claim for an OUD medication			beneficiary demographic and utilization characteristics
OUTCOME: Continuation of counseling after SUD residential treatment	N/A	Number of beneficiaries who receive at least 2 outpatient counseling visits within 60 days after SUD residential treatment	Number of beneficiaries who receive SUD residential treatment	Administrative claims	Quarterly	Interrupted time series; multivariable logistic regression models adjusting for PIHP region, beneficiary demographic and utilization characteristics
PROCESS: Barriers to continuity of SUD care	N/A	Number of beneficiaries who report barriers to continuing MAT, counseling or other SUD treatment services	Number of beneficiaries surveyed	Beneficiary surveys (follow- up)		Comparison of Cohort 1 vs Cohort 2 (chi-square tests; multivariable regression)

Hypothesis 6: Implementation of care coordination strategies will increase the receipt of primary care services during or after SUD/OUD treatment. (Driver 3)

Linked Demonstration Goal:

Goal 5: Establishing coordination of care models between SUD providers, primary care and other behavioral health providers.

Primary research question 6: Does the proportion of beneficiaries with SUD/OUD who receive primary care services increase over the demonstration period? Subsidiary research question 6a: What are barriers and facilitators to receipt of primary care?

Measure Description	Steward	Numerator	Denominator	Data sources	Measurement	Analytic approach
					Frequency	
OUTCOME: Access to preventive/ ambulatory health services	HEDIS	Number of beneficiaries who had an ambulatory or preventive visit in the primary care setting	Number of beneficiaries with a diagnosis of SUD	Administrative claims	Annual	Descriptive comparison over time (frequencies, graphs)
OUTCOME: Receipt of primary care among individuals with comorbid medical conditions	N/A	Number of beneficiaries who had an ambulatory or	Number of beneficiaries with a diagnosis of SUD	Administrative claims	Annual	Descriptive comparison over time (frequencies, graphs)

		preventive visit in the primary care setting	and evidence of a chronic medical condition		
PROCESS: Usual source of primary care	NHIS	Number of beneficiaries who report a doctor's office or clinic as where they would go if sick or needed advice about their health	Number of beneficiaries surveyed	Beneficiary surveys (initial and follow-up)	Comparison of Cohort 1 vs Cohort 2 (chi-square tests; multivariable logistic regression)
PROCESS: Barriers to primary care	N/A	Number of beneficiaries who report barriers to receiving primary care services	Number of beneficiaries surveyed	Beneficiary surveys (initial and follow-up)	Comparison of Cohort 1 vs Cohort 2 (chi-square tests; multivariable logistic regression)

Hypothesis 7: Implementation of high-risk management strategies will result in decreased number of opioid fills among beneficiaries with OUD. (Driver 3)

Linked Demonstration Goal:

Goal 1: Establishing an integrated behavioral health delivery system that includes a flexible and comprehensive SUD benefit and the Michigan continuum of care.

Primary research question 7: Does the average number of opioid fills among enrollees with OUD decreased over the demonstration period?

Subsidiary research question 7a: What are unique barriers and facilitators to effective high-risk management?

Measure Description	Steward	Numerator	Denominator	Data sources	Measurement	Analytic approach
					Frequency	
OUTCOME: Average number of opioid prescriptions	N/A	Total number of filled opioid prescriptions	Number of beneficiaries with at least one filled opioid prescription	Administrative claims	Annual	Descriptive comparison over time (frequencies, graphs)
PROCESS: Experiences of PIHP and Medicaid health plan administrators with new high-risk management tool	N/A	N/A	N/A	Key informant interviews		Qualitative analysis

Health and Health Care Outcomes

Hypothesis 8: Implementation of the demonstration will improve the health and well-being of beneficiaries with SUD/OUD. (Driver 1, 2, & 3)

Linked Demonstration Goal:

Goal 1: Establishing an integrated behavioral health delivery system that includes a flexible and comprehensive SUD benefit and the Michigan continuum of care.

Primary research question 8: Do beneficiaries with SUD/OUD report improved health and well-being over the demonstration period?

Subsidiary research question 8a: What are continued barriers to improved health and well-being?

Measure Description	Steward	Numerator	Denominator	Data sources	Measurement	Analytic approach
					Frequency	
OUTCOME: Mental health status	ECHO/	Number of beneficiaries	Number of	Beneficiary survey		Comparison of Cohort 1 vs
	CAHPS	reporting Excellent or Very	beneficiaries	(follow-up)		Cohort 2 (chi-square tests;
		good mental health	surveyed			multivariable regression)

OUTCOME: Overall health status	CDC	Number of beneficiaries				
	Healthy	reporting Excellent or Very				
	Days	good physical health				
OUTCOME: Health Limitations	CDC	Number of beneficiaries				
	Healthy	reporting 10+ days in the past				
	Days	month where poor physical				
		or mental health prevented				
		daily activities				
OUTCOME: Current employment	PRAPARE	Number of beneficiaries				
		reporting their current work				
		situation as employed				
OUTCOME: Current housing	PRAPARE	Number of beneficiaries				
		reporting they currently have				
		housing				
OUTCOME: Ability to accomplish	ECHO/	Number of beneficiaries				
objectives	CAHPS	reporting their ability to				
		accomplish things they want				
		to do is much better or a little				
		better				
OUTCOME: Overdose death rate	N/A	Number of beneficiaries with	Total number of	State vital records	Annual	Descriptive comparison
		overdose death	Medicaid			over time (frequencies,
			beneficiaries			graphs)

Hypothesis 9: Implementation of the demonstration will decrease utilization of crisis care among beneficiaries with SUD/OUD. (Drivers 1, 2, and 3) Linked Demonstration Goal:

Goal 1: Establishing an integrated behavioral health delivery system that includes a flexible and comprehensive SUD benefit and the Michigan continuum of care.

Primary research question 9: Do rates of crisis care for SUD/ODU decrease over the demonstration period?

Subsidiary research question 9a: Are there differences by PIHP region in utilization of crisis care for SUD/OUD?

Measure Description	Steward	Numerator	Denominator	Data sources	Measurement	Analytic approach
					Frequency	
OUTCOME: Emergency department utilization for SUD	HEDIS*	Number of emergency department visits with a primary diagnosis of SUD	Number of member- months for all Medicaid beneficiaries (rate per 1,000 MM)	Administrative claims	Quarterly	Interrupted time series; multivariable Poisson regression models adjusting for PIHP region, beneficiary demographic and utilization characteristics

OUTCOME: Inpatient utilization for SUD	HEDIS*	Number of inpatient visits with a primary diagnosis of SUD	Number of member- months for all Medicaid beneficiaries (rate per 1,000 MM)	Administrative claims	Quarterly	Interrupted time series; multivariable Poisson regression models adjusting for PIHP region, beneficiary demographic and utilization characteristics
OUTCOME: All-Cause Readmission after SUD inpatient visit	HEDIS*	Number of subsequent inpatient visits within 30 days of an inpatient visit with a primary diagnosis of SUD	Number of inpatient visits with a primary diagnosis of SUD	Administrative claims	Quarterly	Interrupted time series; multivariable Poisson regression models adjusting for PIHP region, beneficiary demographic and utilization characteristics

Costs of the Demonstration

Hypothesis 10: Implementation of Michigan's Behavioral Health Demonstration Waiver will be sustainable for the Medicaid program with regard to costs. (Driver 1, 2, & 3) Linked Demonstration Goal:

Goal 1: Establishing an integrated behavioral health delivery system that includes a flexible and comprehensive SUD benefit and the Michigan continuum of care.

Primary research question 10: Does the average total cost for beneficiaries with SUD/OUD change over the demonstration period?

Subsidiary research question 10a: Does average total cost differ by PIHP region or beneficiary characteristics?

Measure Description	Steward	Numerator	Denominator	Data sources	Measurement	Analytic approach
					Frequency	
OUTCOME: Total SUD spending	N/A	Total dollars reported as	N/A	State cost reports	Annual	Descriptive comparison
		spent on SUD, all sources				over time (frequencies;
						graphs)
OUTCOME: SUD spending for	N/A	Total paid amount for	Total number of	Administrative	Quarterly	Interrupted time series;
inpatient treatment, per member-		residential or inpatient	enrolled months for	claims		multivariable linear
month		treatment within IMDs	Medicaid			regression models
			beneficiaries			adjusting for PIHP region,
						beneficiary demographic
						and utilization
						characteristics
OUTCOME: MAT spending, per	N/A	Total paid amount for SUD	Total number of	Administrative	Quarterly	Interrupted time series;
member-month		pharmacotherapy	enrolled months for	claims		multivariable linear
			Medicaid			regression models
			beneficiaries			adjusting for PIHP region,
						beneficiary demographic

Attachment C

						and utilization characteristics
OUTCOME: ED costs for SUD, per member-month	N/A	Paid amount for ED visits with a primary diagnosis of SUD	Total number of enrolled months for Medicaid beneficiaries	Administrative claims	Quarterly	Interrupted time series; multivariable linear regression models adjusting for PIHP region, beneficiary demographic and utilization characteristics
PROCESS: Proportion of PIHP spending by category	N/A	Dollars spent per category (e.g., detox, residential, outpatient, MAT, case management, recovery support)	Total dollars spent	PIHP site visits and audits	Annual	Descriptive comparison over time (frequencies, graphs)

Institutional Review Board (IRB) Review and Data Use Agreement

The evaluation team anticipates that this evaluation will be exempt from the standard regulatory process, per the 2018 Common Rule (45 CFR 46.101(b)). Exemption category 5 states: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Per regulation, we will expect that the demonstration project will be included on the CMS list of research and demonstration projects, available on a publicly accessible CMS website, prior to commencing any activities involving human subjects.

We will submit the evaluation plan to the University of Michigan Medical School IRB to obtain final approval from the Director of the Human Research Protection Program (HRPP), per standard policy for Exemption 5 projects. In addition, we will submit the evaluation plan to the MDHHS IRB for approval, and to the MDHHS Compliance Office for a HIPAA Privacy Waiver. We will execute a project-specific Data Use Agreement that delineates the specific state data sources to be used for the project, and that outlines key privacy protections, based on existing protocols the evaluation team has used for other MDHHS projects.

C.2. Data sources, evaluation measures, and analytic approach

The evaluation data sources, measures and analytic approach are presented in Table 2 and described below.

C.2.1. State administrative data

Data source

Michigan offers a rich data environment to evaluate the impact of health policy changes. The backbone of the data environment is the state's Enterprise Data Warehouse. The Data Warehouse maintains individual-level, identifiable data for numerous programs within MDHHS, including:

- Medicaid enrollment files include individual eligibility for different benefit plans, enrollment start and end dates, contact information (address, phone, email), key demographic characteristics (gender, race/ethnicity), and third-party liability coverage.
- <u>Medicaid administrative claims</u> include service-level data on paid claims (fee-for-service) and encounters (managed care), with accompanying billing information (e.g., CPT and ICD-10 diagnosis codes, billing/rendering provider, paid amount) for inpatient, outpatient, pharmacy, durable medical equipment, dental, lab, and other services.
- <u>Specialty behavioral health files</u> include individual-level data on services provided through PIHPs and CMHSPs, including assessments and treatment recommendations.

The University of Michigan Institute for Healthcare Policy and Innovation (IHPI), including several members of the evaluation team, has a longstanding history of working with MDHHS on projects using data from the state Data Warehouse. MDHHS and the University of Michigan have a joint Business Associates Agreement in place to authorize direct access to the Data Warehouse via an existing secure portal; under this authorization, the lead analyst for this evaluation has extracted data directly from the Data Warehouse to use in a variety of projects, including prior evaluations of 1115 waiver demonstration projects. The lead analyst has led the development of internal protocols for extracting, processing and storing state data. MDHHS and the University of Michigan also execute project-specific Data Use Agreements, which outline the parameters of data access, level of identification, and data storage using file encryption, secure networks, multiple layers of password protection, and other strategies to ensure data privacy.

Regarding data quality, administrative claims and encounter data undergo regular and rigorous quality testing by MDHHS. The lead analyst employs internal processes to assess data completeness and consistency prior to creating variables or generating results based on administrative claims; she regularly communicates with MDHHS staff to raise data issues (e.g., apparent lag in data loading to the warehouse) and understand the expected timeframe in which MDHHS will make corrections.

We will also benchmark key evaluation outcomes against other sources, including the state's monitoring reports, ongoing quality measurement results for Michigan's Medicaid program, and the CMS Medicaid Adult Core Measure Set. In addition, Michigan's Medicaid program, along with two members of the evaluation team (Zivin, Clark) participates in the Medicaid Outcomes Distributed Research Network (MODRN)¹⁴, a consortium of 12 states that are generating SUD-focused measures using a common data model. MODRN measures represent an additional option for benchmarking. A list of current MODRN measures and participating states is included with this revised evaluation plan.

Variables

We will extract and process data from the state Data Warehouse to generate outcome and predictor variables for evaluation analyses. These variables will include:

<u>Utilization-related variables</u> will be based on counts of unique events (e.g., ED visits, prescription medication fill, inpatient stay). Diagnosis and procedure codes will be used to categorize the type of service (e.g., SUD treatment, primary care), to distinguish between subcategories of SUD (e.g., alcohol, opioid, other drugs), and to identify beneficiaries with co-occurring medical or behavioral conditions. We will use Place of service codes and state specific PIHP and provider taxonomy codes will be used to distinguish the location of care. Claims processing for utilization-related variables will draw on specifications from established measures from the National Quality Forum (NQF), the Healthcare Effectiveness Data and Information Set (HEDIS), and the CMS Core Set of Adult Quality

¹⁴ https://www.academyhealth.org/MODRN

Measures for Medicaid. Specific utilization measures for the evaluation appear in Table 2. When appropriate, we will modify measures to focus on beneficiaries with SUD/OUD; for example, we will adjust HEDIS measures that typically are limited to individuals with continuous enrollment to use a standardized rate per enrolled month, due to lack of enrollment continuity for the SUD/OUD population. Importantly, we will modify criteria for key outcome measures to generate quarterly results, which we will use in our interrupted time series analysis.

- <u>Enrollment-related variables</u> will include enrollment continuity (e.g., number of months enrolled in Medicaid in the prior year) and enrollment disruptions (number and length of disruptions in enrollment in a specified period). Enrollment variables will be used in multivariate regression models.
- <u>Demographic variables</u> will include beneficiary age, race/ethnicity, geographic region PIHP, income level (% FPL), and health plan. Demographic variables will be used in multivariate regression models

Analytic approach

We will generate outcome measures based on administrative data for the demonstration period (FY2020-FY2024), as well as additional pre-demonstration years (FY2017 -FY2019) to extend our ability to appreciate trends over time. Prior to generating each subsequent year's measures, we will assess data completeness using established internal protocols.

For administrative claims measures produced annually (see Table 2), we will generate a descriptive comparison of results over time for the state overall, for each PIHP region, and for racial/ethnic subgroups; we will use these subgroup analyses to evaluate any differences in SUD treatment by race and by PIHP region.

For administrative claims measures produced quarterly (see Table 1), we will assess changes over time using an interrupted time series approach.

```
our interrupted time series models will reflect: y = \alpha + \beta_1 time + \beta_2 \ post + \beta_3 \ post * time + \theta^T X + \varepsilon Where y = outcome measure time = \text{quarters from beginning of the study} post = 1 \text{ for post-intervention and 0 for pre-intervention time periods.} X = \text{Control variables} \alpha = \text{Intercept, pre-intervention} \beta_1 = \text{Slope, pre-intervention} \beta_2 = \text{Intercept (level) change, post-intervention} \beta_3 = \text{Slope (trend) change, post-intervention} \theta = \text{vector of parameters corresponding to control variables} \varepsilon \sim \text{N } (0, \sigma^2)
```

For proportions, we will use the logit of the proportions (p) as outcomes in the interrupted time-series model:

$$logit(p) = \alpha + \beta_1 time + \beta_2 post + \beta_3 post * time + \theta^T X$$

To incorporate beneficiary-level demographic (e.g., age, gender, race/ethnicity) and clinical (e.g., number of ED visits in prior year) characteristics, we will perform regression analyses that examines the change across years controlling for PIHP and beneficiary characteristics:

Binary outcomes (y), logistic regression analysis:

$$logit(p(y=1|year,X)) = \alpha + \beta_1 * year + \theta^T X$$

Where X = Control variables
 α = Intercept
 β_1 = year effect
 θ = vector of parameters corresponding to control variables

Count outcomes (y), Poisson regression analysis:

$$log((y|year, X)) = \alpha + \beta_1 * year + \theta^T X$$

We will use negative binomial regressions for count data with variability greater than what can be accounted for in Poisson regression. We will also examine interaction effects between year and beneficiary characteristics.

C.2.2. Beneficiary surveys

Data source

The evaluation team will conduct surveys of Medicaid beneficiaries with SUD/OUD to collect key patient-reported measures. The beneficiary surveys will be conducted in two cohorts that reflect the timing of key waiver strategies outlined in the state's revised implementation plan. Data collection for Cohort 1 will occur in FY2021 through early FY2022; this timeframe reflects the period prior to full implementation of the state's key strategies to improve SUD care, including ASAM-based assessment and treatment recommendations, and health IT improvements to support care coordination. Data collection for Cohort 2 will occur in the second half of FY2023 through FY2024; this timeframe reflects the period after implementation of these key strategies. Thus, comparison of beneficiary-reported outcomes from Cohort 1 (pre-implementation) vs Cohort 2 (post-implementation) will highlight the impact of the demonstration project on beneficiaries' SUD/OUD treatment experiences.

We will continue monthly sampling will continue until we achieve the target number of completed surveys.

Beneficiary surveys will consist of an initial survey, timed to occur approximately 2-3 months after the beneficiary begins SUD/OUD treatment, and a follow-up survey approximately 6 months later.

The initial survey will focus on the appropriateness and acceptance of treatment placement

recommendations; access problems or other barriers to SUD/OUD treatment; support for transitions in SUD/OUD care and coordination between behavioral health and primary care providers; and mental and physical health status.

The follow-up survey will explore ongoing access to and compliance with treatment, including MAT, unmet needs and barriers to treatment, ongoing care coordination, mental and physical health status, and well-being (e.g., housing, employment).

To identify the eligible survey population, we will query the state data warehouse monthly during the survey period to identify individuals who received a new SUD/OUD diagnosis and/or comprehensive SUD assessment between 8 and 12 weeks prior, followed by initiation of residential or outpatient SUD treatment. Preliminary testing of this algorithm yielded an eligible population of roughly 2800-3200 unique beneficiaries each month. From each month's eligible population, we will select approximately 800 individuals for the survey sample according to a priori sampling frame based on age and geographic region; this is necessary to ensure adequate representation of beneficiaries in all PIHPs. We will require selected individuals to have complete data warehouse field for address and phone, and a preferred language of English, Spanish, or Arabic, which are the languages spoken by our interviewers.

Survey cohort and sample size

Our target for each cohort is 2,000 completed surveys for each Cohort (initial and follow-up), with at least 150 completed surveys in each PIHP region to ensure adequate representation across all areas of the state. Based on the evaluation team's recent experience conducting surveys of Medicaid beneficiaries for the state's Medicaid expansion evaluation, we estimate an initial survey participation rate of 40%, and a follow-up survey participation rate of 85%. Thus, for each Cohort, we will recruit 6,000 beneficiaries to achieve 2,000 completed (initial and follow-up) surveys.

For two-tailed hypothesis testing with Type I error of 5% (p<0.05), this sample size will provide 90% statistical power to detect a 5 percentage-point difference between Cohort 1 and Cohort 2 in the proportions of beneficiaries who report adequate access to SUD/OUD treatment, in the proportion who report receipt of care coordination and peer support services, and in the proportion who report excellent/very good mental health status at the time of their follow-up survey.

Survey administration

We will build on strategies used successfully in the evaluation team's previous Medicaid-focused projects when conducting beneficiary survey administration. We will utilize a Computer Assisted Telephone Interviewing (CATI) system to administer the surveys; this system includes options for multi-modal survey administration for supplemental or follow-up questions (e.g., through web-based or text responses). Survey questions will be programmed into the CATI system, enabling for branching of survey items based on characteristics known prior to the survey and for responses given during the survey. The CATI system will integrate individual characteristics (e.g. gender, Medicaid health plan) to allow for tailored question wording.

Interviewers will be trained on the survey instrument, including prompts and definitions, and appropriate response to questions about coverage or services.

We will mail sampled individuals an introductory packet containing a letter and brochure explaining the survey purpose, and a postage-paid postcard that can be used to indicate a preferred time/day for the interview or their refusal to participate. The letter will provide a toll-free number and email address for individuals who wish to indicate a preferred time/day for the interview or refusal to participate. For sampled individuals who do not refuse, interviewers will place phone calls between the hours of 9:00 AM and 8:30 PM. Non-respondents will receive two additional mailings with a brief letter and brochure encouraging participation.

Once we reach sampled individuals by phone, interviewers will explain the purpose of the project, emphasize the confidentiality of responses, and obtain agreement to participate. Interviewers will note that completion of the survey is voluntary and that only aggregate data will be reported. Interviewers will ask to record the interview; in recent telephone surveys with Medicaid beneficiaries, over 95% of respondents agreed to be recorded. We will mail a \$25 gift card to individuals who complete the survey; individuals will indicate their preferred address for the gift card mailing. We will administer the incentives through the University of Michigan research incentive system, to allow for tracking and replacement of lost cards.

At the end of the survey, interviewers will ask if the respondent agrees to be re-contacted for follow-up surveys and interviews and, if yes, the preferred contact information to use. The incentive for survey completion will not be contingent upon agreement to be re-contacted.

We will monitor survey participation rates cross demographic groups (age, geographic region) to identify disparities in participation. If necessary, we will use other survey modalities (e.g., written survey, in-person interview) to allow for broad participation.

Measures

Outcome and process measures derived from beneficiary surveys are outlined in Table 1. Most items use existing validated items and scales in beneficiary surveys, including the Experiences of Care and Health Outcomes survey from the Consumer Assessment of Healthcare Providers and Systems (ECHO/CAHPS); the Center for Disease Control and Prevention's (CDC) Healthy Days survey; and the National Health Interview Survey (NHIS); and the Protocol for Responding to and Assessing Patients' Assets, Risks and Experiences (PRAPARE). When necessary, we will adapt survey wording to clarify meaning (e.g., use terms specific to Michigan Medicaid coverage; clarify which setting or provider type the question pertains to), as has been done successful in recent beneficiary surveys conducted by the evaluation team. ^{15,16}

¹⁵ Goold SD, Kullgren J, et al. Report on the 2016 Healthy Michigan Voices Enrollee Survey. https://www.michigan.gov/documents/mdhhs/2016_Healthy_Michigan_Voices_Enrollee_Survey_-Report Appendices 1.17.18 final 618161 7.pdf

¹⁶ Clark SJ, Goold SD. Report on the Healthy Michigan Voices 2016-17 Survey of Individuals No Longer Enrolled in the Healthy Michigan Plan. https://www.michigan.gov/documents/mdhhs/HMV_No_Longer_Enrolled_2016-2017_Report.9.27.18_647095_7.pdf

The survey will include several open-ended questions to allow beneficiaries to describe their experiences in greater detail. Open-ended questions will explore barriers and facilitators to accessing SUD/OUD treatment, satisfaction with providers, unmet needs, and experiences of discrimination.

Regarding data cleaning and validation, trained research assistants will review recordings to verify the accuracy of coding and to categorize responses to open-ended questions. For quantitative variables, we will use logic checks to ensure that responses are within the allowable range. For open-ended questions, we will use qualitative analysis techniques to identify the key themes articulated in responses to open-ended questions. We will incorporate a summary of the key themes in the final report, including individual quotes to illustrate beneficiary experiences.

Analytic approach

Sample design and survey nonresponse will be handled through weights as well as adjustments to the weights. From the sample design, we will have base weights that account for potential over- or under-sampling based on the stratification. After the baseline survey, we will conduct a non-response bias analysis using data from Medicaid administrative files (e.g., demographic characteristics, enrollment continuity in past year) to examine nonresponse patterns. A response propensity score model will be developed with multiple predictors. Using the estimated response propensity scores, we will develop weighting classes that include both respondents and nonrespondents and compensate for the potential nonresponse bias by adjusting the base weights of respondents.

Furthermore, we will post-stratify our sample to match the group population. To minimize an undesirable effect of large weight variation that increases variability of estimates, the final weights will be prepared after weight trimming. A combination of the base weight, the nonresponse adjustment, and the post-stratification will project our respondents to the intended sample and to the target population.

For follow-up surveys, we will conduct non-response bias analyses using information from the frame as well as any surveys conducted previously and fit a response propensity score model. Similar to the baseline survey, we will make nonresponse adjustments and post-stratification.

Statistical Analysis

We will compare survey responses from Cohorts 1 and 2 to understand the extent to which implementation of key demonstration strategies is associated with improvements in beneficiaries' access to SUD/OUD treatment, receipt of care coordination and peer support, mental and physical health status, and well-being (e.g., employment, housing). All multivariable analyses will control for differences in beneficiary characteristics between the two cohorts.

First, we will perform unadjusted analyses, comparing categorical outcome variables for Cohort 1 vs Cohort 2 using the Chi-square test.

We will use multivariable regression to understand the differences in outcomes <u>between</u> <u>cohorts controlling for differences in</u> key demographic characteristics, including PIHP region, race/ethnicity, type of SUD diagnosis (OUD only; OUD + other SUD), co-occurring mental health condition or chronic medical condition, age, income, and continuity of Medicaid enrollment.

For binary outcome variables, we will use logistic regression analysis of the outcome variable on cohort indicator controlling for differences PIHP region and key beneficiary characteristics.

```
logit(p(y=1|cohort,X)) = \alpha + \beta_1 * Cohort + \theta^T X

Where y = outcome measure

X = Control variables

\alpha = Intercept

\beta_1 = Cohort effect

\theta = parameters corresponding to control variables
```

For nominal outcome variables, with more than two response categories, we will use multinomial logit regression. There are J-1 (J=total # of categories) logistic regression models fit simultaneously compared to a selected reference outcome category.

```
log(p_j(cohort,X)/p_{Ref}(cohort,X)) = \alpha_j + \beta_{1j} * Cohort + \theta_j^T X

Where Outcome level j is compared with reference outcome level Ref

X = Control variables

\alpha_j = Intercept for the jth logit

\beta_{1j} = Cohort effect on the jth logit

\theta_j = parameters corresponding to control variables on the jth logit
```

C.2.3. State monitoring reports/PIHP audit data

Data source

Throughout the demonstration period, the state will collect and report on monitoring metrics, as required by CMS, in key areas such as assessment of need and qualification for SUD treatment services, access to critical levels of SUD/OUD care, provider capacity at critical levels of care, implementation of comprehensive treatment and prevention strategies, improved care coordination and transitions between levels of care, health outcomes, and spending.

In addition, throughout the demonstration project, the state will conduct routine PIHP site reviews that include review of clinical records to evaluation SUD treatment placement recommendations. Once each PIHP selects an ASAM-based assessment tool, the routine audits will determine appropriate application and fidelity to the ASAM assessment and placement criteria. Routine audits will also assess PIHP validation processes for network provider credentialing. We will conduct key informant interviews with state and PIHP officials; the key informant interviews will incorporate a review of monitoring data, along with key informant perspectives on barriers and facilitators to improvement.

Measures

Outcome and process measures derived from state monitoring reports and PIHP audit data are outlined in Table 2. Key outcome measures documented in monitoring reports include SUD provider capacity, fidelity to evidence based ASAM criteria for SUD assessment and treatment recommendations, number of beneficiaries receiving certain types of SUD services, overdose deaths, and use of health IT functionality to support care coordination.

Analytic approach

We will review monitoring reports and PIHP audit data to document progress toward full implementation of the demonstration. We will track key measures over time and conduct descriptive comparisons of measure progress across PIHPs.

In addition, we will highlight information from state monitoring reports and PIHP audits during key informant interviews (described below), to prompt informants to describe barriers and facilitators to success in the context of trends in key measures for the demonstration.

C.2.4. Key informant interviews

Data source

We will conduct key informant interviews with representatives from BHDDA, Medicaid, PIHPs, and SUD treatment providers. Interviews will include a review of monitoring and quality improvement reports related to the demonstration, and discussion of barriers and facilitators to successful implementation and widespread adoption of key elements of the demonstration.

The evaluation team will develop structured interview protocols for each group key informants and will identify monitoring and quality improvement reports to review with each group. We will conduct baseline key informant interviews beginning in FY2020 and complete them in early FY2021; midpoint interviews in FY2022; and final interviews in FY2023. To the extent possible, we will interview the same individuals at each time point, to facilitate the option to "revisit" key informant perspectives from prior interviews.

Survey cohort & sample size

We will conduct key informant interviews with the following groups:

- State-level BHDDA officials (3-6 individuals) selected from the group of BHDDA officials with responsibilities for implementation of the demonstration
- State-level Medicaid officials (3-5 individuals) selected from the group of Medicaid involved in care coordination, policy review/change, or other elements of the demonstration
- PIHP regional officials (2-3 individuals per PIHP) selected from the administrative leadership of each PIHP
- SUD providers (2-3 individuals in residential and 2-3 individuals in outpatient settings, for a total of 4-6 individuals per PIHP) – selected from the network of SUD/OUD providers with designated ASAM qualifications in each PIHP

Overall, we will interview 66-100 key informants at each time point. Interviews will be conducted in-person or by teleconference/webinar and are expected to last 30-45 minutes. Interviews may include more than one representative of a group. Participants will be asked for their permission to record the interview, to facilitate transcription of interview responses.

Measures

The structured interview protocols for the key informant interviews will include questions targeted to the individual's organizational roles and responsibilities.

For BHDDA officials, questions will include:

- Evidence-based assessment and placement: review of PIHP audit data, strategies to address deficiencies (e.g., additional training)
- Availability of SUD treatment: review of PIHP audits, strategies to address indicators of inadequate availability for certain regions and/or specific levels of care
- Utilization of SUD treatment services: review of quality improvement reports, discussion of areas of concern
- Health IT to support care coordination: update on implementation, barriers and facilitators

For Medicaid officials, questions will include:

- Utilization of primary care vs EDs for beneficiaries with SUD/OUD: review of quality improvement reports, discussion of strategies to address problematic trends
- Health IT to support care coordination: review data on use of health IT strategies by Medicaid health plans, barriers and facilitators
- Management of high-risk beneficiaries: update on co-management strategies, efforts to promote collaboration between Medicaid health plans and PIHPs

For PIHP officials, questions will include:

- Evidence-based assessment and placement: review of PIHP audit data, strategies to address deficiencies (e.g., additional training]
- Availability of SUD treatment: review of PIHP audits, strategies to address indicators of inadequate availability for certain regions and/or specific levels of care
- Utilization of SUD treatment services: review of quality improvement reports, discussion of areas of concern
- Health IT to support care coordination: update on use of health IT strategies to support transition across settings, collaboration with Medicaid health plans

For SUD providers, questions will include

- Availability of SUD treatment: barriers and facilitators to maintaining access, including hiring/retaining providers
- Utilization of SUD treatment services: barriers and facilitators to beneficiary initiation and continuation with treatment, including access to supportive services

• Health IT to support care coordination: use of and satisfaction with health IT strategies to support transition across settings,

Analytic approach

We will record and transcribe all interviews. Two evaluation team members will review each transcript to identify key themes, with a focus on identifying commonalities and differences across regions in the barriers and facilitators to implementation of key elements of the demonstration. Themes will be described in evaluation reports.

C.2.5. Program administrative cost data

Data source

Data sources for evaluation of cost data will include state cost reports for the Medicaid program and for the BHDDA (which includes services provided through state general funds, SAMHSA grants, and other non-Medicaid sources); we will supplement state cost reports with payment data linked to Medicaid administrative claims. Baseline costs will reflect the predemonstration period (state fiscal years 2017 and 2018).

Measures

Cost measures are outlined in Table 2 and will include total SUD spending and spending per member-month for specific cost drivers, including residential/inpatient treatment, medication assisted therapy, and emergency department visits.

Additionally, we will track PIHP spending by category (e.g., detox, residential, outpatient, MAT, case management, recovery support) reported in annual PIHP reporting to the state.

Analytic approach

Two broad measures – total SUD spending from all sources and PIHP spending by category – will be analyzed as descriptive comparisons across years, from FY2017 to FY2024. In particular, the analysis of PIHP spending patterns will highlight changes in the relative proportion of SUD spending devoted to certain types of services and suggest whether the demonstration project promotes greater consistency across PIHPs in the proportion of dollars spent in different treatment categories.

For cost measures derived from paid amounts on administrative claims (e.g., spending for SUD inpatient treatment, spending for MAT, ED costs for SUD), we will conduct an interrupted time series analysis. We will sum total paid amounts for each quarter from FY2017 through FY2023, along with total enrolled member-months. This analysis will estimate different linear effects in the pre-implementation period (FY2017-FY2020) through post-implementation (FY2021-FY2023). We will run separate models for SUD inpatient/residential treatment, medication assisted therapy, and ED visits with a primary diagnosis of SUD, and will report marginal effects and standard errors. We will use the following model:

Costs =
$$\alpha + \beta_1 time + \beta_2 post + \beta_3 post * time + \theta^T X + \varepsilon$$

Where TIME is a quarterly count variable; POST is the indicator variable for whether the month occurred on or after implementation of key waiver strategies; and *X* include beneficiary age, gender, race, enrollment, and PIHP.

We will also perform multivariable linear regression analyses that examines the change in cost across years controlling for PIHP, beneficiary demographics and utilization characteristics:

Costs = $\alpha + \beta_1 * year + \theta^T X$ Where X = Control variables α = Intercept β_1 = year effect θ = vector of parameters corresponding to control variables

C.3. Evaluation period, timeline and budget

The evaluation period will be for October 1, 2019, through September 30, 2025, which reflects the full demonstration period, with an additional year for final data analysis and reporting. Of note, data from administrative claims and other routine state reporting sources will be available for FY2017-2018, allowed for an extended baseline period.

Table 3. Major evaluation reporting deliverables, as specified in the STCs, include the following:

Date	Deliverable
December	Midpoint Assessment (will include baseline and midpoint key informant
2022	interviews, and baseline administrative and beneficiary survey data)
September	Interim Report (will include baseline and midpoint key informant interviews, and
2023	baseline administrative and beneficiary survey data)
March 2026	Final Report (will include all evaluation results)

We provide an evaluation budget and timeline in the Appendix.

D. Methodological limitations

Our proposed evaluation has several limitations.

The primary limitation is related an inability to attribute changes in outcomes to the activities undertaken in the demonstration. This limitation is in part due to the lack of a comparison group, as well as other SUD-related programmatic and policy changes occurring in Michigan during the time period of this demonstration project.

To address the lack of comparison group, we will analyze key evaluation outcomes using an interrupted time series design; this is the strongest available design option in the absence of a randomized controlled trial or matched control group. Our results may not be generalizable outside of Michigan although we will seek to benchmark results to other states with 1115 SUD waivers.

To address the potential impact of other changes in Michigan's SUD-focused policies and programs on the outcomes measured in this evaluation, we will document a broad range of SUD policy and program changes and note in evaluation reports how they may intersect with key outcomes. In addition, we will use key informant interviews to explore which policy and program changes represent key facilitators or barriers to improving SUD treatment.

Implementation of key elements of the demonstration is expected to be uneven across PIHP regions, including the use of single-region pilot tests for several health IT strategies. To address this likelihood, we will explore and describe regional differences in each of the five data elements (administrative data, beneficiary surveys, state monitoring reports/PIHP audits, key informant interviews, and cost reports). This will allow us to document any unevenness in implementation, and to examine the extent to which uneven implementation is associated with evaluation process or outcome measures.

Gaining participation for the beneficiary survey will be challenging due to expected changes in beneficiary contact information, churn in Medicaid enrollment, and possible reluctance to provide sensitive information. We will employ methods used successfully in recent surveys of Michigan Medicaid beneficiaries, including multiple modes of recruitment, interviewer training on non-judgmental administration of survey questions, and use of gift cards as an incentive for participation. In addition, survey administration by telephone may not be appropriate for all beneficiaries; we will work with MDHHS officials to identify alternate mechanisms for participation, such as in-person interviews. In addition, we will employ a weighting scheme that utilizes demographic characteristics from the state data warehouse to compare survey participants to sampled non-participants, and to the eligible population for the survey.

A final limitation involves data completeness and reliability. Michigan has a long tradition of managed care for both medical and behavioral health benefits and has developed an excellent structure for administrative claims processing. As such, we feel confident in the completeness and reliability of most fields, including diagnosis and procedure codes, place of service and service type codes, billing and rendering provider identifiers, and pharmacy codes. Our greatest area of concern involves paid amounts. We will work with MDHHS officials to learn about their internal assessments of cost fields. In addition, our key informant interviews with PIHP administrators will include questions about the reliability of the paid amounts submitted with their administrative claims.

E. Evaluation Team Independent evaluator

The CMS approval of the Michigan's Behavioral Health Demonstration Waiver requires that the evaluation be designed and conducted by researchers who will meet the scientific rigor and research standards of leading academic institutions and academic journal peer review. The University of Michigan Institute for Healthcare Policy and Innovation is an interdisciplinary campus-wide institute at a premier public research university. The mission of the Institute is to improve the quality, safety, equity, and affordability of health care. The Institute includes more

than 600 health services researchers from 14 schools and colleges across the university. IHPI faculty members and staff are national leaders in health services research, health economics, and population health with substantial experience conducting rigorous evaluations of access to care, quality of care, costs of care, and health outcomes. IHPI faculty members participating on the evaluation team have substantial experience in the evaluation of Medicaid demonstration programs and other state and federal policy initiatives.

The University of Michigan contracted with the MDHHS from 2014-2019 as the independent evaluator for the Healthy Michigan Plan 1115 Demonstration Waiver. As result of these previous relationships, MDHHS identified University of Michigan as a potential independent evaluator to conduct this demonstration evaluation and reached out to them. They held several preliminary meetings and discussions that led UM to develop a proposal for MDHHS, leading to their final selection to conduct the Demonstration evaluation.

The State attests that the relationship between the Contracting Party, the University of Michigan, shall be, and only be, that of an independent contractor and the Contracting Party shall not be construed to be an employee, agent, or in joint venture with, the State and/or agency. The University of Michigan attests that we will conduct a fair and impartial evaluation and prepare an objective Evaluation Report.

We have included a description of the core members of the team and certify that they do not have any conflict of interest in conducting this evaluation and that they will conduct a fair and impartial evaluation and prepare an objective Evaluation Report.

Evaluation team

The evaluation team includes three faculty leads who will guide all aspects of the proposed evaluation, including interacting with MDHHS, engaging with stakeholders, survey development and data collection, dissemination efforts, and ensuring responsiveness and on-time, high quality deliverables.

Anne Fernandez, PhD, MA, is Assistant Professor of Psychiatry, and the Clinical Program Director of two Michigan Medicine clinics, the University of Michigan Addiction Treatment Service and the Multi-Disciplinary Alcohol-Related Liver Disease Clinic. She is a licensed clinical psychologist and a clinical researcher with more than ten years of experience conducting research on substance and alcohol use disorders (SUD/AUD) and their treatments across a variety of settings and populations. She brings her extensive research and clinical expertise in addiction treatment and health outcomes to this project. Dr. Fernandez is the Principal Investigator (PI) of two grants focused on developing and improving treatment for substance use disorders. She is PI of an NIH-funded study to develop and pilot test a tailored preoperative alcohol use intervention. She is also the PI of a precision health study that aims to prevent opioid misuse using machine learning-based risk prediction coupled with patient-centered early intervention. Her other areas of research focus on motivational interviewing, overdose, and polysubstance use. She has more than 30 peer-reviewed publications and expertise in both quantitative and qualitative methodologies.

Sarah J. Clark, MPH, is Research Scientist in the Department of Pediatrics, based in the Susan B. Meister Child Health Evaluation and Research (CHEAR) Center at the University of Michigan. Since joining the University of Michigan faculty in 1998, Ms. Clark has worked closely with Michigan Medicaid and other units within the MDHHS on projects evaluating programs and policies, including co-leading the evaluation of the Healthy Michigan Plan. Her prior state projects have used a variety of methods, including analysis of Medicaid administrative data and primary data collection with Medicaid beneficiaries and providers. She collaborates with Dr. Zivin on a federally funded study to generate and track OUD measures across state Medicaid programs (Medicaid Outcomes Distributed Research Network). Ms. Clark has published more than 200 articles, including many related to analyses of Michigan Medicaid policies and programs. She supervises an experienced team of technical staff who will support the evaluation, including a call center for structured telephone interviews.

Kara Zivin, PhD, MS, MA, is Professor of Psychiatry at the University of Michigan Medical School, Professor at the School of Public Health, Faculty Affiliate at the Institute for Social Research, Research Investigator at the Department of Veterans Affairs (VA), and Senior Health Researcher at Mathematica Policy Research. Dr. Zivin has extensive experience in leading integrated physical and behavioral health care evaluations, including the Washtenaw County Community Mental Health (WCCMH) Health Home program. She served as a senior advisor and subject matter expert to CMS for the Comprehensive Primary Care initiative. She has led several analyses and evaluations for CMS contracts, including cost analyses of the Medicaid Emergency Psychiatric Demonstration, quality measure development for physical and mental health integration, and adaptation of substance use quality measures for use in Medicaid. She led a mixed methods pilot study of a change to an electronic health record default for opioid prescriptions for the Assistant Secretary for Planning and Evaluation (ASPE) within the U.S. Department of Health and Human Services. She led quantitative analyses of primary and behavioral health care integration sites for individuals with serious mental illness receiving physical health treatment in community mental health centers for the Substance Abuse and Mental Health Services Administration. Dr. Zivin served as the behavioral health committee chair for AcademyHealth, the preeminent health services research and policy organization. Dr. Zivin has been funded by multiple federal contracts and research grants and has over 150 peerreviewed scientific publications.

The faculty leads will be supported by a technical staff experienced in Medicaid administrative claims data management and analysis, biostatistics, structured interviewing techniques, qualitative data analysis, cost analysis, policy analysis, and project management.

Appendix

REVISED EVALUATION BUDGET: Michigan 1115 Behavioral Health Demonstration

	10/1/2019 - 9/30/2020	10/1/2020 - 9/30/2021	10/1/2021 - 9/30/2022	10/1/2022 - 9/30/2023	10/1/2023 - 9/30/2024	10/1/2024 - 9/30/2025	10/1/2025 - 9/30/2026	TOTAL
	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5	YEAR 6	YEAR 7	
	Salary	Salary	Salary	Salary	Salary	Salary	Salary	
Subtotal	\$47,824	\$216,630	\$262,184	\$263,244	\$262,865	\$194,714	\$97,277	\$1,344,737
	Fringe	Fringe	Fringe	Fringe	Fringe	Fringe	Fringe	
Subtotal	\$14,655	\$61,377	\$75,854	\$76,090	\$76,144	\$59,838	\$30,186	\$394,155
	Supplies and Materials	Supplies and Materials	Supplies and Materials	Supplies and Materials	Supplies and Materials	Supplies and Materials	Supplies and Materials	
Subtotal	\$398	\$5,200	\$5,200	\$5,200	\$5,200	\$200	\$200	\$21,598
	Travel	Travel	Travel	Travel	Travel	Travel	Travel	
Subtotal	\$553	\$553	\$553	\$553	\$553	\$553	\$0	\$3,319
	Interviews and Surveys	Interviews and Surveys	Interviews and Surveys	Interviews and Surveys	Interviews and Surveys	Interviews and Surveys	Interviews and Surveys	
Subtotal	\$150	\$55,000	\$56,000	\$58,150	\$50,500	\$950	\$150	\$220,900
Total Directs	\$63,590	\$338,760	\$399,792	\$403,237	\$395,261	\$256,261	\$127,813	\$1,984,709
Total Indirects	\$12,718	\$67,752	79,958	\$80,647	\$79,052	\$51,251	\$25,563	\$396,942
TOTAL	\$76,308	\$406,512	\$479,750	\$483,884	\$474,313	\$307,506	\$153,375	\$2,381,650

EVALUATION TIMELINE: Michigan 1115 Behavioral Health Demonstration

	Administrative data analysis	Beneficiary Surveys (phone interviews) 2000 per cohort (200 per PIHP)	Key Informant Interviews	Deliverables
10/1/19- 9/30/20	Draft Data Use Agreements and obtain approvals Generate administrative measures for FY17 and FY18	Develop interview guide & protocol, finalize sampling plan	Develop interview guide Begin BASELINE key informant interviews	Finalize Evaluation Plan (response to CMS comments)
10/1/20- 9/30/21	Generate administrative measures for FY19 Analyze pre-waiver data	Cohort 1 – administer Initial Surveys (baseline) and begin Follow up Surveys	Complete baseline key informant interviews Summarize baseline data	
10/1/21- 9/30/22	Generate administrative measures for FY20	Cohort 1 – complete remaining Follow up Surveys Analyze Cohort 1 results	Conduct MIDPOINT key informant interviews Summarize midpoint data	MIDPOINT ASSESSMENT Due 12/31/2022
10/1/22- 9/30/23	Generate administrative measures for FY21	Cohort 2 – administer Initial Surveys (baseline) and begin Follow up Survey	Conduct FINAL key informant interviews	INTERIM EVALUATION REPORT Due 9/30/23 Finalize interim report (respond to CMS comments)
10/1/23- 9/30/24	Generate administrative measures for FY22	Cohort 2-complete remaining Follow-up Surveys Analyze Cohort 2 results	Analyze key informant data	
10/1/24- 9/30/25	Generate administrative measures for FY23; analyze data trends over demonstration period			

Attachment C

10/1/25-	Generate administrative		SUMMATIVE EVALUATION
9/30/26	measures for FY24; analyze		REPORT due 3/31/26
3/30/20	data trends over demonstration period		Respond to CMS questions as needed

Medicaid Outcomes Distributed Research Network – Opioid Use Disorder Project (MODRN-OUD)

	medical descences Distributed Research Technology Opening See Distributed Research	002,
List of #	measures (March 2019) Performance measure	Source
Ident	ification, initiation, and engagement measures	
1	Initiation & engagement of alcohol and other drug dependence treatment (with sub-analysis of OUD)	NCQA-IET
2	Identification of alcohol and other drug services (with sub-analysis of OUD)	NCQA-IAD
3	Rates of medication-assisted treatment among enrollees with OUD	
Medi	cation, treatment duration, counseling and monitoring	
4	Continuity of pharmacotherapy for OUD	NQF-3175
5	Urine drug screens for enrollees with pharmacotherapy for OUD	
6	Behavioral health counseling with pharmacotherapy for OUD	
Follo	v-up and general, preventive medical care	
7	Follow-up after Emergency Department visit for alcohol and other drug abuse or dependence (with sub-analysis of OUD)	NCQA-FUA-AD
8	Screening for HIV, HCV, HBV among enrollees with an OUD diagnosis	
9	PCP visits among enrollees with OUD diagnosis	
Opioi	d and benzodiazepine prescribing	
10	Any opioid fills among enrollees with OUD diagnosis	
11	Any benzodiazepine fills among enrollees with OUD diagnosis	
12	Use of opioids at high dosages in enrollees without cancer (not limited to OUD)	PQA
13	Multiple opioid prescribers and pharmacies in enrollees without cancer (not limited to OUD)	PQA
14	Concurrent use of opioids and benzodiazepines in enrollees without cancer (not limited to OUD)	PQA
Acute	care use and overdose outcomes	
15	Emergency department use for SUD and OUD, per 1000 member months	
16	Inpatient hospitalizations for SUD and OUD, per 1000 member months	
17	Opioid and heroin poisoning overdose deaths among Medicaid enrollees	
Pregr	ancy and OUD/Neonatal Abstinence Syndrome (NAS)	
18	Number of children 0-12 months diagnosed with NAS at birth $\&$ in first year per 1,000 Medicaid-covered births	
19	Days in NICU for children 0-12 months diagnosed with NAS at birth hospitalization	
20	Percentages of children diagnosed with NAS receiving >= 1 and >=6 well-child visits in first 15 months	modified HEDIS

Current States Participating in MODRN-OUD

Delaware	Pennsylvania
Kentucky	Tennessee
Maryland	Virginia
Michigan	West Virginia
North Carolina	Wisconsin
Ohio	

38

ATTACHMENT D:

State of Michigan Michigan Department of Health and Human Services

Michigan's 1115 Behavioral Health Demonstration Attachment D: Opioid/Substance Use Disorder Implementation Plan

(Revised April 2020)

Access to Critical Levels of Care for Opioid Use Disorder (OUD) and other Substance Use Disorders (SUD)

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 American Society of Addiction Medicine (ASAM) care continuum, including residential and withdrawal management services in an IMD setting for adults age 21-64.

To effectuate a strong SUD network capable of delivering a comprehensive benefit consistent with ASAM Level of Care requirements, Michigan Department of Health and Human Services (MDHHS) is embarking on a process intended to enable the state to generate comprehensive and refreshable reports for future planning and decision-making. Through this work, MDHHS will develop a strategy to effectively utilize existing state-specific and other publicly available data to help achieve the following:

- 1. 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 Screening, Brief Intervention, and Referral to Treatment (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
- 2. 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, withdrawal management, outpatient, early intervention and opioid treatment programs
 - By requiring all providers to meet ASAM level of care standards prior to participating in Medicaid
- 3. 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 can 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

Michigan provides coverage for an extensive array of SUD treatment and recovery support services. Access to these services will be achieved within 18-30 months of the demonstration's approval. Table 1 below lists all the SUD services available under the waiver, including those newly covered under the 1115 waiver, delineated by the ASAM Level of Care. Recovery

Support Services are available to individuals regardless of ASAM care level. Unless otherwise noted, all services are available to adults and children/adolescents.

Table: 1

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability			
SUD TRE	SUD TREATMENT							
0.5 - Ear	ly 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.	Currently Available			
	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. State approval for ASAM level of care. 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.	Currently Available			
Level 1 -	Level 1 - Opioid Treatment Program (OTP)							
	Approved pharmacological support services	Oral medication administration, direct observation, physician evaluations, individual and person-centered assessments, nursing assessments, counseling and laboratory testing	Services must be provided under the supervision of a physician licensed to practice medicine in	Service limitations as indicated by state and federal requirements (e.g., physical	Currently Available			

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability
		and access to primary care (approved for use of Methadone and/or Buprenorphine).	Michigan. Programs must meet applicable state licensure, CSAT certification, DEA licensure and accreditation requirements.	examination, laboratory tests, etc.).	
			State approval for ASAM level of care.		
Level 1 -	Outpatient Services				
	Psychiatric evaluation	Physician evaluation/exam	Psychiatrist or psychiatric mental health nurse practitioner.	Services provided as medically necessary.	Currently Available
	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. State approval for ASAM level of care. 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.	Currently Available
	Treatment planning	Activities associated with the development and periodic review of the plan of service, including	Provider agency licensed and accredited	Services provided as medically necessary.	Currently Available

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability
		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. Monitoring of the individual plan of service including specific services, when not performed by the case manager or supports coordinator, is	as substance abuse treatment program. State approval for ASAM level of care. Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.		
	Therapy (Individual, Group, Family)	included in this coverage. 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.	Provider agency licensed and accredited as substance abuse treatment program. State approval for ASAM level of care. 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.	Currently Available
	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	Provider agency licensed and accredited as substance abuse	Services provided as medically necessary.	Currently Available

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability
		purpose of enhancing their life. The counselor helps the client set the goals that pave the way for positive change to occur.	treatment program. State approval for ASAM level of care. Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS. 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.		
	Didactics and education	Services that are designed or intended to teach information about addiction and/or recovery skills.	Provider agency licensed and accredited as substance abuse treatment program. State approval for ASAM level of care. Clinical service provided by Substance Abuse Treatment Specialist	Services provided as medically necessary.	Currently Available

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability
			(SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS. 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.		
	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.	Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS. Services can be provided by appropriately trained staff when working under the supervision of a SATS or SATP. A recovery coach or SUD	Services provided as medically necessary.	Currently Available

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability
			peer specialist must be certified through an MDHHS-approved training program.		
	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.	Currently Available
	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.	Currently Available
Level 2.1	. – Intensive Outpatient S	ervices			
	Intensive Outpatient Services (IOP)	Includes assessment, counseling, crisis intervention, and activity therapies or education.	Provider agency licensed and accredited as substance abuse	Provided as 9 to 19 hours of structured programming per week	Currently Available

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability
		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.	treatment program. State approval for ASAM level of care. Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.	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.	
Level 2.5	- Partial Hospitalization So	ervices			
	Partial hospitalization (Expanded Intensive Outpatient)	20 or more hours of service/week for multidimensional instability not requiring 24-hour care.	Provider agency licensed and accredited as substance abuse treatment program. State approval for ASAM level of care. Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS.	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.	Currently Available
Level 3.1	. – Clinically Managed Low-	intensity Residential Services			

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability	
	Clinically Managed Low-Intensity Residential Services	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 like low intensity outpatient services focused on improving the individual's functioning and coping skills in Dimension 5 and 6. 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. 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.	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. Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this level of care.	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; medical evaluation and linkage to services; connection to next provider and medical services; preparation for next step. At least 5 hours of life skills and self-care per week.	Currently Available	
Level 3.3	Level 3.3 – Clinically Managed Population-specific High-Intensity Residential Services					
	Clinically Managed Population-specific High-Intensity	The program provides a structured recovery environment in combination with medium-intensity clinical services to support recovery.	Provider agency licensed and accredited	Not less than 13 hours per week of core services (Assessment; Episode of	Currently Available	

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability
	Residential Services (Adult only)	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. The deficits for clients at this level are primarily cognitive, either temporary or 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. The client's level of impairment is more severe at this level, requiring services be provided differently for maximum benefit to be received. 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.	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. Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this level of care.	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 linkage to services; connection to next provider and medical services; preparation for next step. Not less than 13 hours per week of life skills and self-care services.	

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability
Level 3.5	- Clinically Managed High-	Intensity Residential Services			
	Clinically Managed High- Intensity Residential Services	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. Staff provide targeted interventions to rebuild social, psychological, educational/ vocational and employment limitations and support preparation and development for outpatient treatment. 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.	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. Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this level of care.	Not less than 20 hours per week of core services (services (Assessment; Episode of Care Planaddressing 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. Not less than 20 hours per week of life skills and self-care services.	Currently Available

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability		
Level 3.7	Level 3.7 – Medically Monitored High-Intensity Inpatient Services						
	Medically Monitored High-Intensity Inpatient Services	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. The service, when clinically indicated, is an alternative to acute medical care provided by licensed health care professionals in a hospital setting. The skills of the interdisciplinary team and the availability of support services can accommodate withdrawal management	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. Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this level of care. These services must be staffed 24-hours-perday, seven-days-perweek by a licensed physician or by the designated representative of a licensed physician.	Not less than 20 hours per week of core services (services (Assessment; Episode of Care Planaddressing 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. Not less than 20 hours per week of life skills and self-care services.	Currently Available		
4 – Medi	cally Managed Intensive In	patient Services					

ASAM			Provider / Practitioner		
Level	Service Title	Service Description	Qualifications	Limits	Availability
of Care	Medically Managed	Organized service delivered in an acute care	A hospital providing	Service provided as	Currently
	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.	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. The staff are licensed and credentialed by the hospital and meet the accreditation standards	Service provided as medically indicated and through established medical protocols.	Currently Available
			related to practice within their licensures.		
Level 1-V	WM – Ambulatory Withdra	wal Management without Extended On-site Monit	oring (Outpatient Withdra	wal Management)	
	Ambulatory Withdrawal Management without Extended On-site Monitoring (Outpatient Withdrawal Management)	Ambulatory sub-acute detoxification without extended on-site monitoring for patients expected to demonstrate mild withdrawal with daily or less than daily outpatient supervision. Supervised monitoring of withdrawal occurs by personnel trained in SUD and withdrawal	Provider agency licensed and accredited as substance abuse treatment program. Clinical service provided by Substance Abuse	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	Currently Available
		management during identified hours.	Treatment Specialist (SATS) or Substance	successful or complete and authorization	

ASAM Level	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability
of Care		Services must have arrangements for access to licensed medical personnel as needed.	Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS. Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this	requirements continue to be met.	
Lovel 2 V	NAA Ambulatan, Withdra	 wal Management with Extended On-site Monitori	level of care.	Managament	
Level 2-v	Ambulatory Withdrawal	Ambulatory sub-acute detoxification with	Provider agency	Initial length-of-stay	Currently
	Management with Extended On-site Monitoring (Outpatient Withdrawal Management)	extended on-site monitoring for patients expected to demonstrate moderate withdrawal with all day withdrawal management and support and supervision. Services must have arrangements for access to licensed medical personnel as needed. Patient has a supportive family or living situation at night.	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. Ambulatory detoxification services must be monitored by appropriately credentialed and licensed nurses.	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.	Available

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability
			Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this level of care.		
Level 3.2	2-WM – Clinically Managed	Residential Withdrawal Management (Residential	Withdrawal Management)	
	Clinically Managed Residential Withdrawal Management (Residential Withdrawal Management)	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. Services must have arrangements for access to licensed medical personnel as needed.	Provider agency licensed and accredited as substance abuse treatment program. Licensure as a subacute detoxification program is required. Clinical service provided by Substance Abuse Treatment Specialist (SATS) or Substance Abuse Treatment Practitioner (SATP) when working under the supervision of a SATS. Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this level of care.	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.	Currently Available

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability
Level 3.7	WM – Medically Monitor	ed 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 that are based in dysfunctional actions and require habilitation. The service is limited to stabilization of the medical effects of the withdrawal, and referral to necessary ongoing treatment and/or support services. The service, when clinically indicated, is an alternative to acute medical care provided by licensed health care professionals in a hospital setting.	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. These services must be staffed 24-hours-perday, seven-days-perweek by a licensed physician or by the designated representative of a licensed physician. Providers assessed by the state or its designee and confirmed to meet ASAM program level requirements for this level of care.	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.	Currently Available

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability			
Level 4 WM – Medically Managed Intensive Inpatient								
	Medically Monitored Inpatient Withdrawal Management	Severe, unstable withdrawal requiring 24-hour nursing care and daily physician visits. 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 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.	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. The staff are licensed and credentialed by the hospital and meet the accreditation standards related to practice within their licensures. The inpatient unit must be staffed by physician and nursing personnel.	Service provided as medically indicated and through established medical protocols.	Currently Available			

ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability
	Recovery 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. Recovery programs are designed and delivered to 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.	Currently Available
	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.	Currently Available
	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.	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	Available as medically necessary.	Currently Available

the supervision of a SATS.	ASAM Level of Care	Service Title	Service Description	Provider / Practitioner Qualifications	Limits	Availability
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.				SATS. 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		

Use of Evidence-Based SUD Specific Patient Placement Criteria

One of the critical expectations that CMS set forth for 1115 demonstration waivers 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 previously indicated, Michigan has developed the continuum of SUD services using the treatment and recovery services for adolescents and adults recommended by the American Society of Addiction Medicine (ASAM).

To support the use of the ASAM criteria and aid in matching individuals with the appropriate level of care, Michigan is requiring its contracted Prepaid Inpatient Health Plans (PIHPs) and their SUD provider networks to use an assessment tool that utilizes the ASAM criteria. Some potential tools include, but are not limited to, the Global Appraisal of Individual Needs Initial Core (GAIN-I) assessment and the Level of Care Index (LOCI) assessment. Regardless of what tool is utilized, it must collect necessary information to provide a Diagnostic and Statistical Manual based diagnosis and recommend ASAM placement needs.

Pursuant to the STCs, MDHHS requires each PIHP to identify, select, and recommend to MDHHS an assessment tool for its region/SUD network within 18 months of the demonstration approval. Upon MDHHS review and approval, each PIHP must ensure the assessment tool is fully operational within 18-30 months of the demonstration's approval. After 30 months of the demonstration's approval, any assessment tool not approved will not be authorized for use. MDHHS is strongly encouraging and working with the PIHPs to implement a statewide solution for an assessment tool for the purposes of optimal efficiency and effectiveness in implementation, reliability of placements, and for evaluation rigor.

The PIHPs will continue to make authorization decisions for all treatment services regarding length of stay (including continued stay), change in level of care, and discharge based on the ASAM criteria. The PIHP will apply these 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 established medical necessity criteria.

The use of an ASAM assessment tool will allow the appropriate review and application of the ASAM dimensions and assist in matching the individual with a residential program that has been approved to provide the identified level of care. The PIHPs will also use the ASAM dimensions to establish the appropriate level of care for withdrawal management, outpatient and opioid treatment programs. This approach will solidify ASAM as the foundation of the entire SUD service system in Michigan.

For residential and withdrawal management services, PIHPs will use the six ASAM dimensions as a component of decision making for needed level of care. These are delineated below in Table 2:

Table 2:

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 is high severity in this dimension but not in others. The client needs a Level I motivational enhancement program (Early Intervention)	Has marked difficulty engaging in treatment, with dangerous consequences; or there is high severity in this dimension but not in others. The client needs a Level I motivational enhancement program (Early Intervention)	Low interest in treatment and impulse control is poor, despite negative consequences; needs motivating 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 o	Has no recognition of skills needed to prevent continued use, with imminently 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	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

Level of Care	Level 3.1	Level 3.3	Level 3.5	Level 3.7
	24-hour structure is available			

<u>Use of Nationally Recognized SUD-Specific Program Standards to Set Provider</u> <u>Qualifications for Residential Treatment Facilities</u>

An expectation for Michigan's 1115 Behavioral Health Demonstration is that the state implements a process to assess and demonstrate that residential providers meet ASAM criteria prior to participating in the Medicaid program. MDHHS ensures that providers meet key program requirements set forth by ASAM for each of the residential levels of care. Approximately 75 organizations provide the residential level of SUD treatment services in Michigan.

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 for programs 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 of standards 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 SUD provider 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.

Michigan has set forth various treatment policies that establish additional guidance to providers and PIHPs regarding expectations for the structure of specific services and qualifications of providers. The policies on outpatient, residential, withdrawal management and opioid treatment programs are reflective of the ASAM requirements and delineate the criteria for levels of care within each respective area. These policies were effective for the fiscal year 18 contract the state has with the PIHPs for providing Medicaid services.

While the combination of licensing and policy guidance provides a firm foundation for providers to meet the program requirements set forth by ASAM, the State has taken an additional step to review providers against those requirements. 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. The state has initiated and completed the initial ASAM designation enrollment process for early intervention, outpatient, residential, withdrawal management and opioid treatment programs. All PIHP contracted SUD treatment providers currently have an established ASAM level of care. A copy of the residential, withdrawal management and outpatient application instruments are in Attachment A.

The ASAM designation application process is always open, which allows new programs to apply so they may join a PIHP network. An online application process is being developed by the state to manage the assignment procedure. It is targeted to be available for use by the end of fiscal year 21 and moving forward. Until then, it will continue to be a manual, paper process. Michigan is working directly with national experts to provide training on the use of ASAM criteria. The training is targeted to providers to assist in overall education and program development. These trainings began in fiscal year 20 and will be complete in fiscal year 22

Standards of Care

The PIHPs are 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 and individual need, not the designation of the provider program that may be conducting an assessment. 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, clinical records will be reviewed to determine appropriate application and fidelity to ASAM 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 and determining an appropriate level of care. If the PIHP, or the state, 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 state and PIHP will take the necessary corrective action.

The PIHP, through its contract with the state, is required to ensure an ongoing validation and revalidation 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 must 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 C.F.R. §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, reenrollment, 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.

<u>Sufficient Provider Capacity at Each Level of Care Including Medication Assisted</u> Treatment for OUD

The ASAM enrollment work already completed by the state has established the initial provider capacity in the publicly funded system. The regional PIHPs can provide access to each ASAM Level of Care and the support services identified in Table 1. Residential treatment is available in all areas of the state. However, even with the use of IMD's, access to the more intensive level (3.7) has some limitations due to the geographic location of the program which may result in having to travel several hours to access this service from the rural areas of the state. Likewise, level 3.7-WM for withdrawal management, is in the same situation. There is access to this service however, getting to the program from a frontier or rural area may result in a significant amount of travel. The medically managed residential (4.0) and withdrawal management (4-WM)

levels of care, which are not a component of this 1115 Waiver, are more readily available due to these services being provided in a medical hospital setting. These services are being identified to demonstrate that the full ASAM Level of Care continuum is available in the state.

Opioid Use Disorder treatment has accessibility beyond just the Opioid Treatment Programs due to the availability of the Office Based Opioid Treatment services through primary care and other private practice practitioners. Many contracted providers work with these practitioners to provide the required treatment and support services that are not typically available in a primary care or other practice setting. Additionally, the state recognizes the importance of having medication assisted treatment available to address opioid abuse (and other substances when appropriate) in any level of care. PIHPs are required to ensure that their network providers support all avenues to an individual's recovery by providing access to medication assisted treatment when it is clinically appropriate. This access can be provided directly by a program or through an arrangement with another provider. In addition to providing access during treatment in a program, there must be appropriate arrangements for continuing treatment as part of the discharge and recovery plan for each beneficiary. Finally, MDHHS promulgated policy requiring its PIHPs to comply with network adequacy standards, including opioid treatment programs. This policy was activated in FY19.

The state has a commitment to ensure the SUD treatment needs of children and adolescents are met. Statewide, an estimated 127,000 (14%) youth aged 16-21 have a substance use disorder. Thirty-seven percent of those youth also had identified mental health concerns. 4% of adolescents (12-16) used pain relievers for nonmedical reasons. In 2018, a total of 2,591 substance abuse treatment admissions for youth were reported by publicly funded SUD programs.

Adolescents require different models of service than adults. As indicated in Table 1, adolescents that are enrolled in the Medicaid program and have or are at risk of a 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 are receiving SUD treatment services.

In response, the state has developed the Michigan Youth Treatment Improvement and Enhancement (MYTIE) initiative. This began with a two-year Planning project (SYT-P grant October 2015), and has extended an extra four years (SYT-I grant ending September 2021). MYTIE is guiding the state through the development and implementation 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 age and developmentally appropriate evidence-based practices, and implementing financial mechanisms;
- Implementation of a statewide assessment tool to increase ease of transfer of services within the continuum of care and to reduce trauma caused by the recounting of historical traumatic events by the client;
- 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. Information from the gap's analysis in the MYTIE program will assist the State and PIHPs in their network development strategies, including age-appropriate recovery support services for adolescents.

<u>Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD</u>

Former Governor Rick Snyder created a Prescription Drug and Opioid Task Force in 2015 to address the growing prescription drug and opioid problem in Michigan. This work has been continued by current Governor Gretchen Whitmer. The task force reported the following information on the escalation of Michigan's problem.

According to published raw data from the Michigan Automated Prescription System (MAPS), more than 11 million prescriptions for controlled substances were written in 2016. This is roughly one million more prescriptions than were written in 2011, even though Michigan's population slightly decreased over the same time period.

Of the 11 million controlled substance prescriptions written in 2016, 10 million 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 four million schedule II prescriptions in 2011. This acute increase in schedule II prescriptions was due to the addition of Hydrocodone to the list of schedule II drugs in 2014.

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 (MAT).

Prevention

- 1. Require additional training for all professionals who will be prescribing controlled substances, including training on the new CDC prescribing guidelines.
 - a. State Targeted Response (STR) grant funds a project through the University of Michigan that has been offering training on the CDC prescribing guidelines.
 - b. Medicaid is also tracking prescribing outliers and offering technical assistance and guidance to reducing the prescribing appropriately. (State Opioid Response {SOR} grant funded)
- 2. Development and maintenance of relationships among state and local agencies to provide necessary information regarding prescription drug abuse, prevention and treatment.
 - a. Partnership for Success (PFS) funding provides resources to establish State and Community level infrastructure for Prevention Prepared Communities that includes the capacity to develop and implement data guided programming. PFS funds State and Community level Epidemiological Outcomes Workgroups charged with collecting, analyzing and reporting on morbidity, mortality, prevalence, incidence, trend and social indicator data need to identify the extent of prescription drug abuse and the need for prevention and treatment services at the State and Community levels.
- 3. Collaboration among local coalitions, pharmacies, health profession boards, state agencies and the DEA to increase the availability of prescription drop off bins.
 - a. Collaboration among coalitions, pharmacies, DEA State and local law enforcement continues to occur in various Prepaid Inpatient Health Plan target communities funded by the PFS and other federal, state and local resources.
- 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.
 - a. MDHHS employs a Benefits Monitoring System that flags Medicaid Beneficiaries that are pharmacy shopping and doctor shopping to acquire additional opioid prescriptions than legally prescribed. Beneficiaries that are flagged are contacted and limited to one pharmacy and one prescriber for opioid prescriptions.

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. (www.michigan.gov/opioids)

Treatment

- 1. Pursue increased public awareness regarding the laws that limit civil and criminal liabilities for administering Naloxone.
 - a. While Michigan has laws that limit civil and criminal liabilities for administering Naloxone, there has not been any major public campaigns to publicize the laws. Children's Services Agency staff are not allowed to carry it or be trained because of potential liability issues.
- 2. Explore the possibility of limited statutory immunity for low-level offenses involved in reporting an overdose and seeking medical assistance.
 - a. Michigan has a Good Samarian Law which prevents drug possession charges against those that seek medical assistance in certain circumstances.
- 3. 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.
 - a. The State Targeted Response (STR) and SOR grant both increase access to care, increase access to case management and peer services, and increase access to MAT through DATA 2000 waiver training and development of a SUD specific curriculum for medical schools.
 - b. Initiation of an Opioid Health Home in a PIHP region to make treatment more assessible for Medicaid beneficiaries with an OUD. Look alike model being developed for Michigan's Upper Peninsula using SOR funding.
- 4. Explore ways to increase the number of addiction specialists practicing in Michigan.
 - a. SOR project promoting the development of a curriculum specific to substance use disorders to be used in medical schools to prepare physicians entering the field.
- 5. 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 former Governor Rick Snyder in his 2015 Criminal Justice Message, as well as expanding the courts' ability to create pilot programs for the use of MAT.
 - a. There has been a significant increase in the number of Drug Courts implementing MAT programming. MDHHS has provided several trainings on the efficacy of MAT to Michigan Drug Court Professionals including judges.

- 6. Require a bona-fide physician-patient relationship as defined in Michigan law prior to prescribing controlled substances.
- 7. 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.
 - a. The state and other entities are piloting several initiatives to identify pregnant women who are using opioids and connect them to any services needed including treatment and other supports.

Regulation

- 1. Consider legislation to better define and identify pain management practice for the purposes of licensing.
 - 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.
- 2. 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.
- 3. Review the Michigan College of Emergency Physicians policy and then endorse a best practices policy that hospitals and doctors could use as a model.
- 4. Review the limitation of the sale of pseudoephedrine by pharmacies only.

Policy and Outcomes

- 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.

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.
 - a. The MAPS upgrades were completed with the new Appriss software. STR grant funds were used to help support the additional NarxCare portion of the Appriss program.
- 2. Allow broader access to MAPS for law enforcement purposes when investigating questionable business practices by prescribers.
 - a. Requires legislation with is being reviewed.
- 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.

To compliment and implement the recommendations of the Task Force, the former Governor, in June 2016, established the Prescription Drug and Opioid Abuse Commission (PDOAC). Consequently, the former Governor and a bi-partisan group of legislators announced a package of bills to combat opioid and prescription drug misuse which were signed into law in December of 2017. The legislation included:

- Prescribers documenting a bona-fide patient relationship prior to prescribing opioids;
- A seven-day prescribing limit for acute pain;
- The development of a prescription drug education curriculum in schools; and
- Mandated greater patient education requirements including a new consent form effective 2018

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 and the implementation strategies provided by the PDOAC. 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.
- o Provide training to strengthen infrastructure to enhance substance use disorder prevention and mental health promotion at the community/coalition level.
- o 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.
- o Secure federal discretionary funding to implement the activity listed above.
- Broaden statewide media messages
 - O Promote the use of statewide media campaigns entitled: Stop Overdoses (www.michgan.gov/stopverdoses) and Do Your Part: Be the Solution to Prevent Prescription Drug Abuse (www.michigan.gov/doyourpart), that include 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
 - o Ensure on-going surveillance to monitor data relevant to drug overdoses and deaths from drug overdoses

Michigan published Medication Assisted Treatment guidelines that are consistent with the federal guidelines and contain detailed guidance for treating people addicted to heroin and other opiates. The guidelines define mild, moderate and severe levels of addiction and then recommend appropriate medication and behavioral therapy that research has shown to be most effective for that level of addiction. These guidelines are considered best practice and have led efforts on changing how treatment should be delivered and viewed in Michigan during the implementation of the waiver.

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 was passed to allow family members of those with opioid prescriptions to receive Naloxone as an additional way to prevent death from overdose.

Improved Care Coordination and Transitions Between Levels of Care

Care Transitions

Benefit management for SUD services has been the responsibility of the PIHPs since 2014. The PIHP employs utilization management for prior authorization and continued stay reviews which

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:

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:

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 personcentered 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 parity rules, 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 process based on significant research evidence and application. As set forth in the Standards of Care discussion, PIHPs 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.

Care Coordination and Integration Models

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. This includes the implementation of Michigan's Opioid Health Home (OHH) under Section 1945 of the US Social Security Act. Michigan's OHH is predicated on the evidence-based collaborative care model and utilizes a multidisciplinary team to serve the whole-person. This includes primary, behavioral, and social services under the auspice of a recovery-oriented philosophy. Michigan implemented the OHH in one PIHP region in FY19 and is in the process of expanding the OHH several more regions at the beginning of FY21. Michigan will continue to 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.

In FY19, MDHHS was also awarded a five-year SAMHSA Promoting the Integration of Primary and Behavioral Health Care (PIPBHC) grant, which is predicated on integrating care between Community Mental Health Services Programs (CMHSPs) and Federally Qualified Health Centers (FQHCs). MDHHSs subgrantees indicated SUD as a focal point for integration, particularly in the context of assuring access to medication assisted treatment and overarching physical and behavioral health needs. Michigan also has several Certified Community Behavioral Health Care (CCBHC) expansion grantees, which primes Michigan as a potential expansion state should the CMS demonstration be augmented. This would further Michigan's vision to optimize its care integration/coordination for Medicaid beneficiaries with SUD.

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

MDHHS 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.

MHPs and PIHPs have collaborated with MDHHS to establish a uniform process for identifying high-risk individuals and stratify populations as required under the MHP <u>contract</u>, which state in part that MHPs must work collaboratively with PIHPs to:

- <u>Identify and coordinate the provision of services</u> to shared members who have significant behavioral health issues and complex physical co-morbidities.
- Jointly create and implement a <u>method for stratifying</u> shared members who have significant behavioral health issues and complex physical co-morbidities.
- Jointly <u>develop care management standards</u> for providing care management services to shared members with significant behavioral health issues and complex physical comorbidities based on patient needs and goals.
- Jointly develop and implement <u>processes for providing coordinated complex care</u> <u>management services</u> for shared members with significant behavioral health issues and complex physical co-morbidities.
- Jointly <u>create a care management tool</u> 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.

SUD Health IT Plan

See Michigan's Approved SUD Health IT Plan

Attachment A

- Document #1: MDHHS ASAM Residential Level of Care Designation Questionnaire
- Document #2: MDHHS ASAM Outpatient Level of Care Designation Application
- Document #3: MDHHS ASAM Withdrawal Management Level of Care Designation Application

MDHHS ASAM Residential Level of Care Designation Questionnaire

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:
Facility Address:
City/State/Zip:
License Number:
Treatment Capacity:
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
Please indicate which Pre-paid Inpatient Health Plan(s) the program is currently contracted with or planning to contract with to provide services: (check all that apply) Community Mental Health Partnership of Southeast Michigan Detroit Wayne Mental Health Authority Lakeshore Regional Entity Macomb County Community Mental Health Services Mid-State Health Network Northcare Network Northern Michigan Regional Entity Oakland County Community Mental Health Authority Region 10 Pre-paid Inpatient Health Plan Southwest Michigan Behavioral Health

SERVICE DELIVERY and SETTING

Please indicate the type of setting where services are provided.

,	☐ Freestanding community setting. ☐ Unit within a licensed health care facility. ☐ Secure community setting in the criminal justice system. 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
	SULLORI SISIEMS
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. YesNo
	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

Yes	□No											
4) Please indicate	progra	ım staff	conduc	ting eac	h servic	e.						
Check all that	apply o	on the fo	ollowing	g table:								
License or	License or Individual		Gro		Dida	actic/		CO	D	Medical		al
Certification/	Coun	seling	Couns	-	Educa	ational	Trea	tme	ent		RX	
MD/DO		j									\Box	
LP/LLP/TLLP												
LMFT/LLMFT												
LPC/LLPC												
RN, NP, LPN												
PA												
LMSW/LLMSW												
LBSW/LLBSW												
CADC-M/CADC												
CAADC												
CCJP-R												
CCDP												
CCDP-D												
CCS-M												
CCS-R												
DP-S												
DP-C												
				THER	APIES							
Please describe the the	erapy s	ervices	that are	availab	le:							
1) Planned clinic	al prog	ram act	ivities (professi	onally d	irected)	hours p	er '	week:			
2) Focus of count	seling a	and clin	ical pro	gram ac	tivities:							
3) Recovery supp	ort ser	vices av	ailable:	•								
4) Involvement o		y meml	ers and	signific	cant othe	ers?						
Yes	∐No											
5) Medication ass	sisted to	reatmen	ıt availa	ble?								

3) One or more clinicians available on site or by telephone 24 hours a day.

	AUTHORIZE D INDIVIDIJAL	TITLE	SIGNATURE	DATE
OPI	ERATION OF THI	S PROGRAM IS ACCU	OVIDED REGARDING JRATE, TRUE, AND CO signatures are acceptable	OMPLETE e)
5)	Ongoing transition/ Yes N	continuing care planning	?	
4)	Physical examination assessment/admission Yes	on process?	performed as part of initia	al
3)	Daily assessment o	f progress and treatment of	changes?	
2)	Individualized treat personal goals? Yes N	•	collaboration with client a	nd reflects client's
1)	Individualized, con ☐Yes ☐N	nprehensive bio-psychoso Io	ocial assessment utilized?	
Does t	he program's assessi	ment & treatment plan rev	view include:	
	A	SSESSMENT/ TREAT	MENT PLAN REVIEW	
8)	other treatment serv	vices labeled, in order to vices labeled, in order to vices mmatic documentation the	with the individual, group, validate the service hours at will support the ASAM	listed above. Please
7)	Use of random drug Yes N	g screens to monitor complo	pliance?	
6)	Monitoring of medical Yes N		navioral health and physic	al health)?

NAME	TITLE	EMAIL	TELEPHON
OHHS ASAM Outpatient e Michigan Department of AM level of care for all lice ermination, the following	Health and Human Servensed outpatient treat	vices (MDHHS) is requ ment programs. In orde	er to make this
eking to provide publicly fuestionnaire will allow MDI	unded services. The info	ormation provided and s	submitted with this
ogram/Facility Name:			
cility Address:			
ty/State/Zip:			
cense Number:			
reatment Capacity: Applicable)			
ease indicate the ASAM Le	evel being applied for (se	elect only one):	
0.5 Early Interver 1 Outpatient Serv 2.1 Intensive Outp	ices patient Services		
2.5 Partial Hospit	anzadon services		

Community Mental Health Partnership of Southeast Michigan
Detroit Wayne Mental Health Authority
Lakeshore Regional Entity Macomb County Community Mental Health Services
Mid-State Health Network
Northcare Network
Northern Michigan Regional Entity
Oakland County Community Mental Health Authority
Region 10 Pre-paid Inpatient Health Plan
Southwest Michigan Behavioral Health
SERVICE DELIVERY and SETTING
Please indicate the type of setting where services are provided.
Behavioral health clinic/office-based program
Primary care office/clinic
☐ Integrated care clinic (combined physical and behavioral health)
☐ Work sites
☐ School
Community based
☐ Individuals home
On average, over the past 90 days, what percentage of clients with a substance use disorder were served (Level 0.5 programs can skip this): (Total must equal 100%)
 d. Without a co-occurring mental health disorder – % e. Combined with a co-occurring mental health disorder – %
SUPPORT SYSTEMS
Please select "yes" or "no" for each of the following questions:
rease select yes of no for each of the following questions.
6) Does your program provide referral and linking to ongoing treatment?

5)	Is counseling/therapy provided by appropriately licensed and credentialed professionals?
6)	Is there a generalist physician(s) and/or physician assistant(s) available? Yes No
7)	Are nursing staff available? YesNo
8)	Is the physician(s) or physician assistant specially trained in addiction medicine? Yes No
9)	Are staff cross-trained in mental health, psychotropic medications and interactions with addictive substances?
7)	Please indicate program staff conducting each service.
	Check all that apply on the following table:

License or	Screen	ning	Indi	vidual	Group		Didactic/		COD		Medical
Certification/	and/	or	Counselin		Counselin		Educationa		Treatmen		RX
Registration	Assessi	ment	g Sessions		g Sessions		1 Sessions		t Services		
MD/DO											
LP/LLP/TLLP											
LMFT/LLMFT]]	
LPC/LLPC											
RN, NP, LPN											
PA]									
LMSW/LLMS											
LBSW/LLBSW											
Occupational											
Therapist									Ш		
Recreational		1				7				1	
Therapist		,		_	_				_		
CADC-		<u> </u>								<u> </u>	
CAADC											
CCJP-R											
CCDP											
CCDP-D											
CCS-M											
CCS-R											
DP-S											
DP-C]									
Recovery											
Specifically,		1				7				1	
trained staff											

Specifically, trained staff explanation:

THERAPIES

Please <u>describe</u> the following in reference to the program:
9) Focus of program activities for the level of care requested in this application:
10) Recovery support services:
Please select "yes" or "no" for each of the following questions:
11) Individual therapy/counseling/psychotherapy provided? Yes No
12) Group therapy provided? Yes No
13) Family therapy provided? Yes No a. If provided is there involvement of family members, guardians and significant others in the assessment, treatment and continuing care of the client? Yes No
14) Educational/didactic services provided? Yes No
15) Occupational therapy? Solution Services Ser
16) Recreational therapy available? Yes No
17) Medication management (SUD) available? Yes No
18) Medication management (mental health) available? Yes No
19) Monitoring of medication adherence (for behavioral health and physical health)? Yes No

20) Use of laboratory and toxicology services (on-site/consultation/referral)? Yes No
21) For Levels 2.1 and 2.5 please submit a weekly schedule of services with the individual, group, educational and/or other treatment services labeled to verify the minimum number of hours of skilled treatment services for the level are available.
ASSESSMENT/ TREATMENT PLAN REVIEW
Indicate if the program's assessment & treatment plan review processes include the following?
6) Screening to rule in or out substance related addictive disorders? Yes No
7) Assessment of ASAM dimensional risk and severity of need performed prior to and throughout the process of delivering services? Yes No
8) Individualized, comprehensive bio-psychosocial assessment utilized? Yes No
9) Physical examination by (MD/DO, PA, NP) available for conditions as warranted based on physician approved protocols?
10) Individualized treatment plan, developed in collaboration with client and reflects client's personal goals?
□Yes □No
11) Treatment plan reviews are conducted at specified times, as noted in the plan or with a frequency as determined by appropriately credentialed staff?
12) Documentation of mental health problems and relationship to substance use disorder? Yes No
13) Documentation of progress and treatment changes? Yes No
14) Ongoing recovery/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)

AUTHORIZE	TITLE	SIGNATURE	DATE
D			
INDIVIDITAL.			

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

NAME	TITLE	EMAIL	TELEPHONE

MDHHS ASAM Withdrawal Management Level of Care Designation Application

The Michigan Department of Health and Human Services (MDHHS) is required to designate the ASAM level of care for all licensed **withdrawal management** 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:
Facility Address:
City/State/Zip:
License Number:
Treatment Capacity:
Please indicate the ASAM Level being applied for: (Select Only One)
 □ Level 1-WM – Ambulatory Withdrawal Management without Extended On-site Monitoring (Outpatient Withdrawal Management) □ Level 2-WM – Ambulatory Withdrawal Management with Extended On-site Monitoring (Outpatient Withdrawal Management)

 □ Level 3.2-WM – Clinically Managed Residential Withdrawal Management (Residential Withdrawal Management) □ Level 3.7-WM – Medically Monitored Inpatient Withdrawal Management (Residential Withdrawal Management)
Please indicate the population served by the program: Adolescent Adult
Please indicate which Pre-paid Inpatient Health Plan(s) the program is currently contracted with or planning to contract with to provide services: (check all that apply) Community Mental Health Partnership of Southeast Michigan Detroit Wayne Mental Health Authority Lakeshore Regional Entity Macomb County Community Mental Health Services Mid-State Health Network NorthCare Network Northern Michigan Regional Entity Oakland County Community Mental Health Authority Region 10 Pre-paid Inpatient Health Plan Southwest Michigan Behavioral Health
SERVICE DELIVERY and SETTING
Please indicate the type of setting where services are provided:
 Client Home Office or agency setting Healthcare facility Day hospital or residential type setting Freestanding withdrawal management facility
Please indicate how services are provided in the program:
Regularly scheduled services. Services delivered under physician approved policies and procedures or clinical protocols.
SUPPORT SYSTEMS
Please select "yes" or "no" for each of the following questions:

,

1) Available specialized psychological and psychiatric/clinical consultation and supervision.

	∐Yes ∐No
2)	Comprehensive medical history and physical examination completed as part of admission. Yes No
3)	Affiliation with other levels of care, including other specialty substance use disorder treatment. Yes No
4)	Ability to conduct and or arrange for laboratory/toxicology tests. Yes No
5)	24-hour access to emergency medical consultation services. Yes No
6)	Ability to provide/assist with access to safe transportation services. Yes No
	~~·
	STAFF
Please	STAFF e select "yes" or "no" for each of the following questions:
1)	e select "yes" or "no" for each of the following questions: Physicians and/or nurses present as needed. Yes No
1) 2)	e select "yes" or "no" for each of the following questions: Physicians and/or nurses present as needed. Physicians and/or nurses readily available. Yes No No
1) 2) 3)	Physicians and/or nurses present as needed. Yes No Physicians and/or nurses readily available. Yes No Physicians and/or nurses present at all times. Yes No
1) 2) 3)	Physicians and/or nurses present as needed. Yes No Physicians and/or nurses readily available. Yes No Physicians and/or nurses present at all times. Yes No Counseling staff available or accessed through affiliation relationships.
1) 2) 3) 4)	Physicians and/or nurses present as needed. Yes No Physicians and/or nurses readily available. Yes No Physicians and/or nurses present at all times. Yes No

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

THERAPIES

Please describe the therapy services that are available:

1)	Medication supported withdrawal management.
	□Yes □No
2)	Self-administered withdrawal management medications.
	□Yes □No
3)	Supervised self-administered withdrawal management medications.
	□Yes □No
4)	Non-medication supported withdrawal management.
	□Yes □No
5)	Education/didactics.
	□Yes □No
6)	Involvement of family members and significant others.
	□Yes □No
7)	Discharge/transfer planning.
	□Yes □No
8)	Physician/nurse monitoring/management of intoxication and/or withdrawal

	☐ Yes ☐ No Range of therapies available in group and/or individual format (cognitive, behavioral, medical). ☐ Yes ☐ No Please submit a weekly schedule of services with the individual, group, educational and/or other treatment services labeled to verify what is reported above and attach other programmatic documentation that will support the ASAM Level being sought.
	ASSESSMENT/TREATMENT PLAN REVIEW
	he program's assessment and treatment plan review include: Addiction focused history part of initial assessment and conducted or reviewed by physician. No
2)	Physical examination (by MD/DO, PA, NP) performed as part of initial assessment. Yes No
3)	Biopsychosocial screening assessments used to determine level of care and to address treatment priorities in ASAM dimensions 2-6.
4)	Interdisciplinary team available to participate in treatment and to obtain and interpret information regarding client needs.
5)	Individual treatment plan, with problem identification for ASAM dimensions 2-6, with treatment goals and measurable objectives.
6)	Daily assessment of progress and treatment changes. Yes No
7)	Transfer/discharge planning beginning at point of admission. Yes No
8)	Referral and linking arrangements for continuing care. Yes No
9)	Medical assessments, using appropriate measures of withdrawal. 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 accentable)

IN ALL MATERIAL AS	PECIS. (Electronic sign	natures are acceptable)	
AUTHORIZED	TITLE	SIGNATURE	I
INDIVIDUAL			

AUTHORIZED INDIVIDUAL	TITLE	SIGNATURE	DATE

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

NAME	TITLE	EMAIL	TELEPHONE

ATTACHMENT E: OUD/SUD Monitoring Protocol

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

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

a.	State	Michigan
b.	Demonstration name	Michigan's 1115 Behavioral Health Demonstration
c.	Approval date for demonstration	04/05/2019
d.	Approval period for SUD	10/01/2019 – 09/30/2024
e.	Approval date for SUD, if different from above	N/A
f.	Implementation date of SUD, if different from above	N/A
g.	SUD (or if broader demonstration, then SUD - related) demonstration goals 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.

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

Summary of proposed modification	Related metric (if any)	Justification for modification			
1. Assessment of Need and Qualif	ication for SUD	Services			
N/A	3, 4, 5,	Michigan has no modification expectations for this topic.			
☐ The state has reviewed the corresponding information with the modified in t		s for narrative information in the SUD Monitoring Report Template and confirms that it will report the bed above.			
☐ The state has reviewed the corre	sponding promp	ts for narrative information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information as requested ((no modifications	s).			
2. Access to Critical Levels of Car	re for OUD and	other SUDs (Milestone 1)			
N/A	6, 7, 8, 9, 10,	Michigan has no modification expectations for Milestone 1.			
	11, 12, 36				
		s for narrative information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information with the modi					
	☑ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the				
narrative information as requested (
3. Use of Evidence-based, SUD-sp	ecific Patient P				
N/A		There are no CMS-provided metrics related to Milestone 2.			
		s for narrative information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information with the modi					
		ts for narrative information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information as requested (,	, and the second			
·	UD-specific Pro	ogram Standards to Set Provider Qualifications for Residential Treatment Facilities (Milestone 3)			
N/A		There are no CMS-provided metrics related to Milestone 3.			
	☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the				
narrative information with the modifications described above.					
☑ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the					
narrative information as requested (`				
		of Care including for Medication Assisted Treatment for OUD (Milestone 4)			
N/A	13, 14	Michigan has no modification expectations for Milestone 4.			

Summary of proposed modification	Related metric (if any)	Justification for modification			
		ts for narrative information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information with the mod					
		ts for narrative information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information as requested					
		and Prevention Strategies to Address Opioid Abuse and OUD (Milestone 5)			
N/A	15, 18, 19, 20, 21, 22	Michigan has no modification expectations for Milestone 5.			
☐ The state has reviewed the corre narrative information with the mod		ts for narrative information in the SUD Monitoring Report Template and confirms that it will report the bed above.			
	esponding promp	ts for narrative information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information as requested					
7. Improved Care Coordination a	and Transitions	between Levels of Care (Milestone 6)			
N/A	17	Michigan has no modification expectations for Milestone 6.			
☐ The state has reviewed the correnarrative information with the mod		ts for narrative information in the SUD Monitoring Report Template and confirms that it will report the			
		ts for narrative information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information as requested					
8. SUD Health Information Tech	`	, and the second			
Please see detailed outline in part					
A					
☐ The state has reviewed the corre	sponding prompt	ts for narrative information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information with the mod	ifications describ	ped above.			
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the					
narrative information as requested (no modifications).					
9. Other SUD-related Metrics					
N/A	23, 24, 25,	Michigan has no modifications for other SUD-related metrics.			
	26, 27, 28,				
	29, 30, 31,				
	32, 33, 34, 35				

Summary of proposed	lated etric	Justification for modification			
modification	any)	Justification for mounication			
☐ The state has reviewed the correspond	g prompts for narrativ	we information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information with the modification	ns described above.				
☐ The state has reviewed the correspond	ng prompts for narrati	ve information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information as requested (no mo	lifications).				
10. Budget Neutrality					
N/A	Michigan	has no modifications for the budget neutrality.			
☐ The state has reviewed the correspond	g prompts for narrativ	we information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information with the modification	ns described above.				
☐ The state has reviewed the correspond	ng prompts for narrati	ve information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information as requested (no mo	lifications).				
11. SUD-Related Demonstration Opera	ions and Policy				
N/A	Michigan	has no modifications for SUD-related demonstration operations and policy.			
☐ The state has reviewed the correspond	g prompts for narrativ	we information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information with the modification	ns described above.				
☐ The state has reviewed the correspond	ng prompts for narrati	ve information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information as requested (no mo	lifications).				
12. SUD Demonstration Evaluation Up	ate				
N/A	Michigan	has no modifications for SUD demonstration evaluation.			
☐ The state has reviewed the correspond	g prompts for narrativ	we information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information with the modification	ns described above.				
	ng prompts for narrati	ve information in the SUD Monitoring Report Template and confirms that it will report the			
narrative information as requested (no mo	lifications).				
13. Other Demonstration Reporting					
N/A	Michigan	has no modifications for other demonstration reporting.			
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the					
narrative information with the modifications described above.					
☑ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the					
narrative information as requested (no mo	narrative information as requested (no modifications).				
14. Notable State Achievements and/or	nnovations				
N/A					

Summary of proposed modification	Related metric (if any)	Justification for modification			
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the					
narrative information with the modifications described above.					
☑ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the					
narrative information as requested (no modifications)					

3. Acknowledgement of Budget Neutrality Reporting-

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

4. Retrospective reporting

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

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

☐ The state will	ll report retrospectiv	ely for any quai	rters prior to mo	onitoring protocol	approval as
described above	e, in the state's secon	nd monitoring re	eport submission	n after protocol a	pproval.

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

5. Reporting SUD Demonstration Metrics and Narrative Information

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

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

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

Dates of reporting quarter	Broader 1115 DY (if applicable) *	SUD DY	Report due (per STCs schedule)	Measurement period associated with SUD information in report, by reporting category
October 1, 2019- December 31, 2019	N/A	DY1 Q1	12/31/2020	Narrative information for SUD DY1 Q1
January 1, 2020- March 31, 2020	N/A	DY1 Q2	12/31/2020	 Narrative information for SUD DY1 Q2 Other monthly and quarterly metrics for SUD DY1 Q1
April 1, 2020- June 30, 2020	N/A	DY1 Q3	12/31/2020	 Narrative information for SUD DY1 Q3 Other monthly and quarterly metrics for SUD DY1 Q2
July 1, 2020- September 30, 2020	N/A	DY1 Q4	12/31/2020	 Narrative information for SUD DY1 Q4 Other monthly and quarterly metrics for SUD DY1 Q3
October 1, 2020- December 31, 2020	N/A	DY2 Q1	2/28/2021	 Narrative information for SUD DY2 Q1 Other monthly and quarterly metrics for SUD DY1 Q4 Annual metrics that are established quality measures for CY 2019 Other annual metrics for SUD DY1
January 1, 2021- March 31, 2021	N/A	DY2 Q2	5/30/2021	 Narrative information for SUD DY2 Q2 Other monthly and quarterly metrics for SUD DY2 Q1

Dates of reporting quarter	Broader 1115 DY (if applicable) *	SUD DY	Report due (per STCs schedule)	Measurement period associated with SUD information in report, by reporting category
April 1, 2021- June 30, 2021	N/A	DY2 Q3	8/31/2021	 Narrative information for SUD DY2 Q3 Other monthly and quarterly metrics for SUD DY2 Q2
July 1, 2021- September 30, 2021	N/A	DY2 Q4	12/31/2021	 Narrative information for SUD DY2 Q4 Other monthly and quarterly metrics for SUD DY2 Q3
October 1, 2021- December 31, 2021	N/A	DY3 Q1	2/28/2022	 Narrative information for SUD DY3 Q1 Other monthly and quarterly metrics for SUD DY2 Q4 Annual metrics that are established quality measures for CY 2020 Other annual metrics for SUD DY2
January 1, 2022- March 31, 2022	N/A	DY3 Q2	5/30/2022	 Narrative information for SUD DY3 Q2 Other monthly and quarterly metrics for SUD DY3 Q1
April 1, 2022- June 30, 2022	N/A	DY3 Q3	8/31/2022	 Narrative information for SUD DY3 Q3 Other monthly and quarterly metrics for SUD DY3 Q2
July 1, 2022- September 30, 2022	N/A	DY3 Q4	12/31/2022	 Narrative information for SUD DY3 Q4 Other monthly and quarterly metrics for SUD DY3 Q3
October 1, 2022-	N/A	DY4 Q1	2/28/2023	 Narrative information for SUD DY4 Q1 Other monthly and quarterly metrics for SUD DY3 Q4

Dates of reporting quarter	Broader 1115 DY (if applicable) *	SUD DY	Report due (per STCs schedule)	Measurement period associated with SUD information in report, by reporting category
December 31, 2022				 Annual metrics that are established quality measures for CY 2021 Other annual metrics for SUD DY3
January 1, 2023- March 31, 2023	N/A	DY4 Q2	5/30/2023	 Narrative information for SUD DY4 Q2 Other monthly and quarterly metrics for SUD DY4 Q1
April 1, 2023- June 30, 2023	N/A	DY4 Q3	8/31/2023	 Narrative information for SUD DY4 Q3 Other monthly and quarterly metrics for SUD DY4 Q2
July 1, 2023- September 30, 2023	N/A	DY4 Q4	12/31/2023	 Narrative information for SUD DY4 Q4 Other monthly and quarterly metrics for SUD DY4 Q3
October 1, 2023- December 31, 2023	N/A	DY5 Q1	2/28/2024	 Narrative information for SUD DY5 Q1 Other monthly and quarterly metrics for SUD DY4 Q4 Annual metrics that are established quality measures for CY 2022 Other annual metrics for SUD DY4
January 1, 2024- March 31, 2024	N/A	DY5 Q2	5/30/2024	 Narrative information for SUD DY5 Q2 Other monthly and quarterly metrics for SUD DY5 Q1
April 1, 2024- June 30, 2024	N/A	DY5 Q3	8/31/2024	 Narrative information for SUD DY5 Q3 Other monthly and quarterly metrics for SUD DY5 Q2

Dates of reporting quarter	Broader 1115 DY (if applicable) *	SUD DY	Report due (per STCs schedule)	Measurement period associated with SUD information in report, by reporting category
July 1, 2024- September 30, 2024	N/A	DY5 Q4	12/31/2024	 Narrative information for SUD DY5 Q4 Other monthly and quarterly metrics for SUD DY5 Q3
July 1, 2024- September 30, 2024	N/A	N/A	2/28/2025	 Annual metrics that are established quality measures for CY 2022 Other annual metrics for SUD DY4

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

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