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

State Demonstrations Group

May 10, 2021

Kate Massey
Senior Deputy Director
Michigan Department of Health and Human Services (MDHHS)
100 South Capital Avenue
Lansing, Michigan 48909

Dear Ms. Massey:

The Centers for Medicare & Medicaid Services (CMS) has approved the evaluation design for the COVID-19 amendment in Michigan's section 1115 demonstration entitled, "Michigan 1115 Pathway to Integration" (Project Number 11-W00305/5), and effective through the date that is sixty calendar days after the public health emergency expires. We sincerely appreciate the state's commitment to efficiently meeting the requirement for an evaluation design stated in the demonstration's Special Terms and Conditions (STC), especially under these extraordinary circumstances.

The approved evaluation design may 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 on Medicaid.gov.

Please note that, in accordance with Attachment F of the STCs, a final report, consistent with the approved evaluation design, is due to CMS one year after the end of the COVID-19 section 1115 demonstration authority.

We look forward to our continued partnership with you and your staff on the Michigan 1115 Pathway to Integration COVID-19 amendment. If you have any questions, please contact your CMS project officer, Mr. Thomas Long, who may be reached by email at Thomas.Long@cms.hhs.gov.

Sincerely,

Danielle Daly -S
Digitally signed by Danielle Daly -S
Date: 2021.05.10 10:28:43 -04'00'

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

Andrea J. Casart -S
Digitally signed by Andrea J. Casart -S
Date: 2021.05.10 16:27:58 -04'00'

Andrea Casart
Director
Division of Eligibility and Coverage Demonstrations

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

Covid-19 Addendum

Section 1. Introduction and Background

On March 13, 2020, the President of the United States issued a proclamation that the Coronavirus Disease 2019 (COVID-19) outbreak in the United States constitutes a national emergency by the authorities vested in him by the Constitution and the laws of the United States. On March 13, 2020, the Secretary of Health and Human Services invoked his authority to waive or modify certain requirements of titles XVIII, XIX, and XXI of the Act as a result of the consequences of the COVID-19 pandemic, to the extent necessary, as determined by the Centers for Medicare & Medicaid Services (CMS), to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the respective programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of such requirements as a result of the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse. This authority took effect as of 6:00 PM Eastern Standard Time on March 15, 2020, with a retroactive effective date of March 1, 2020. The emergency period will terminate, upon termination of the public health emergency (PHE), including any extensions.

To assist Michigan in delivering the most effective care to its beneficiaries in light of the COVID-19 PHE, CMS approved the COVID-19 PHE amendment to the Michigan 1115 Pathway to Integration Demonstration on October 27, 2020, authorized retroactively from March 1, 2020, through 60 days after the end of the PHE (including any renewal of the PHE). Approval of this demonstration amendment is subject to the limitations specified in the flexibilities listed in Attachment F (Expenditure authorities granted under the Section 1115 COVID Demonstrations) and the previously approved expenditure authorities and Standard Terms and Conditions (STCs). The demonstration amendment will likely promote the objectives of the Medicaid statute by helping Michigan furnish medical assistance to protect the health, safety, and welfare of individuals and providers affected by COVID 19.

As noted in attachment F of the approval letter, the demonstration approves time-limited expenditure authority and requirements for the state of Michigan to enable the state to deliver the most effective care during the PHE to beneficiaries receiving Home and Community Based Services (HCBS). The demonstration amendment aims to help the state achieve the following goals:

- Expedited eligibility for Home and community-based Long-Term Care Services and Supports (LTSS) and delivery in alternative settings
- Increase payment rates to HCBS service providers to maintain capacity to address the needs of beneficiaries during PHE
- Temporary changes to requirements for functional assessments
- Payment for Supports in Alternative Settings
- Modifications to Person-Centered Planning
- Increased use of telehealth for evaluations, assessments, and service planning as well as consent processes
- Suspension of some data collection requirements for quality reviews
- More flexible Incident Report requirements

The Michigan Department of Health and Human Services (MDHHS) will test whether and how the approved expenditure authorities affected Michigan's response to the PHE using evaluation questions that pertain to the approved expenditure authorities. The evaluation will also track administrative costs and health services expenditures for demonstration beneficiaries and assess how these outlays affected Michigan's response to the PHE.

Section 2. Evaluation Overview

This evaluation will test whether and how the approved expenditure authorities affected the state's response to the PHE by investigating the specific evaluation questions:

Evaluation Questions:

1. What changes in rates of HCBS initiation and utilization occurred during the COVID-19 PHE?

2. How did changes in initiation and utilization of HCBS during the PHE compare to changes for other services administered through the PIHPs?

3. In what ways did the PHE impact HCBS providers?

4. What strategies or adaptations were most effective in achieving the essential goals of the demonstration?

5. How did HCBS-related expenditure patterns change during the COVID-19 PHE?

Section 3. Methodology

3.1 Evaluation Design Summary

We propose an evaluation design consistent with evaluation design recommendations and requirements outlined in the "COVID-19 PHE Medicaid Section 1115 Demonstration: Guidance for Monitoring and Evaluation Final Report" document. We will use a quasi-experimental evaluation design based on comparing trends in service initiation and utilization over time (before and during the PHE). We will also employ a mixed methods design that incorporates both quantitative and qualitative data collection and analysis to answer key evaluation questions. We will stratify results by Prepaid Inpatient Health Plan (PIHP) region, and adjust for PIHP region in multivariable models. These regional analyses will allow us to assess the consistency of outcomes across the diverse PIHP regions and to identify any differential impacts of the demonstration for specific regions.

The State will track separately all expenditures associated with the COVID-19 Demonstration, including but not limited to, administrative costs and program expenditures. We will examine expenditure patterns specific to HCBS and for all services (total expenditures) among the population of beneficiaries who receive HCBS, and calculate the proportion of total expenditures attributable to costs. We hypothesize that total and HCBS-specific expenditures will decrease during the PHE but that the proportion of total expenditures attributable to HCBS will remain relatively constant.

3.2. Data sources, evaluation measures, and analytic approach

The evaluation data sources, measures, and analytic approach appear in Table 1.

Table 1. Research Questions for Evaluation of Michigan's COVID-19 PHE Amendment of the Michigan 1115 Pathway to Integration Demonstration

Question 1. What changes in rates of HCBS initiation and utilization occurred during the COVID-19 PHE?				
Measures	Data Sources	Numerator	Denominator	Analytic Approach
Initiation of HCBS (monthly) before and during PHE	Administrative Claims	Number of beneficiaries with any new HCBS claim who did not have an HCBS claim in the prior 12 months	Total number of eligible beneficiaries	Descriptive monthly trends over time (Jan 2019 through end of PHE), statewide and by PIHP region
Utilization of HCBS (monthly) before and during PHE	Administrative Claims	Number of beneficiaries with any HCBS claim in current month	Total number of eligible beneficiaries	Descriptive monthly trends over time (Jan 2019 through end of PHE), statewide and by PIHP region
Volume of HCBS claims (mean and median) per HCBS user	Administrative Claims	Total number of HCBS claims per individual beneficiary in current month	Total number of eligible beneficiaries	Descriptive monthly trends over time (Jan 2019 through end of PHE), statewide and by PIHP region
Continuity of HCBS (monthly): Proportion of prior month's HCBS users who continued HCBS service	Administrative Claims	Number of beneficiaries who had an HCBS claim in current month	Number of beneficiaries who had an HCBS claim in previous month	Descriptive monthly trends over time (Jan 2019 through end of PHE), statewide and by PIHP region

Question 2. How did changes in initiation and utilization of HCBS during the PHE compare to changes in initiation and utilization of other PIHP-administered services (such as substance use disorder; SUD)?				
Measures	Data Sources	Numerator	Denominator	Analytic Approach
Initiation of other PIHP services (monthly)	Administrative Claims	Number of beneficiaries with any new SUD claim who did not have an SUD treatment claim in the prior 12 months	Total number of eligible beneficiaries	Descriptive monthly trends over time (Jan 2019 through end of PHE), statewide and by PIHP region; **comparison with parallel HCBS measure**
Utilization of Other PIHP Services (monthly)	Administrative Claims	Number of beneficiaries with any SUD treatment claim in current month	Total number of eligible beneficiaries	Descriptive monthly trends over time (Jan 2019 through end of PHE), statewide and by PIHP region; **comparison with parallel HCBS measure**
Utilization of Other PIHP Services (monthly)	Administrative Claims	Total number of SUD treatment claims per individual beneficiary in current month	Total number of eligible beneficiaries	Descriptive monthly trends over time (Jan 2019 through end of PHE), statewide and by PIHP region; **comparison with parallel HCBS measure**
Continuity of Other PIHP Services (monthly)	Administrative Claims	Number of beneficiaries who had an SUD treatment claim in current month	Number of beneficiaries who had an SUD claim in previous month	Descriptive monthly trends over time (Jan 2019 through end of PHE), statewide and by

				PIHP region; **comparison with parallel HCBS measure**
Question 3. In what ways did the PHE impact HCBS service providers?				
Measures	Data Sources	Numerator	Denominator	Analytic Approach
Total number of providers for HCBS	Administrative Claims	n/a	n/a	Descriptive monthly trends over time (Jan 2019 through end of PHE), statewide and by PIHP region
Challenges and facilitators to retaining HCBS providers	Key informant interviews	n/a	n/a	Qualitative Analysis
Facilitators and barriers to ensuring beneficiary access to care planning and HCBS services during the PHE	Key informant interviews	n/a	n/a	Qualitative Analysis
Unresolved or ongoing challenges related to care delivery during the PHE for providers	Key informant interviews	n/a	n/a	Qualitative Analysis

Question 4. What strategies or adaptations were most effective in achieving the essential goals of the demonstration?				
Measures	Data Sources	Numerator	Denominator	Analytic Approach

Which demonstration flexibilities or changes were most effective in retaining HCBS providers and facilitating HCBS delivery during the PHE?	Key informant interviews	n/a	n/a	Qualitative Analysis
What additional strategies or adaptations would you recommend	Key informant interviews	n/a	n/a	Qualitative Analysis

Question 5. How did HCBS-related expenditure patterns change during the COVID-19 PHE?				
Measures	Data Sources	Numerator	Denominator	Analytic Approach
Average expenditures for HCBS, per beneficiary (monthly)	Administrative Claims	Total paid amounts for all HCBS claims in month	Number of beneficiaries with any HCBS claim in month	Descriptive monthly trends over time (Jan 2019 through end of PHE), statewide and by PIHP region
Average expenditures for all services, per beneficiary with HCBS (monthly)	Administrative Claims	Total paid amounts for all services, among beneficiaries with any HCBS claim in month	Number of beneficiaries with any HCBS claim in month	Descriptive monthly trends over time (Jan 2019 through end of PHE), statewide and by PIHP region
Proportion of total expenditures attributable to HCBS (monthly)	Administrative Claims	Total paid amounts for all HCBS claims in month	Total paid amounts for all services, among beneficiaries with any HCBS	Descriptive monthly trends over time (Jan 2019 through end of PHE),

			claim in month	statewide and by PIHP region

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.

3.2. Data Sources

Qualitative Data

We will conduct key informant interviews with representatives from HCBS and PIHP regions. Interviews will include a review of the principal challenges and responses associated with engagement with beneficiaries and ability to provide access to care during this PHE. The goal is to give context to quantitative data analysis and identify which flexibilities were most effective in achieving the goals of the demonstration and what challenges remain.

State administrative data

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
- Administrative Program Records include PIHP Community Mental Health Service Programs demographic and cost data reports sent the state (908s and 905s)

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.

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:

- Initiation-related variables will include the presence of a new procedure code for any beneficiary who did not have an HCBS or LTSS procedure code in the 12 months prior.
- Utilization-related variables will include counts of unique events. We will use diagnosis and procedure codes to categorize the type of service. 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 Measures for Medicaid. We will modify criteria for key outcome measures to generate quarterly results, which we will use in our analysis.
- Expenditure-related variables will include paid amounts linked to fee-for-service claims, managed care encounters, and pharmacy services.
- Demographic variables will include beneficiary age, race/ethnicity, geographic region PIHP, income level (% FPL), and health plan.

3.3. Analytical Approach

We will generate outcome measures based on administrative data for 24 months prior to the start of the COVID-19 PHE period through the end of the PHE period. This will allow us to appreciate trends over time.

We will generate monthly measures of HCBS utilization, including:
#/% of beneficiaries with any HCBS
#/% of beneficiaries with new HCBS
Volume (mean # units) per HCBS user
#/% of HCBS users with an HCBS gap of ≥28 days

We will generate these monthly measures for the state overall, for each PIHP region, and for demographic subgroups (age, Medicaid benefit program). We will assess the extent to which decreases of ≥10% in HCBS utilization observed for 3 continuous months are reversed in the subsequent quarter.

3.4. Timeline

Table 2. EVALUATION TIMELINE: Michigan COVID-19 PHE Medicaid Section 1115 Demonstration Waiver

	Administrative data analysis	Administrative program record data analysis	Key Informant Interviews	Deliverables
FY21 Q1				Finalize Evaluation Plan - due to CMS 12/27/20
FY21 Q2	Draft Data Use Agreements and obtain approvals	Identify programmatic data from PIHP reports to MDHHS	Develop interview guide and protocol	

FY21 Q3	Develop programming code for measures based on administrative claims	Obtain programmatic data for FY2020	Begin conducting key informant interviews Make adjustments to interview guide as needed	

FY21 Q4	Generate monthly administrative measures through Dec 2020	Analyze FY2020 programmatic data	Continue key informant interviews Iterative qualitative analysis of interviews	
Potential extension of PHE	Generate monthly administrative measures from Jan 2021 through the end of the PHE period	Obtain programmatic data for FY2021	Iterative qualitative analysis of interviews	
1 year + 60 days after end of PHE	Summarize monthly measures; compare HCBS vs SUD treatment service trends	Summarize programmatic data; use information to supplement interpretation of administrative claims and key informant interviews	Summarize key informant interview data	Final report - due to CMS one year after the state's COVID-19 related waiver and expenditure authorities expire

Section 4. Methodological Limitations

Our proposed evaluation has several limitations. The primary limitation is related to 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. Given the nation-wide, unplanned nature of the

PHE no comparison group is readily available. Qualitative data collection will help provide explanatory context and insight into quantitative findings; however, sampling for qualitative interviews is not statistically representative of the population and findings lack generalizability. Implementation of key elements of the demonstration is expected to be uneven across PIHP regions. To address this likelihood, we will explore and describe regional differences in each of the three data elements (administrative data, program data, and key informant interviews). This will allow us to document any differences in implementation, and to examine the extent to which implementation differences are associated with evaluation process or outcome measures.

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, paid amounts for both fee-for-service and managed care encounters, billing and rendering provider identifiers. Our greatest area of concern involves accurately identifying changes in utilization of HCBS due to beneficiaries (or their families) being uncomfortable being in close proximity to care providers during the PHE. This could result in differential changes in initiation, utilization, and continuity of HCBS compared to SUD treatment services. To address this challenge, we will include questions of key informants to understand their experiences with beneficiaries suspending or refusing services due to COVID precautions.