State Demonstrations Group

June 9, 2020

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

Dear Mr. Gordon:

The Centers for Medicare & Medicaid Services (CMS) has approved the evaluation design for Michigan's section 1115 Behavioral Health Demonstration entitled, "Michigan's 1115 Behavioral Health Demonstration Waiver" (Project Number 11-W-00305/5), and effective through September 30, 2024. We sincerely appreciate the state's commitment to a rigorous evaluation of your demonstration.

CMS has added the approved evaluation design to the demonstrations Special Terms and Conditions (STC) as part of Attachment C. A copy of the STCs, which includes the new attachment, is enclosed with this letter. The approved evaluation design should now be posted to the state's Medicaid website within thirty days, per 42 CFR 431.424(c). CMS will also post the approved evaluation design as a standalone document, separate from the STCs, on Medicaid.gov.

Please note that an interim evaluation report, consistent with the approved evaluation design is due to CMS one year prior to the expiration of the demonstration, or at the time of the renewal application if the state chooses to extend the demonstration. Likewise, a summative evaluation report, consistent with this approved design, is due to CMS within 18 months of the end of the demonstration period.

We look forward to our continued partnership with you and your staff on your section 1115 Behavioral Health Demonstration. If you have any questions, please contact your CMS project officer, Mr. Thomas Long. Mr. Long may be reached by email at Thomas.Long@cms.hhs.gov.

Sincerely,

Danielle Daly
Director
Division of Demonstration
Monitoring and Evaluation

Andrea J. Casart
Director
Division of Eligibility and Coverage
Demonstrations

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

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

2-6-2020

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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 l-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.[1] 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.[2] Drug-related overdose deaths in Michigan increased from roughly 985 in 2005 to nearly 2,700 in 2017.[3] 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

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[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.[5] 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.[7] 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

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[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,[9] 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

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[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_-_Report__Appendices_1.17.18_final_618161_7.pdf

[11] Dennis, M., Titus, J., White, M., Unsicker, J. & Hodgkins, 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).

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

Table 1. Anticipated Timing of Implementation

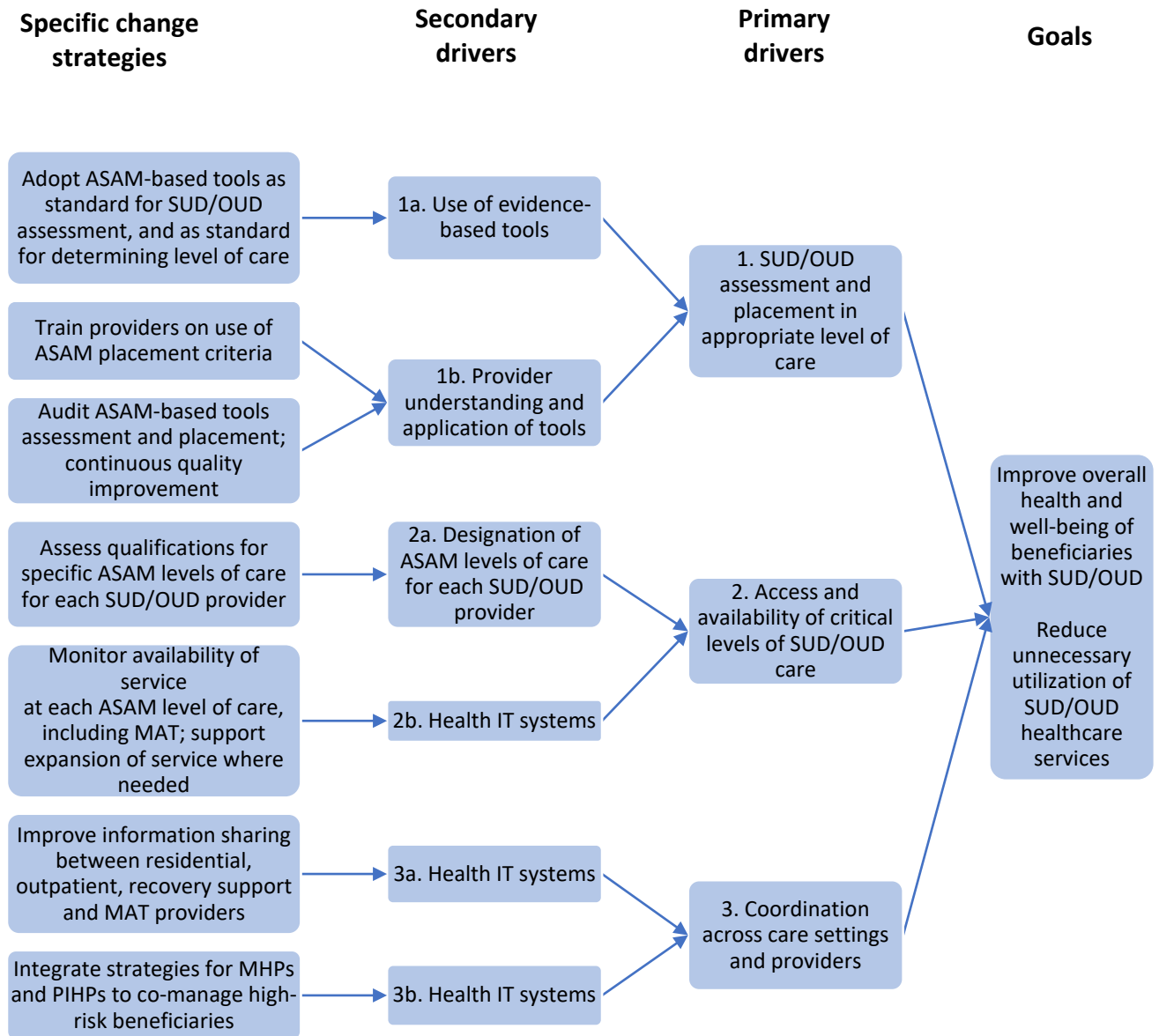|	FY2019	FY2020	FY2021	FY2022	FY2023
ASAM-based tools for assessment & treatment recommendations		PIHP selection of assessment tools by the end of FY2020 Sept. 30 2020	Training and integration Oct. 1 2020- Sept.30 2021	Full implementation will take place by the beginning. of FY2022 Oct. 1. 2021- Sept. 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

Specific change strategies	Secondary drivers	Primary drivers	Goals

Adopt ASAM-based tools as standard for SUD/OUD assessment, and as standard for determining level of care → 1a. Use of evidence-based tools

Train providers on use of ASAM placement criteria →

Audit ASAM-based tools assessment and placement; continuous quality improvement → 1b. Provider understanding and application of tools

1. SUD/OUD assessment and placement in appropriate level of care

Assess qualifications for specific ASAM levels of care for each SUD/OUD provider → 2a. Designation of ASAM levels of care for each SUD/OUD provider

Monitor availability of service at each ASAM level of care, including MAT; support expansion of service where needed → 2b. Health IT systems

2. Access and availability of critical levels of SUD/OUD care

Improve information sharing between residential, outpatient, recovery support and MAT providers → 3a. Health IT systems

Integrate strategies for MHPs and PIHPs to co-manage high-risk beneficiaries → 3b. Health IT systems

3. Coordination across care settings and providers

Improve overall health and well-being of beneficiaries with SUD/OUD

Reduce unnecessary utilization of SUD/OUD healthcare services

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 guidance[13] on selection of comparison groups include: 1) a pre-intervention 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

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

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

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

Measure Description	Steward	Numerator	Denominator	Data sources	Measurement Frequency	Analytic approach
(continued)			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 Frequency	Analytic approach
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 had a follow-up visit with a corresponding primary	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

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

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

OUTCOME: Overall health status	CDC Healthy Days	Number of beneficiaries reporting Excellent or Very good physical health				
OUTCOME: Health Limitations	CDC Healthy Days	Number of beneficiaries reporting 10+ days in the past 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 objectives	ECHO/ CAHPS	Number of beneficiaries 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 overdose death	Total number of Medicaid beneficiaries	State vital records	Annual	Descriptive comparison over time (frequencies, 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 Frequency	Analytic approach
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 Frequency	Analytic approach
OUTCOME: Total SUD spending	N/A	Total dollars reported as spent on SUD, all sources	N/A	State cost reports	Annual	Descriptive comparison over time (frequencies; graphs)
OUTCOME: SUD spending for inpatient treatment, per member-month	N/A	Total paid amount for residential or inpatient treatment within IMDs	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
OUTCOME: MAT spending, per member-month	N/A	Total paid amount for SUD pharmacotherapy	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
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.
- Medicaid administrative claims 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.
- Specialty behavioral health files 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

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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.

- Enrollment-related variables 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 trend in a specified period). Enrollment variables will be used in multivariate regression models.
- Demographic variables 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 = quarters from beginning of the study
post = 1 for post-intervention and 0 for pre-intervention time periods.
X = Control variables
α = Intercept, pre-intervention
β_1 = Slope, pre-intervention
β_2 = Intercept (level) change, post-intervention
β_3 = Slope (trend) change, post-intervention
θ = vector of parameters corresponding to control variables
ε ~ N (0, σ^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]

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[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 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

        α = Intercept

        β_1 = Cohort effect

        θ = 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

        α_j = Intercept for the jth logit

        β_{1j} = Cohort effect on the jth logit

        θj = 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 pre-demonstration 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:

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

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 2022	Midpoint Assessment (will include baseline and midpoint key informant interviews, and baseline administrative and beneficiary survey data)
September 2023	Interim Report (will include baseline and midpoint key informant interviews, and 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 pre-operative 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 peer-reviewed 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			

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

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

List of measures (March 2019)

#	Performance measure	Source
Identification, 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	
Medication, 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	
Follow-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	
Opioid 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	
Pregnancy 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	