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

February 9, 2022

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

Dear Ms. Hanley:

The Centers for Medicare & Medicaid Services (CMS) approved the Evaluation Design for Michigan's Managed Care Risk Mitigation COVID-19 Public Health Emergency (PHE) amendment to the section 1115 demonstration entitled "Flint Michigan Section 1115 Demonstration" (Project Number 11-W-00302/5), effective through September 30, 2026. We sincerely appreciate the state's commitment to efficiently meeting the requirement for an Evaluation Design, as was stipulated in the approval letter for this amendment dated February 4, 2022, 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(e). CMS will also post the approved Evaluation Design on Medicaid.gov.

Consistent with the approved Evaluation Design, the draft Final Report will be due to CMS 18 months after either the expiration of the demonstration approval period or the end of the latest rating period covered under the state's approved expenditure authority, whichever comes later.

We look forward to our continued partnership with you and your staff on the Flint Michigan Section 1115 Demonstration. If you have any questions, please contact your CMS project officer, Mr. Julian Taylor. Mr. Taylor can be reached by email at Julian.Taylor@cms.hhs.gov.

Sincerely,

Danielle Daly -S

Digitally signed by Danielle Daly -S
Date: 2023.02.09 14:23:04 -05'00'

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

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

Christine Davidson, Acting State Monitoring Lead, CMS Medicaid and CHIP Operations Group

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

February 4, 2022

Ms. Kate Massey
State Medicaid Director
State of Michigan, Medical Services Administration
400 South Pine Street
Lansing, MI 48913

Dear Ms. Massey:

Michigan submitted a Managed Care Risk Mitigation COVID-19 Public Health Emergency (PHE) section 1115 demonstration application on January 20, 2022. This letter serves as time-limited approval of the request included in the state's Managed Care Risk Mitigation COVID-19 PHE section 1115 demonstration application, which will be approved as an amendment under the "Flint Michigan" section 1115(a) demonstration (Project Number 11-W-00302/5).

On March 13, 2020, the President of the United States issued a proclamation that the 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, including sections 201 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.), and consistent with section 1135 of the Social Security Act (Act) as amended (42 U.S.C. 1320b-5). On March 13, 2020, pursuant to section 1135(b) of the Act, 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 on March 15, 2020, with a retroactive effective date of March 1, 2020. We note that the emergency period will terminate upon termination of the public health emergency (PHE), including any extensions.

In response to the section 1115(a) demonstration opportunity announced to states on March 22, 2020 in State Medicaid Director Letter (SMDL) #20-002,[1] on January 20, 2022, Michigan submitted an 1115 COVID-19 demonstration application to address the COVID-19 PHE. CMS has determined that the state's application is complete, consistent with the exemptions and

[1] See SMDL #20-002, "COVID-19 Public Health Emergency Section 1115(a) Opportunity for States," available at https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20002-1115template.docx.

flexibilities outlined in 42 CFR § 431.416(e)(2) and 431.416(g).[2] CMS expects that states will offer, in good faith and in a prudent manner, a post-submission public notice process, including tribal consultation as applicable, to the extent circumstances permit.

This amendment would test whether, in the context of the current COVID-19 PHE, an exemption from the regulatory prohibition in 42 CFR § 438.6(b)(1) promotes the objectives of Medicaid. To that end, the expenditure authority is expected to support states with making appropriate, equitable payments during the PHE to help maintain beneficiary access to care. This exemption allows states to enter into or modify a risk mitigation arrangement with a Medicaid managed care plan after the applicable rating period has begun.

CMS has determined that this amendment – including the expenditure authority detailed below – promotes the objectives of Medicaid because it is necessary to ensure appropriate, equitable payment for services during the PHE, and it assists the state in delivering the most effective care to its beneficiaries in light of the COVID-19 PHE. To that end, the demonstration amendment is expected to help the state furnish medical assistance in a manner intended to protect, to the greatest extent possible, the health, safety, and welfare of individuals and providers who may be affected by the COVID-19 PHE. This authority is effective regardless of whether the state substantially complied with the regulation by, for example, submitting unsigned contracts and rate certification documents for CMS review either before or after the effective date of the new regulation but before the start of the rating period.

As part of ongoing managed care oversight, CMS will investigate how providing this authority results in either increased or decreased payments to plans, given the significant fluctuations in utilization that may occur during a pandemic. In addition, CMS's managed care oversight efforts will include an assessment of whether and how payments under the retroactive risk mitigation arrangements, which must be developed in accordance with all other applicable requirements in 42 CFR § 438, including §§ 438.4 and 438.5, and generally accepted actuarial principles and practices, are sufficient to cover costs under the managed care contract. Finally, CMS will ascertain how the implementation of risk mitigation after the start of the rating period, which may not truly address the uncertainty inherent in setting capitation rates prospectively, compares to not allowing retroactive risk sharing during a PHE, which may lead to substantially inaccurate or inequitable payments given the severe disruption in utilization. As with all section 1115 demonstrations, CMS will take into account the experience of the state and managed care plans in this demonstration, gathering more information about the efficacy of such a demonstration during a PHE.

[2] Pursuant to 42 CFR 431.416(g), CMS has determined that the existence of unforeseen circumstances resulting from the COVID-19 PHE warrants an exception to the normal state and federal public notice procedures to expedite a decision on a proposed COVID-19 section 1115 demonstration. States applying for a COVID-19 section 1115 demonstration are not required to conduct a public notice and input process. CMS is also exercising its discretionary authority to expedite its normal review and approval processes to render timely decisions on state applications for COVID-19 section 1115 demonstrations. CMS will post all section 1115 demonstrations approved under this COVID-19 demonstration opportunity on the Medicaid.gov website.

Expenditure Authority

CMS is approving expenditure authority for the state to add or modify a risk sharing arrangement after the start of the rating period to maintain capacity during the emergency. This expenditure authority applies only to contracts and rating periods that begin or end during the COVID-19 PHE. This expenditure authority allows the state to add or modify the risk sharing mechanism(s) after the start of the rating period as specified in the state's contracts with its Medicaid managed care plans. The authority would exempt, as necessary, the state from compliance with the current requirements in section 438.6(b)(1), until the end of the PHE. The authority would allow one or more retroactive risk mitigation arrangements to remain in place even if the state and the managed care plan had agreed to these arrangements after the requirements in section 438.6(b)(1) became effective. This authority is effective regardless of whether the state substantially complied with the regulation by, for example, submitting unsigned contracts and rate certification documents for CMS review either before or after the effective date of the new regulation, but before the start of the rating period.

If the contract and rating period begins or ends during the COVID-19 PHE and the contract was signed prior to the last day of the PHE, CMS is hereby granting expenditure authority to permit the state to retroactively implement one or more risk sharing arrangements for the full duration of the rating period. If the rating period *ended* on or after March 1, 2020 and ended prior to the last day of the PHE, the state can retroactively implement one or more risk sharing arrangements for the full duration of the rating period. If the rating period *began* after March 1, 2020, and prior to the last day of the PHE, the state can retroactively implement one or more risk sharing arrangements for the full duration of the rating period. A state can only retroactively implement risk sharing arrangements under this demonstration for multiple rating periods if the contract signature criteria as well as the rating period beginning and/or ending criteria are met for each rating period.

Monitoring and Evaluation Requirements

Consistent with CMS requirements for monitoring and evaluation of section 1115 demonstrations, the state will be required to develop an Evaluation Design and a Final Report, that will consolidate the demonstration's monitoring and evaluation requirements. The draft Evaluation Design will be due to CMS no later than 180 calendar days after approval of the demonstration. The draft Final Report will be due to CMS 18 months after either the expiration of the demonstration approval period or the end of the latest rating period covered under the state's approved expenditure authority, whichever comes later.

CMS will provide guidance to help the state fulfill the monitoring and evaluation requirements, including assistance in developing the Evaluation Design. Given the unique circumstances and time-limited nature of the demonstration, CMS expects Michigan to undertake data collection or analyses that are meaningful but not unduly burdensome for the state. Specifically, the state should focus on qualitative methods and descriptive statistics to address evaluation questions that will support understanding the successes, challenges, and lessons learned in implementing the demonstration. The state is also expected to review 42 CFR § 431.428 to ensure that the Final Report captures all applicable requirements stipulated for an annual report (e.g., incidence and results of any audits, investigations or lawsuits, or any state legislative developments that may

impact the demonstration). The Evaluation Design and the Final Report will cover all risk sharing arrangements and rating periods under the scope of the demonstration.

Once approved, per 42 CFR § 431.424(e), the state is required to post the Evaluation Design to its Medicaid agency website within 30 calendar days of CMS approval. Likewise, per the standard Public Access requirement associated with section 1115 demonstration deliverables, the state will post the CMS-approved Final Report to its website within 30 calendar days of CMS approval.

Per 42 CFR § 431.420(f), the state must comply with any requests for data from CMS and/or its federal evaluation contractors.

In addition to the section 1115 monitoring and evaluation requirements outlined above, the state must separately comply with the applicable managed care reporting requirements per 42 CFR § 438.66 and section 1936(b) of the Social Security Act.

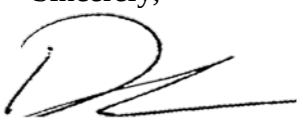
Other Information
Approval of this expenditure authority is conditioned upon continued compliance with the previously approved STCs, which set forth in detail the nature, character and extent of anticipated federal involvement in the project.

In addition, the approval is subject to CMS receiving written acceptance of this award within 15 days of the date of this approval letter. Your project officer is Thomas Long. Mr. Long is available to answer any questions concerning implementation of the state's section 1115(a) demonstration amendment and his contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop S2-25-26
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Email: Thomas.Long@cms.hhs.gov

We appreciate your state's commitment to addressing the significant challenges posed by the COVID-19 pandemic, and we look forward to our continued partnership on the Flint Michigan section 1115(a) demonstration. If you have any questions regarding this approval, please contact Ms. Judith Cash, Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (410) 786-9686.

Sincerely,



Daniel Tsai
Deputy Administrator and Director

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

COVID-19 Section 1115(a) Demonstration Application Template

The State of Michigan, Department of Heath and Aging Administration proposes emergency relief as an affected state, through the use of section 1115(a) demonstration authority as outlined in the Social Security Act (the Act), to address the multi-faceted effects of the novel coronavirus (COVID-19) on the state's Medicaid program.

I. DEMONSTRATION GOAL AND OBJECTIVES

Effective retroactively to March 1, 2020, the State of Michigan, seeks section 1115(a) demonstration authority to operate its Medicaid program without regard to the specific statutory or regulatory provisions (or related policy guidance) described below, in order to furnish medical assistance in a manner intended to protect, to the greatest extent possible, the health, safety, and welfare of individuals and providers who may be affected by COVID-19. Specifically, this demonstration action tests whether, in the context of the current COVID-19 public health emergency (PHE), an exemption from the regulatory prohibition in 42 C.F.R. § 438.6(b)(1) promotes the objectives of Medicaid. CMS will investigate how relaxing this regulatory requirement to permit retroactive risk sharing results in either increased or decreased payments to plans, given the significant fluctuations in utilization that may occur during a pandemic. In addition, CMS will evaluate whether payments under the retroactive risk mitigation arrangements are developed in accordance with all applicable requirements in 42 C.F.R. § 438, including §§ 438.4 and 438.5, and generally accepted actuarial principles and practices. CMS will ascertain whether the harms contemplated by the 2020 managed care final rule, i.e., the implementation of risk mitigation after the start of the rating period may not truly reflect shared risk, are outweighed by the harms of not allowing retroactive risk sharing during a public health emergency, i.e., substantially inaccurate or inequitable payments, given the severe disruption in utilization. In addition, CMS will analyze what the state and managed care plans ultimately negotiate as a result of the implementation of retroactive risk sharing, and this analysis will inform future rulemaking about potential exceptions to retroactive risk mitigation including guardrails that will be required in such agreements.

To that end, the expenditure authority is expected to support the state with making appropriate, equitable payments during the PHE to help maintain beneficiary access to care, and to facilitate meeting any alternative or additional objectives specified by the state in its requests for the demonstration authority. This exemption allows the state to enter into a risk mitigation arrangement with a Medicaid managed care plan after the applicable contract period has begun, provided that the contract and rating period begin or end during the COVID-19 PHE.

This authority is effective regardless of whether the state substantially complied with the regulation by, for example, submitting unsigned contracts and rate certification documents for CMS review either before or after the effective date of the new regulation but before the start of the rating period.

II. DEMONSTRATION DELIVERY SYSTEM PROJECT FEATURES

A. Delivery System:

Check to Apply	Delivery System Description
X	The health care delivery system for the provision of services under this demonstration will be implemented in the same manner as under the state's current state plan.
	Other as described here: [*state to insert description*]

III. ENROLLMENT AND EXPENDITURE PROJECTIONS

A. Enrollment and Enrollment Impact. This demonstration will not impact the eligibility, enrollment, or coverage of Medicaid beneficiaries. The state projects that the Medicaid managed care plans impacted by this demonstration will continue to provide coverage for approximately _2,230,000_____ individuals for the period of the demonstration.

B. **Expenditure Projection.** The state projects that the total aggregate expenditures associated with this section 1115 demonstration will be $_11,493,600,700_.

In light of the unprecedented emergency circumstances associated with the COVID-19 pandemic and consistent with the President's proclamation that the COVID-19 outbreak constitutes a national emergency consistent with section 1135 of the Act, and the time-limited nature of demonstrations that would be approved under this opportunity, the Department will not require the state to submit budget neutrality calculations for section 1115 demonstration projects designed to combat and respond to the spread of COVID-19. In general, CMS has determined that the costs to the Federal Government are likely to have otherwise been incurred and allowable. The state will still be required to monitor and descriptively evaluate the effectiveness of the risk mitigation arrangements implemented as part of the state's response to the public health emergency through this

opportunity. Due to the COVID-19 public health emergency (PHE), this demonstration is deemed budget neutral.

IV. EXPENDITURE AUTHORITY

The only authority available under this section 1115 demonstration opportunity is the expenditure authority provided below. Note: Any requests for waiver or expenditure authorities in addition to those identified in this template will not be considered.

Expenditure Authority
Pursuant to section 1115(a)(2) of the Act, the state is requesting the following expenditure authority:

Permit Michigan to add or modify risk sharing mechanisms such as reinsurance, risk corridors, or stop-loss limits after the start of a rating period provided that the contract and rating period(s) begin or end during the COVID-19 PHE. This expenditure authority exempts the state from compliance with the requirements under 42 C.F.R. § 438.6(b)(1) and allows Michigan to add or modify the risk sharing mechanism(s) after the start of the rating period as specified in the state's contracts with its Medicaid managed care plans. The authority would exempt, as necessary, states from compliance with the current requirements in section 438.6(b)(1), until the end of the PHE. The authority would allow one or more retroactive risk mitigation arrangements to remain in place even if the state and the managed care plan had agreed to these arrangements after the requirements in section 438.6(b)(1) became effective. This authority is effective regardless of whether the state substantially complied with the regulation by, for example, submitting unsigned contracts and rate certification documents for CMS review either before or after the effective date of the new regulation but before the start of the rating period. This authority lasts only for the duration of the PHE.

More specifically, if the contract and rating period(s) begin or end during the COVID-19 PHE and the contract was signed prior to the last day of the PHE, the state can retroactively implement one or more risk sharing arrangements for the full duration of the rating period. If the rating period(s) ended on or after March 1, 2020 and ended prior to the last day of the PHE, the state can retroactively implement one or more risk sharing arrangements for the full duration of the rating period. If the rating period began after March 1, 2020, and prior to the last day of the PHE, the state can retroactively implement one or more risk sharing arrangements for the full duration of the rating period. A state can only retroactively implement risk sharing arrangements for multiple rating periods if the contract signature criteria as well as the rating period beginning and ending criteria are met for each rating period.

V. PUBLIC NOTICE

Pursuant to 42 C.F.R. § 431.416(g), the state is exempt from conducting a state public notice and input process as set forth in 42 C.F.R. § 431.408 to expedite a decision on this section 1115 demonstration that addresses the COVID-19 public health emergency.

VI. EVALUATION REQUIREMENTS

A. Evaluation Hypotheses and Design Parameters. The demonstration will test how the expenditure authority permitting retroactive risk mitigation arrangements with Medicaid managed care plans support the state with making appropriate, equitable payments during the course of the COVID-19 public health emergency to help maintain beneficiary access to care. The parameters of the state's Evaluation Design, which will be expected no later than 180 calendar days after the approval of the demonstration, will support an evaluation that will advance CMS's understanding of the successes and challenges in implementing potential exceptions to retroactive risk mitigation through future rulemaking.

CMS will provide further guidance on appropriate evaluation questions for the Evaluation Design.

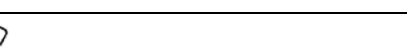
B. Final Report. The state is required to prepare and submit a Final Report, that will consolidate the monitoring and evaluation reporting requirements for this section 1115 demonstration authority. The draft Final Report will be due to CMS 12 months after the expiration of the demonstration approval period. The Final Report should provide analysis and discussion of qualitative and descriptive data to address evaluation questions that support understanding the successes, challenges, and lessons learned in implementing the demonstration. Per 42 C.F.R. § 431.428, the Final Report will also capture all *applicable* requirements stipulated for an annual report (e.g., incidence and results of any audits, investigations or lawsuits, or any state legislative developments that may impact the demonstration). CMS will provide further guidance on the scope, structure, and content of the Final Report.

In the event that the demonstration authority is approved in the 60 days after the end of the federal PHE, CMS will coordinate with the state to establish a reasonable timeline for the due dates of the Evaluation Design and the Final Report.

VII. STATE CONTACT AND SIGNATURE

State Medicaid Director Name: Kate Massey
Telephone Number: 517-284-1179
E-mail Address: masseyk4@michigan.gov

State Lead Contact for Demonstration Application: Jacqueline Coleman
Telephone Number: 517-284-1190
E-mail Address: colemanj@michigan.gov

Authorizing Official (Typed): Brian Keisling
Authorizing Official (Signature): 
Date: 01/20/2022

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1148 (Expires 03/31/2024). The time required to complete this information collection is estimated to average 1 to 2 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. Your response is required to receive a waiver under Section 1115 of the Social Security Act. All responses are public and will be made available on the CMS web site. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. ***CMS Disclosure*** Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact Teresa DeCaro at 410-786-9686 or at 1115demorequests@cms.hhs.gov.