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

January 30, 2023

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) completed its review of the Evaluation Design, which is required by the Special Terms and Conditions (STCs), specifically, STC 32, of Michigan's section 1115 demonstration, "Flint Michigan Section 1115 Demonstration" (Project No: 11-W-00302/5), effective through September 30, 2026. CMS has determined that the Evaluation Design, which was submitted on March 14, 2022 and revised on October 4, 2022, meets the requirements set forth in the STCs and our evaluation design guidance, and therefore approves the state's Evaluation Design.

CMS has added the approved Evaluation Design to the demonstration's STCs as Attachment C. A copy of the STCs, which includes the new attachment, is enclosed with this letter. In accordance with 42 CFR 431.424, the approved Evaluation Design may now be posted to the state's Medicaid website within thirty days. 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 extension 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. In accordance with 42 CFR 431.428 and the STCs, we look forward to receiving updates on evaluation activities in the demonstration monitoring reports.

We appreciate our continued partnership with Michigan on the Flint Michigan Section 1115 Demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle Daly -S

Digitally signed by Danielle Daly -S
Date: 2023.01.30 14:23:23 -05'00'

Danielle Daly
Director
Division of Demonstration
Monitoring and Evaluation

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

CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER AUTHORITY

NUMBER: 11-W00302/5

TITLE: Flint Michigan Section 1115 Demonstration

AWARDEE: Michigan Department of Health and Human Services

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived in this list, shall apply to the Demonstration from the approval date, through September 30, 2026 specified.

Under the authority of section 1115(a) (1) of the Social Security Act (the Act), the following waivers shall enable Michigan to implement the Michigan Flint Section 1115 demonstration.

1. Freedom of Choice **Section 1902(a)(23)(A)**

To the extent necessary to enable the state to restrict freedom of choice of provider for children and pregnant women with respect to targeted case management (TCM) services. Also, to the extent necessary to enable the state to limit beneficiary choice of providers for beneficiaries enrolled in a Managed Care Entity (MCE) and a Prepaid Inpatient Health Plan (PIHP) under the demonstration to those providers that are within the MCE and PIHP networks. No waiver of freedom of choice is authorized for family planning providers.

2. Provision of Medical Assistance **Sections 1902(a)(8) and 1902(a)(10)**

To the extent necessary to permit the state to limit the provision of medical assistance for individuals described in the eligibility group under 1902(a)(10)(A)(ii)(XX) and the state plan, to children up to age 21 and pregnant women who were served by the Flint water system at any time from April 2014 until the state determines that the public health crisis has ended including any child born to a pregnant woman served by the Flint water system from April 2014 to the state-specified date. For this purpose, an individual was served by the Flint water system if, for more than one day, the individual consumed water drawn from the Flint water system and: 1) resided in a dwelling connected to this system; 2) had employment at a location served by this system; or, 3) received child care or education at a location connected to this system.

3. Comparability **Section 1902(a)(17)**

To the extent necessary to enable the state to not charge premiums to beneficiaries in the demonstration individuals who resided in the area served by the Flint water system from April 2014 up to the date specified in accordance with STC 17a.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: 11-W-00302/5
TITLE: Flint Michigan 1115 Demonstration

AWARDEE: Michigan Department of Health and Human Services

I. PREFACE

The following are the Special Terms and Conditions (STC) for the "Flint Michigan" section 1115(a) Medicaid demonstration (hereinafter "demonstration"), to enable the Michigan Department of Health and Human Services (hereinafter "state") to operate this demonstration. These STCs set forth conditions and limitations on the waiver authorities, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS related to the demonstration. These STCs neither grant additional waiver authorities, nor expand upon those separately granted. The demonstration will be approved for a five-year period, from September 15, 2021 through September 30, 2026, unless otherwise specified.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Eligibility and Enrollment
V. Program and Benefits
VI. Cost Sharing
VII. Delivery System
VIII. General Reporting Requirements
IX. Evaluation of the Demonstration
X. General Financial Requirements Under Title XIX
XI. Monitoring Budget Neutrality for the Demonstration
XII. Schedule of Deliverables for the Demonstration Period

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

Attachment A: Developing the Evaluation Design
Attachment B: Preparing the Interim and Summative Evaluation Reports
Attachment C (Reserved): Approved Evaluation Design

II. PROGRAM DESCRIPTION AND OBJECTIVES

On March 3, 2016, the Centers for Medicare & Medicaid Services (CMS) approved Michigan's application to establish a five-year Medicaid demonstration entitled "Flint Michigan Section

1115 Demonstration," (Project Number 11-W-00302/5) in response to the public health emergency of lead exposure related to the Flint water system. Implementation of the demonstration and associated state plan amendment will expand coverage to low-income children up to age 21 years and pregnant women served by the Flint water system during a state-specified time period and who would not be otherwise eligible for Medicaid. This population included children in households with incomes from 212 percent of the federal poverty level (FPL) up to and including 400 percent of FPL and pregnant women in households with incomes from 195 percent of FPL up to and including 400 percent of FPL.

When the demonstration was originally approved, the state listed the following goals and objectives:

- To expand Medicaid and Children's Health Insurance Program (CHIP) eligibility for select individuals (i.e. children up to age 21 and pregnant women) in the Flint area impacted by the water crisis
- To coordinate comprehensive benefits and resources through the provision of Targeted Case Management services (TCM)

On April 30, 2020, Michigan submitted a demonstration renewal request to continue promoting core objectives of their Medicaid program, including improved access, and to promote increases in blood lead tests for children, and blood lead screenings for pregnant women, and consistently high levels of access for prenatal care. The Flint 1115 demonstration extension builds on success already achieved by first preserving coverage for the thousands of beneficiaries enrolled. Through the demonstration, there has been a steady increase in developmental and behavioral screenings, indicating an opportunity for further improving access and awareness. As the full impact of lead exposure and subsequent healthcare needs become more visible in the population, the number of individuals seeking assistance will continue to grow. Further, as trust in state institutions and operations is slowly regained, participation can grow as well.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).

2. **Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver authority documents (of which these terms and conditions are part), apply to the demonstration.

3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur

during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state thirty (30) business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
    a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7) as a result of the change in FFP.

    b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

5. **State Plan Amendments.** The state will not be required to submit title XIX or XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP state plans govern.

6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the

state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

a. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;

b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;

c. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;

d. An up-to-date CHIP allotment worksheet, if necessary;

e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

8. Extension of the Demonstration. States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer of the state in accordance with the requirements of 442 42 Code of Federal Regulations (CFR) 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit phase-out plan consistent with the requirements of STC 9.

9. Demonstration Phase-Out. The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.

a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a thirty (30) day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the thirty (30) day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.

c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than fourteen (14) calendar days after CMS approval of the transition and phase-out plan.

d. Transition and Phase-out Procedures. The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210 and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR §431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

e. Exemption from Public Notice Procedures 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).

f. Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.

g. Federal Financial Participation (FFP). If the project is terminated or any relevant waivers are suspended by the state, FFP must be limited to normal closeout costs associated with the termination or expiration of the demonstration including services,

continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

10. **Withdrawal of Waiver Authority.** CMS reserves the right to withdraw waiver authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX and title XXI. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

11. **Adequacy of Infrastructure.** The state will ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.

12. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state notice procedures as required in 42 CFR section 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

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

13. **Federal Financial Participation (FFP).** No federal matching funds for expenditures for this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.

14. **Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, MCOs, and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

15. **Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is

for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(d)(5).

16. **Transformed Medicaid Statistical Information Systems Requirements (T-MSIS).** The state shall comply with all data reporting requirements under section 1903(r) of the Act, including but not limited to Transformed Medicaid Statistical Information Systems Requirements.

IV. ELIGIBILITY AND ENROLLMENT

17. **Eligibility Groups Affected by the Demonstration.** This demonstration affects individuals who are, or will be, described in the state plan and section 1902(a)(10)(A)(ii)(XX), limiting eligibility and coverage for individuals described in that population to any pregnant woman or child up to age 21 with household income up to and including 400 percent of the FPL who has been served by the Flint water system during the specified time period. Eligibility also applies to any child born to a pregnant woman served by the Flint water system during the specified time period. Once eligibility has been established for a child, the child will remain eligible until age 21 as long as other eligibility requirements are met. An individual was served by the Flint water system if he or she consumed water drawn from the Flint water system and: 1) resided in a dwelling connected to this system; 2) had employment at a location served by this system; or, 3) received child care or education at a location connected to this system. Individuals impacted by the demonstration will be referred to hereinafter as "Flint beneficiaries," regardless of whether they reside in Flint, Michigan. The specified period of time is from April 2014 up to the date specified in STC 17(a).
    a. Specification of end of special eligibility period. The state shall determine the end date of the special eligibility period. The state will provide at least 60 days advance public notice of a proposed end date, based on its analysis of water safety in the Flint system, and permit at least a 30 day public comment period. After considering public comments, the state shall issue a final determination of the end date, and notify CMS.

V. PROGRAM AND BENEFITS

18. **Program Benefits.** Flint beneficiaries will receive all Medicaid state plan benefits including, for children, Early and Periodic Screening, Detection, and Treatment (EPSDT) benefits. Such Medicaid benefits include a Targeted Case Management (TCM) ~~benefits~~ benefit that are set forth in the state plan.

VII. COST SHARING

19. Cost Sharing. There will be no cost or premiums charged to individuals within this demonstration.

VIII. DELIVERY SYSTEM

20. Delivery System. Flint beneficiaries will receive services through the same managed care and fee-for-service arrangements as currently authorized in the state.

21. TCM Services. Flint beneficiaries will have a TCM benefit under the state plan that is intended to assist beneficiaries to gain access to all needed medical, educational, social and other services and is targeted to individuals with potential lead exposure, as specified in STC 17. The state will designate specific organizations to provide the TCM services. Providers must:

a. Be a Michigan Medicaid Provider;
b. Demonstrate the capacity to provide all core elements of TCM, including comprehensive assessment and development of a plan of care, referrals and linking to services, and monitoring of services and related follow-up activities;
c. Have a sufficient number of staff and/or contractual arrangements (as approved by the State) to meet the service needs of the target population and the administrative capacity to ensure the provision of quality services in accordance with state and federal requirements;
d. Have experience in the coordination of and linkage to community services and resources; and
e. Have the willingness and capabilities to coordinate with the individual's Medicaid Health Plan, as applicable.

The state will ensure that:

f. Ensure that individuals have choice of case manager at the TCM provider agency;
g. There is adequate capacity among providers to ensure timely access to TCM services, and the state will monitor access on an ongoing basis; and
h. Beneficiaries receive high quality services.

IX. GENERAL REPORTING REQUIREMENTS

22. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

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

a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state's written extension request.
c. If CMS agrees to an interim corrective plan in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.
d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement with respect to required deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified in these STCs, the deferral(s) will be released.
e. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

23. Submission of Post-Approval Deliverables. The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.

24. Compliance with Federal Systems Updates. As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state will work with CMS to:

a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
c. Submit deliverables to the appropriate system as directed by CMS.

25. Monitoring Reports. The state must submit three (3) Quarterly Monitoring Reports and one (1) Annual Monitoring Report each DY. The fourth quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual

Monitoring Report. The Quarterly Monitoring Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The Annual Monitoring Report (including the fourth quarter information) is due no later than ninety (90) calendar days following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

a. Operational Updates. Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, and how challenges are being addressed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. In addition, Monitoring Report should describe key achievements, as well as the conditions and efforts to which these successes can be attributed. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
b. Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration's goals, and must cover all key policies under this demonstration. Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, and grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and should follow the framework provided by CMS to support federal tracking and analysis.
c. Budget Neutrality and Financial Reporting Requirements – Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on the CMS-64.
d. Evaluation Activities and Interim Findings. Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

26. Corrective Action Plan Related to Monitoring. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A

state corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where monitoring data indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS will withdraw an authority, as described in STC 10, when metrics indicate substantial and sustained directional change inconsistent with the state's demonstration goals, and the state has not implemented corrective action. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

27. Close-Out Report. Within one hundred twenty (120) calendar days after the expiration of the demonstration, the state must submit a Draft Close-Out Report to CMS for comments.

a. The draft close-out report must comply with the most current guidance from CMS.
b. The state will present to and participate in a discussion with CMS on the close-out report.
c. The state must take into consideration CMS's comments for incorporation into the final close-out report.
d. The final close-out report is due to CMS no later than thirty (30) calendar days after receipt of CMS's comments.
e. A delay in submitting the draft or final version of the close-out report may subject the state to penalties described in STC 22.

28. Monitoring Calls. CMS will convene monthly conference calls with the state.

a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to) any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, enrollment and access, budget neutrality, and progress on evaluation activities.
b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.
c. The state and CMS will jointly develop the agenda for the calls.

29. Post Award Forum. Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least thirty (30) calendar days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state must also post the most recent annual report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Annual Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Monitoring Report.

XI. EVALUATION OF THE DEMONSTRATION

30. **Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 22.

31. **Independent Evaluator.** Upon approval of the demonstration, the state must arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party to sign an agreement that the independent party will conduct the demonstration evaluation in an independent manner in accordance with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

32. **Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design, no later than one hundred eighty (180) calendar days after approval of the extension. The draft Evaluation Design also must include a timeline for key evaluation activities, including evaluation deliverables, as outlined in STCs 33 and 34.

    The draft Evaluation Design must be developed in accordance with:
    - **a.** Attachment A (Developing the Evaluation Design) of these STCs;
    - **b.** Any applicable CMS technical assistance on applying robust evaluation approaches, including establishing appropriate comparison groups and assuring casual inferences in demonstration evaluations; and
    - **c.** All applicable Evaluation Design guidance.

33. **Evaluation Design Requirements.** At a minimum, the draft Evaluation Design must include a discussion of the goals, objectives, and specific hypotheses that are being tested. The draft Evaluation Design will discuss:
    - **a.** The outcome measures to be used in evaluating the impact of the demonstration during the period of approval, particularly among the target population;
    - **b.** The data sources and sampling methodology for assessing these outcomes; and
    - **c.** A detailed analysis plan that describes how the effects of the demonstration will be isolated from other initiatives occurring in the state.

34. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) calendar days after receipt of CMS's comments. Upon

CMS approval of the Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish to its website the approved Evaluation Design within thirty (30) calendar days of CMS approval. The state must implement the Evaluation Design and submit a description of its evaluation implementation progress in each of the Quarterly and Annual Monitoring Reports. Once CMS approves the Evaluation Design, if the state wishes to make changes, the state must submit a revised Evaluation Design to CMS for approval if the changes are substantial in scope; otherwise, in consultation with CMS, the state may include updates to the Evaluation Design in monitoring reports.

35. **Evaluation Questions and Hypotheses.** Consistent with Attachments A (Developing the Evaluation Design) of these STCs, the evaluation design must include a discussion of the evaluation questions and hypotheses that the state intends to test. The evaluation design must outline and address well-crafted hypotheses and research questions for all key demonstration policy components that support understanding the demonstration's impact and also its effectiveness in achieving the goals. The state must also investigate cost outcomes for the demonstration as a whole, including but not limited to: administrative costs of demonstration implementation and operation, Medicaid health service expenditures.

    The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults, and/or measures endorsed by National Quality Forum (NQF).

    The findings from each evaluation component must be integrated to help inform whether the state met the overall demonstration goals, with recommendations for future efforts regarding all components.

36. **Evaluation Budget.** A budget for the evaluation must be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluations such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses, and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.

37. **Interim Evaluation Report.** The state must submit an Interim Evaluation Report based on the evaluation design, as applicable, and for the completed years of the demonstration, and for each subsequent extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for extension, the Interim Evaluation Report should be posted to the state's website with the application for public comment.
    a. The Interim Evaluation Report will discuss evaluation progress and present findings to date as per the approved evaluation design.

b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
c. If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted. If the state made changes to the demonstration in its application for extension, the research questions and hypotheses and a description of how the design was adapted should be included. If the state is not requesting an extension for the demonstration, the Interim Evaluation Report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
d. The state must submit a revised Interim Evaluation Report sixty (60) calendar days after receiving CMS's comments on the draft Interim Evaluation Report. Once approved by CMS, the state must post the final Interim Evaluation Report to the state's website.
e. The Interim Evaluation Report must comply with Attachment B of these STCs.

38. Summative Evaluation Report. The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Interim and Summative Evaluation Report) of these STCs. The state must submit the draft Summative Evaluation Report for the demonstration's current approval period within eighteen (18) months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

a. Unless otherwise agreed upon in writing by CMS, the state must submit a revised Summative Evaluation Report within sixty (60) calendar days of receiving comments from CMS on the draft.
b. Upon approval from CMS, the final Summative Evaluation Report must be posted to the state's Medicaid website within thirty (30) calendar days of approval by CMS.

39. Corrective Action Plan Related to Evaluation. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of an extension process when associated with the state's Interim Evaluation Report, or as part of the review of the summative evaluation report. A corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial and sustained directional change inconsistent with demonstration goals, such as substantial and sustained trends indicating increased difficulty accessing services. A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS further has the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

40. **State Presentations for CMS.** CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the Interim Evaluation Report, and/or the Summative Evaluation Report.

41. **Public Access.** The state shall post the final documents (e.g., Monitoring Reports, Close Out Report, the approved Evaluation Design, Interim Evaluation Report, and Summative Evaluation Report) on the state's website within thirty (30) calendar days of approval by CMS.

42. **Additional Publications and Presentations.** For a period of twelve (12) months following CMS approval of deliverables, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment on or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

XI. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

43. **Allowable Expenditures.** This demonstration project is approved for expenditures applicable to services rendered during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.[1]

44. **Unallowable Expenditures.** In addition to the other unallowable costs and caveats already outlined in these STCs, the state may not receive FFP under any waiver authority approved under this demonstration for any of the following:
    i. Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

45. **Standard Medicaid Funding Process.** The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within thirty (30) days after the end of each quarter, the state shall submit form CMS-64

[1] For a description of CMS's current policies related to budget neutrality for Medicaid demonstration projects authorized under section 1115(a) of the Act, see State Medicaid Director Letter #18-009.

(Quarterly Medicaid Expenditure Report), showing Medicaid expenditures made in the quarter that just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

46. Extent of Federal Financial Participation for the Demonstration. Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole for the following, subject to the budget neutrality expenditure limits described in this section.

a. Administrative costs, including those associated with the administration of the demonstration;
b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.

47. Sources of Non-Federal Share. The state certifies that its match for the non-federal share of funds for this demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

a. The state acknowledges that CMS has authority to review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.
b. The state acknowledges that any amendments that impact the financial status of the demonstration must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

48. State Certification of Funding Conditions. The state must certify that the following conditions for non-federal share of demonstration expenditures are met:

a. Units of government, including governmentally operated health care providers, may certify that state or local monies have been expended as the non-federal share of funds under the demonstration.
b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.

c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR 433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.
d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments.
e. Under all circumstances, health care providers must retain one hundred (100) percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

49. Program Integrity. The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.

50. Demonstration Years. Demonstration Years (DY) for this demonstration are defined in the Demonstration Years table below.

Table 3: Demonstration Years		
Demonstration Year 6	September 15, 2021 – September 30, 2022	12 months
Demonstration Year 7	October 1, 2022 – September 30, 2023	12 months
Demonstration Year 8	October 1, 2023 – September 30, 2024	12 months
Demonstration Year 9	October 1, 2024 – September 30, 2025	12 months
Demonstration Year 10	October 1, 2025 – September 30, 2026	12 months

XIII. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION PERIOD

Table 6: Schedule of Deliverables for the Demonstration Period		
Date	**Deliverable**	**STC**
30 calendar days after approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
180 calendar days after approval date	Draft Evaluation Design	STC 32
60 days after receipt of CMS comments	Revised Evaluation Design	STC 34
1 year prior to expiration, or with extension application	Draft Interim Evaluation Report	STC 37
60 calendar days after receipt of CMS comments	Revised Interim Evaluation Report	STC 37
Within 18 months after March 31, 2025	Draft Summative Evaluation Report	STC 38
60 calendar days after receipt of CMS comments	Revised Summative Evaluation Report	STC 38
Quarterly monitoring reports due 60 calendar days after end of each quarter, except 4th quarter.	Quarterly Monitoring Reports	STC 25
Annual Monitoring Report - Due 90 calendar days after end of each 4th quarter	Annual Monitoring Reports	STC 25

ATTACHMENT A
DEVELOPING THE EVALUATION DESIGN

Introduction

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

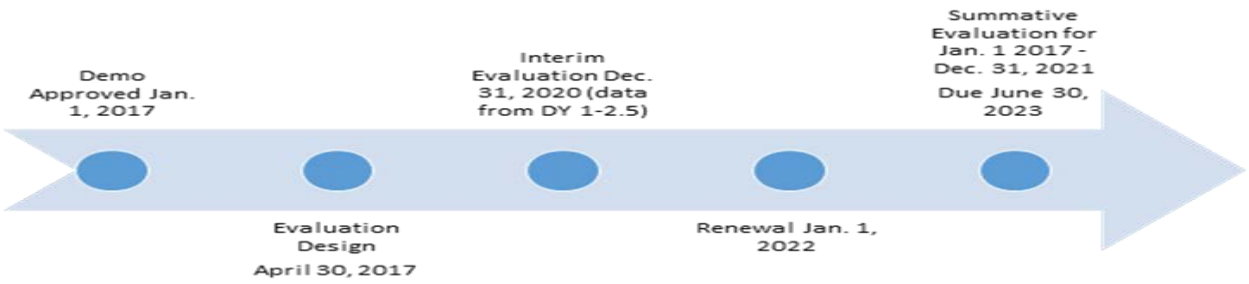
Expectations for Evaluation Designs

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

The format for the Evaluation Design is as follows:
General Background Information;
Evaluation Questions and Hypotheses;
Methodology;
Methodological Limitations;
Attachments.

Submission Timelines

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



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

A. General Background Information – In this section, the state should include basic information about the demonstration, such as:

1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).

2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;

4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

5) Describe the population groups impacted by the demonstration.

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

1) Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.

2) Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf

3) Identify the state's hypotheses about the outcomes of the demonstration:

4) Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;

5) Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

C. Methodology – In this section, the state is to describe in detail the proposed research methodology.

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

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

1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?

2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.

3) *Evaluation Period* – Describe the time periods for which data will be included.

4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:

    a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.

    b. Qualitative analysis methods may be used, and must be described in detail.

    c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.

    d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

    e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).

    f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

    If primary data (data collected specifically for the evaluation) – The methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection. (Copies of any proposed surveys must be reviewed with CMS for approval before implementation).

6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:

    a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.

b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.

c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).

d. The application of sensitivity analyses, as appropriate, should be considered.

7) *Other Additions* – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

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

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

D. Methodological Limitations – This section provides detailed information on the limitations of the evaluation. This could include the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize the limitations. Additionally, this section should include any information about features of the demonstration that effectively present methodological constraints that the state would like CMS to take into consideration in its review. For example:

1) When the state demonstration is:
    a. Long-standing, non-complex, unchanged, or
    b. Has previously been rigorously evaluated and found to be successful, or
    c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)
2) When the demonstration is also considered successful without issues or concerns that

would require more regular reporting, such as:

a. Operating smoothly without administrative changes; and
b. No or minimal appeals and grievances; and
c. No state issues with CMS-64 reporting or budget neutrality; and
d. No Corrective Action Plans (CAP) for the demonstration.

E. Attachments

1) **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include "No Conflict of Interest" signed by the independent evaluator.

2) **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.

3) **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

ATTACHMENT B
Preparing the Interim and Summative Evaluation Reports

Introduction

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

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. As these valid analyses multiply (by a single state or by multiple states with similar demonstrations) and the data sources improve, the reliability of evaluation findings will be able to shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

Intent of this Guidance

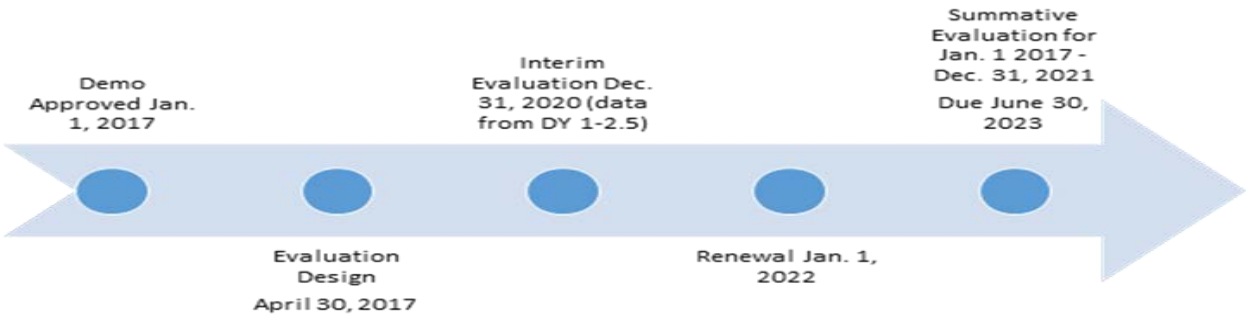
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Guidance is intended to assist states with organizing the required information in a standardized format and understanding the criteria that CMS will use in reviewing the submitted Interim and Summative Evaluation Reports.

The format for the Interim and Summative Evaluation reports is as follows:

A. Executive Summary;
B. General Background Information;
C. Evaluation Questions and Hypotheses;
D. Methodology;
E. Methodological Limitations;
F. Results;
G. Conclusions;
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
I. Lessons Learned and Recommendations; and
J. Attachment(s).

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish to the state's website the evaluation design within thirty (30) days of CMS approval, and publish reports within thirty (30) days of submission to CMS , pursuant to 42 CFR 431.424. CMS will also publish a copy to Medicaid.gov.



Required Core Components of Interim and Summative Evaluation Reports

The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. A copy of the state's Driver Diagram (described in the Evaluation Design guidance) must be included with an explanation of the depicted information. The Evaluation Report should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. Therefore, the state's submission must include:

A. Executive Summary – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.

B. General Background Information about the Demonstration – In this section, the state should include basic information about the demonstration, such as:

1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.

2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;

4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.

5) Describe the population groups impacted by the demonstration.

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

1) Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.

2) Identify the state's hypotheses about the outcomes of the demonstration;
   a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
   b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
   c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

D. Methodology – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design.

The evaluation design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An interim report should provide any available data to date, including both quantitative and qualitative assessments. The Evaluation Design should assure there is appropriate data development and collection in a timely manner to support developing an interim evaluation.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1. *Evaluation Design* – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?
2. *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.
3. *Evaluation Period* – Describe the time periods for which data will be collected
4. *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?
5. *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data.
6. *Analytic methods* – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
7. *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.

   A. Methodological Limitations - This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.

B. Results – In this section, the state presents and uses the quantitative and qualitative data to show to whether and to what degree the evaluation questions and hypotheses of the demonstration were achieved. The findings should visually depict the demonstration results (tables, charts, graphs). This section should include information on the statistical tests conducted.

C. Conclusions – In this section, the state will present the conclusions about the evaluation results.

1) In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?

2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:

   a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

D. Interpretations, Policy Implications and Interactions with Other State Initiatives – In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long range planning. This should include interrelations of the demonstration with other aspects of the state's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretation of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

E. Lessons Learned and Recommendations – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

1. What lessons were learned as a result of the demonstration?

2. What would you recommend to other states which may be interested in implementing a similar approach?

ATTACHMENT C
Approved Evaluation Design

Flint, Michigan Section 1115 Demonstration

#11W 00302/5

2021-2026 Renewal Evaluation

FIRST DRAFT: 03/14/2022
CURRENT DRAFT: 10/04/2022

A. General Background Information

1) *The Issue*

In April 2014, the water source in Flint, Michigan was changed from Lake Huron (via the Detroit Water and Sewerage Department) to the Flint River without appropriate treatment. This change caused lead to leach from the city's water lines (pipes), increasing the incidence of elevated lead levels in tap water and consequently in children's blood. After testing and discovery of the cause of the crisis, the water source was switched back to the original source, eighteen months later, on October 16, 2015. However, lead from the pipes continued to contaminate the tap water of structures served by the City of Flint Water Department and elevated blood lead levels persisted. In January 2016, President Obama declared an emergency in Flint, leveraging federal aid to support state and local response efforts. The declaration expired August 14, 2016, although some federal resources remained.

The State of Michigan's Department of Health and Human Services (MDHHS) applied for a Medicaid Section 1115 Demonstration waiver in February 2016, to expand eligibility and benefits. The demonstration was to support potentially exposed individuals who did not have the resources to manage the adverse health effects of lead exposure ("Flint, Michigan Section 1115 Demonstration" Approval and Special Terms and Conditions, n.d., p. 111.) These efforts were pursued because lead is a known neurotoxin and lead poisoning may result in growth, developmental, and educational difficulties (*Case Studies in Environmental Medicine (CSEM) Lead Toxicity*, n.d.) Young children (under 6 years) and children exposed *in utero* were most at risk (*Case Studies in Environmental Medicine (CSEM) Lead Toxicity*, n.d.) Access to health care and support services was necessary to ensure appropriate screening and monitoring to identify and manage the impacts associated with lead exposure.

MDHHS applied for the waiver because they identified that access to health care services was a concern in the affected region. Access was compromised among this resource poor community due to individuals lacking health insurance. Approximately 10% of the city's population were uninsured around the time of the crisis (*Flint, MI*, n.d.). In addition, some individuals with health insurance lacked sufficient resources to absorb cost-sharing requirements associated with seeking healthcare. According to 2017 United States Census data, Flint had the highest poverty rate compared to other cities of its size in the United States. Nearly 60% of children were living below the federal poverty level and the area ranked 82nd out of 83 counties in the state for general health outcomes and 71st out of 83 counties specifically for child health outcomes (*Flint & Genesee County, Michigan - Community Health Needs Assessment*, 2019). MDHHS estimated that approximately 47,000 individuals were covered by Medicaid in the City of Flint in 2016. The 2019 Community Health Needs Assessment provided additional information that, despite having access to Medicaid, these children experienced higher rates of inpatient hospitalization and longer lengths of stay (*Flint & Genesee County, Michigan - Community Health Needs*

Assessment, 2019). Thus, the demonstration's intent to expand eligibility to higher federal poverty levels, eliminate cost-sharing, and add a targeted case management (TCM) benefit focused on coordinating care was expected to partially address these health care barriers.

Lead pipe replacement was a major factor in reducing the ongoing risk of lead exposure. As of the renewal submission in April 2020, 90% of lead pipes had been replaced, but individuals were still eligible to sign up for free removal. While the lead content in the water is currently below federal standards, the water has not yet been deemed safe. MDHHS applied for, and was granted, a 5-year renewal of the original Flint Michigan 1115 Demonstration, 11-W00302/5 to run 9/15/21 - 9/30/26 reflecting Demonstration Years (DYs) 6-10 because of the ongoing exposure to the community and the need to continue supporting the health and well-being of exposed individuals.

2) The name of the demonstration to be evaluated is the Flint Michigan Section 1115 Demonstration, which was renewed effective September 15, 2021, and will run through September 30, 2026, with a matching evaluation period. The summative final report is due March 31, 2027. The demonstration will be referred to as the *Flint Medicaid Expansion Demonstration* (FME Demonstration) in this proposal.

3) *Description and History of the Demonstration*
This FME demonstration was intended to address potential health issues for individuals exposed to the contaminated water in Flint from April 2014 until a date where the water is deemed safe. Work continues to mitigate ongoing exposure to lead in the water supply through proper treatments and lead pipe replacement. While the concentration of lead contaminants has been reduced below federal thresholds, no amount of lead exposure is acceptable. As of December 2021, the water has not been deemed safe since lead pipe replacement is not finished.

The Flint Michigan Section 1115 Demonstration was originally approved for the period 3/3/16-2/28/21, with an extension through 9/14/21. The years 2016-2021 reflected DYs 1-5. The overarching goals of the FME Demonstration were to "improve access to services, expand Medicaid eligibility, and create better health outcomes." These were addressed through the expansion of eligibility by increasing income thresholds, adding a TCM benefit, and eliminating cost-sharing. The review of the FME Demonstration's influence during DYs 1-5 suggests the activities associated with the FME Demonstration supported the state's goals, although some mixed findings were observed as described in the Summative Evaluation Report.

MDHHS submitted a renewal for the FME Demonstration with no program changes in April 2020. The renewal application was designed with the belief that health care coverage for lead exposed individuals needed to continue and the expectation that additional health care needs would become more apparent over time. The request resulted in the 5-year renewal authorization for DYs 6-10 of the Flint, Michigan, 1115 Demonstration, defined as 9/15/21 - 9/30/26.

4) *Description of changes to the demonstration during the approval period, how Evaluation Design altered/augmented to address changes*
The renewal application was submitted with no program changes. However, lessons learned from DYs 1-5 along with review of other FME Demonstration metrics and public comments provided opportunities to augment the evaluation design. Particularly, the hypotheses associated with FME Demonstration required revision, in consideration of data availability and appropriate comparison group(s) selection. The key goals of the renewal application emphasized access to care, expanded eligibility and improved health outcomes. These goals required slight modifications of the original FME Demonstration's reporting. One modification was the recategorization of specific hypotheses. An example of this was moving the lead assessment measure under the Access to Care Domain. We further incorporated the stand-alone TCM Domain from the original FME Demonstration evaluation as part of the renewal's Access to Care Domain. Another modification was to establish a domain to specifically focus on the Expanded Eligibility goal. The renewal evaluation will be further augmented by increasing enrollee input through surveys, inviting additional partners with education subject matter expertise to the team, and increasing focus on operational aspects of FME that may influence the enrollee experience.

5) *Describe the population groups impacted by the demonstration.*
The FME Demonstration is intended to support individuals who were exposed to the contaminated water from April 2016 through a date when the water is deemed safe. The groups targeted in the original FME Demonstration were children up to age 21 and pregnant women. Lead is known to affect brain development, particularly for fetuses and children. Adults would be less likely to experience adverse neurological impacts. Pregnant women were included due to concerns for the developing fetus. Residence in the City of Flint or Genesee County was not a requirement for eligibility. Individuals could have been exposed through child-care, school, or employer locations. In addition to documented water exposure, eligibility criteria included:
    - Increased income threshold to offer coverage to any pregnant woman or child up to age 21 in households with incomes from 212% federal poverty level (FPL) up to and including 400% FPL during the approved timeframe.
    - Any children born to a pregnant woman during the approved timeframe.

B. Evaluation Questions and Hypotheses

1) MDHHS' stated goals for the renewal FME Demonstration were to:
   - improve access to services,
   - expand Medicaid eligibility, and
   - create better health outcomes.

These goals would be addressed through the specific authorizations including expanding eligibility for pregnant women and children up to age 21 having incomes up to 400% FPL. The expanded income threshold would allow individuals who would not normally qualify for Medicaid coverage to do so. The addition of the TCM benefit would support access to services by offering coordination and linkages to needed medical, social, educational, and other types of services. The ability to obtain health care and other services would in turn result in improved health outcomes.

The following domains are offered to translate the FME Demonstration goals into measurable targets. The domains are briefly described with more detail provided in subsequent sections.

Domain 1: Access to services

Hypothesis 1.1: "Enrollees will access services to identify and address physical or behavioral health issues associated with lead exposure at a rate higher than non-enrollees with similar individual and neighborhood characteristics over the duration of the FME Demonstration." The approved FME Demonstration is expected to continue to provide Medicaid coverage and access to health care services to individuals exposed to the contaminated water. The expanded eligibility will provide health care services to individuals who might otherwise be uninsured. Existing Medicaid enrollees would benefit from the additional TCM benefit and the elimination of existing cost-sharing requirements. Further included in approved expenditures is coverage for evaluation of potential lead exposures in homes of eligible enrollees without documentation of elevated blood lead levels. Hypothesis 1.1 will be broken into sub-hypotheses, each focusing on specific preventive care services recommended for children up to age 21 and pregnant women.

Hypothesis 1.2: *"*Enrollees who participate with TCM services will access medical, social, educational, and other services at a rate higher than enrollees with similar individual and neighborhood characteristics who do not participate with TCM services over the duration of the FME Demonstration.*"* The FME Demonstration provides an additional benefit, specifically TCM, to facilitate enrollee access to needed medical, social, educational, and other services. Required elements of TCM have been described in MDHHS policy and include assessments, planning, linkage, advocacy, coordination, referral, monitoring, and

follow-up activities. The rationale for this hypothesis is that TCM participants will have additional help navigating the health care system and securing resources to assist with the consequences of lead exposure. Conversely, those who do not participate with TCM navigate the system independently and may not know about additional supports or services that could be available to them. This hypothesis will also be further subdivided to measure the impact of TCM on enrollees' adherence to recommended health services.

Domain 2: Expand Medicaid Eligibility

Hypothesis 2: "The proportion of new enrollees between 212-400% FPL will increase over the duration of the FME Demonstration representing an increase in the proportion of individuals having health care coverage." MDHHS received authorization to offer Medicaid coverage to individuals at higher income levels and the uptake of this coverage depends on several factors. Potentially eligible individuals and human service organizations responsible for enrollment would need to be aware of the revised qualifications. Also, enrollment processes need to be understood and easily implemented. In addition to standardized quantitative metrics, such as enrollment and disenrollment counts, enrollee and community organization qualitative inputs will inform evaluation of the processes required to participate with the FME Demonstration as well as the degree to which the expanded eligibility represented a new opportunity to obtain health insurance or was used as replacement coverage for other existing forms of health insurance.

Domain 3: Improved Health Outcomes

Hypothesis 3: "Enrollees will have improved health outcomes compared to non-enrollees with similar individual and neighborhood characteristics over the duration of the FME Demonstration." The approved demonstration will provide opportunities for access to health care and additional support leading to improved overall health status and health outcomes for enrollees. Measures such as complete childhood immunization and birth weight will serve as proxies for overall health outcomes. Individualized feedback will be sought through qualitative processes for self-reported health status measures.

2) **Table 1. Domains as the drivers of the FME demonstration, including primary and secondary drivers of the domain**.

Aim (Goal or Objective of the Work)	**Primary Drivers** (Key Drivers: System components or factors contributing directly to achieving aim)	**Secondary Drivers** (Actions, interventions, or lower-level components necessary to achieve the primary driver)
FME Demonstration enrollees will have increased access to selected health care services compared to non-enrollees having similar individual and neighborhood characteristics by 9/30/2026.	Individual having health care insurance	History of lead exposure from contaminated water
		Household income level (FPL%)
	Individual level of cost-sharing for health care services	Household income level (FPL%)
	Ability to navigate health care system	Eligible population knowledgeable about demonstration eligibility and benefits
		TCM and community service organization staff knowledge about FME demonstration eligibility and benefits
	Health literacy	Enrollees seek care in primary care settings rather than urgent or emergent care settings
		Enrollee knowledgeable about recommended preventive care services
The number and proportion of FME demonstration enrollees at 212-400% FPL will increase by 9/30/26 representing an increase in the proportion of individuals having health care coverage.	Eligible population knowledgeable about demonstration eligibility and benefits	FME Demonstration communications and dissemination to potentially affected community
		Community partner(s) knowledgeable about demonstration eligibility and benefits
		Efficient FME demonstration enrollment processes
	Eligible population willing to choose Medicaid	FME Demonstration provides continuity and Stability of coverage
FME Demonstration enrollees will have improved selected health outcomes compared to non-enrollees having similar individual and neighborhood characteristics by 9/30/2026.	Receipt of age-appropriate recommended preventive care services	Enrollee has reduced financial strain associated with having to pay for health care services
	Receipt of care coordination	Enrollee participation with TCM services.
		Enrollee is more confident in managing chronic conditions
	Healthy living environments	Enrollee awareness of the state's redesigned Elevated Blood Lead-Nurse Case Management (EBL-NCM) program and the Lead Safe Home Program (LSHP)

Outlined here are the FME demonstration Domains and the corresponding sub-hypotheses for each.

Domain 1: Access to Services:

Hypothesis 1.1: "FME Demonstration enrollees will access services to identify and address physical or behavioral health issues associated with lead exposure at a rate higher than ***non-enrollees with similar individual and neighborhood characteristics*** over the duration of the demonstration." This hypothesis will focus on comparing rates of selected services among enrollees to rates among selected comparison group(s). The specific services are identified below.

H1.1.1: FME Demonstration enrollees will access age-appropriate well-child exams at a rate higher than non-enrollees with similar individual and neighborhood characteristics over the duration of the demonstration.
H1.1.2: FME Demonstration enrollees will access age-appropriate developmental screening at a rate higher than non-enrollees with similar individual and neighborhood characteristics over the duration of the demonstration.
H1.1.3: FME Demonstration enrollees will access age-appropriate lead testing and follow-up/retesting as indicated at a rate higher than non-enrollees with similar individual and neighborhood characteristics over the duration of the demonstration.
H1.1.4: Pregnant FME Demonstration enrollees will access timely prenatal and postpartum care at a rate higher than non-enrollees with similar individual and neighborhood characteristics over the duration of the demonstration.
H1.1.5: Pregnant FME Demonstration enrollees will access recommended lead testing at a rate higher than non-enrollees with similar individual and neighborhood characteristics over the duration of the demonstration.
H1.1.6: Pregnant FME Demonstration enrollees will participate in the state's Maternal Infant Health Program (MIHP) at a rate higher than non-enrollees with similar individual and neighborhood characteristics over the duration of the demonstration.
H1.1.7: FME Demonstration enrollees will attest to improved health care access as a result of waiver participation.
H1.1.8: FME Demonstration enrollees will attest to satisfaction with their ability to access health care services as a result of waiver participation.
H1.1.9: FME Demonstration enrollees will attest to having evaluation of potential lead exposure in their home if their pipes have not been replaced.

Hypothesis 1.2: *"*FME Demonstration enrollees who participate with TCM services will access medical, social, educational, and other services at a rate higher than FME ***demonstration enrollees with similar individual and neighborhood characteristics who do not participate with TCM*** services over the duration of the demonstration.*"* This hypothesis will focus on

comparing rates of selected services among enrollees who have TCM involvement to rates among enrollees lacking evidence of TCM involvement. The same services in Hypothesis 1.1 will be targeted.

H1.2.1: FME Demonstration enrollees who participate with TCM will access age-appropriate well-child exams at a rate higher than enrollees who do not participate with TCM over the duration of the demonstration.

H1.2.2: FME Demonstration enrollees who participate with TCM will access age-appropriate developmental screening at a rate higher than enrollees who do not participate with TCM over the duration of the demonstration.

H1.2.3: FME Demonstration enrollees who participate with TCM will access age-appropriate lead testing and follow-up/retesting at a rate higher than enrollees who do not participate with TCM over the duration of the demonstration.

H1.2.4: Pregnant FME Demonstration enrollees who participate with TCM will access timely prenatal and postpartum care at a rate higher than pregnant enrollees who do not participate with TCM over the duration of the demonstration.

H1.2.5: Pregnant FME Demonstration enrollees who participate with TCM will access recommended lead testing at a rate higher than pregnant enrollees who do not participate with TCM over the duration of the demonstration.

H1.2.6: Pregnant FME Demonstration enrollees who participate with TCM will participate with MIHP at a rate higher than pregnant enrollees who do not participate with TCM over the duration of the demonstration.

H1.2.7: FME Demonstration enrollees who participate with TCM will attest to improved health care access as a result of waiver participation at a rate higher than enrollees who do not participate with TCM.

H1.2.8: FME Demonstration enrollees who participate with TCM will attest to satisfaction with their ability to access services as a result of TCM participation.

H1.2.9: FME Demonstration enrollees who participate with TCM will attest to having evaluation of potential lead exposure in their home if their pipes have not been replaced as a result of TCM participation.

Domain 2: Expand Medicaid Eligibility

Hypothesis 2: The proportion of new FME Demonstration enrollees between 212-400% FPL will increase over the duration of the demonstration representing an increase in the proportion of individuals having health care coverage.

H2.1: FME Demonstration enrollees between 212-400% FPL will attest to having information regarding expanded Medicaid eligibility resulting in waiver participation.

H2.2: Community partners involved with Medicaid enrollment will attest to awareness of FME Demonstration eligibility and enrollment processes.

H2.3: Community partners involved with Medicaid enrollment will attest to satisfaction with FME Demonstration enrollment processes.
H2.4: FME Demonstration enrollees between 212-400% FPL will attest that the demonstration authorized expanded Medicaid eligibility offered a new opportunity to obtain health care coverage versus serving as a replacement for existing health care coverage.

Domain 3: Improved Health Outcomes

Hypothesis 3: FME Demonstration enrollees will have improved health outcomes compared to non-enrollees with similar individual and neighborhood characteristics over the duration of the demonstration.

Health Outcomes:

H3.1: FME Demonstration enrollees will have improved age-appropriate completed immunization status compared to non-enrollees with similar individual and neighborhood characteristics over the duration of the demonstration. This outcome is included in Domain 3 as opposed to Domain 1 because a driver of health outcomes is the receipt of recommended preventive care services (Table 1).
H3.2: Pregnant FME Demonstration enrollees will have higher birth weights compared to non-enrollees with similar individual and neighborhood characteristics over the duration of the demonstration.
H3.3: FME Demonstration enrollees will report improved health status as a result of the waiver participation.
H3.4: FME Demonstration enrollees will report improved confidence in chronic condition self-management as a result of the waiver participation.

Educational outcomes:

H3.5: FME Demonstration enrollees will have an increased rate of referrals to specialized programs intended to mitigate potential educational and/or behavioral disabilities during childhood (ages 0-21) as a result of waiver participation.

3) Alignments of the hypotheses with overarching goals of the demonstration are described here.

The hypotheses identified in **Domain 1** evaluate the use of specified services including: well-child visits, developmental screening assessments, testing of blood lead levels in pregnant women and children, prenatal and postpartum care, MIHP participation, improved access to care, satisfaction with access to care, and evaluation of potential lead exposure. The majority of these hypotheses reflect services that are endorsed by the US Preventive Services Task Force to promote overall health. The FME Demonstration's goal to improve access to services may be met through a variety of mechanisms as suggested in the driver diagram. Access to health care is influenced by the availability of health insurance to cover the costs associated with obtaining

these services. Costs may be incurred through paying out of pocket in the absence of health insurance as well as having cost-sharing requirements for each instance of service use even with health insurance coverage. In addition to financial aspects of the health care transaction, the cost-benefit analysis in terms of non-financial costs (i.e., time to receive the service, difficulty navigating to an appointment, stress, and mental health) at the individual level influences adherence to these recommendations. The availability of the TCM benefit is expected to assist enrollees in overcoming barriers to seeking care as well as providing information and education on the importance of these services. The evaluation questions for Domain 1 will inform whether the goal to improve access to care was met by measuring enrollee adherence to having the recommended services as evidenced by claims/encounter data. Qualitative data obtained from surveys from enrollees and TCM professionals will provide context to the types of barriers that may impede access and the types of strategies to overcome these barriers.

The hypothesis identified for **Domain 2** is related to the FME Demonstration's goal to increase enrollment by expanding Medicaid eligibility. Authorization to offer Medicaid coverage to individuals at higher income levels was granted along with the elimination of cost-sharing measures. The intention was to eliminate these financial impediments to health care so exposed individuals could seek needed services. However, expanding eligibility criteria is just the first step to increase enrollment. Potentially eligible individuals need to know they may qualify for coverage under the expanded criteria which would require communication and dissemination of this information in a consumable format. Additionally, community partners who support Medicaid enrollment would need to be informed about changes so that they did not assume ineligibility based on prior criteria and/or have the necessary information to operationally enroll individuals. Even with health insurance, there must then be sufficient healthcare providers willing to accept new Medicaid patients. Administrative data along with survey data will be used to address this hypothesis.

The hypothesis identified for **Domain 3** establishes that individuals participating with the FME Demonstration should experience better health outcomes than similar individuals who do not participate. The specific health outcomes represent proxy measures that might reasonably be susceptible to lead exposure among individuals who would be identified as high-risk for lead exposure and represent the target population for the FME Demonstration application. They represent measures of optimum care which presumably would be facilitated through the increased access to health care coverage and the involvement of TCM. While some of these sub-hypotheses may be more accurately described as process measures, the association of each with optimized health status is well documented. The evaluation question associated with improved health outcomes relates to the belief the FME Demonstration addressed barriers to health care so enrollees could seek services as recommended. The financial constraints are

believed to be reduced through the eligibility expansion and elimination of cost-sharing. The availability of TCM professionals to work with enrollees to provide education, secure referrals for care, identify and provide solutions to barriers to care (i.e., transportation, difficulty making appointments) also supports the ability to obtain recommended services to the fullest extent possible. The evaluation team will reach out to enrollees and TCM professionals to obtain qualitative reports on the factors associated with health outcome status and the degree to which the FME demonstration impacted these factors.

Flint City schools are unique because they are composed of both public schools and charter schools totaling 21 distinct districts (Green, 2019). To further elucidate this, Flint has 68 schools within these districts and many of which have very small enrollment counts. Due to administrative circumstances including the water crisis, the State of Michigan and the Genesee Intermediate School District act as the intermediary for all special education for the 21 school districts. For this reason, not all Flint school data, that are necessary to make accurate reports for the progress of school-age children, are publicly available and housed collectively. Additionally, some schools are so small that valuable data on special education and services are often limited. Although individual level education metrics are unavailable due to the Family Educational Rights and Privacy Act (FERPA), it is the intent of the evaluation team to work with several sources such as Michigan State University College of Education, Flint Registry, and Genesee Health System Neurodevelopmental Center of Excellence. The evaluation team plans to aggregate data from the sources listed with administrative data of families enrolled in the waiver. For instance, each entity may have different levels and types of developmental data such IEPs and special services for behavior and educational delays that can inform reasonably accurate benchmarks and trends. Further, enrollee surveys will be designed to capture qualitative child behavioral and educational data to explore the relation to administrative data and the progression of children in Flint. The primary focus of this methodology is to depict close approximations of developmental milestones observed in Flint children exposed to lead in the tap water.

4) The objective of Title XIX was to provide medical and health related services for individuals with low income. The FME Demonstration includes specific authorizations intended to promote the availability of medical and health related services to more individuals at low-income levels through expanded eligibility and elimination of cost-sharing. The evaluation of the FME Demonstration will document the degree to which newly eligible individuals based on expanded criteria are able to seek health care and the degree to which the FME Demonstration resulted in greater health insurance coverage for the affected community. Another benefit of the FME Demonstration is that it offers case management professionals to assist with navigating the health care system. The evaluation will measure whether enrollees received services to a greater degree

with the involvement of these professionals.

C. Methodology

1) *Evaluation Design*

Depending on the types of outcomes, the renewal evaluation will use different designs. For changes of outcomes over time a pre- and post-period with two-group comparison design will be used; and for cross-sectional outcomes, a two-group comparison design will be used. To avoid selection bias, we will not use beneficiaries in Flint who were potentially eligible as the comparison group. Potentially eligible individuals are those residing in the same allowable areas impacted by the water crisis, having the same income levels, and in the same age group(s) but did not choose to enroll in the FME demonstration. This design choice is based on the concern over self-selection bias; there is no reason to believe that we can use statistical methods to control for all systematic differences between FME Demonstration enrollees and non-enrollees. In addition, some statistical methods (e.g., Heckman's selection model, instrumental variables) require researchers to observe factors that are meaningfully related to decisions to participate but are not related to the outcomes to correct the selection bias. Thus, the comparison groups will be selected using a two-step procedure which will first focus on some geographic areas with the larger policy environment like that of Genesee County and then selection of individuals within those areas.

Specifically, in the *first* step, we will use 1) the K-means clustering method to select up to 3 or 4 counties in the Lower Peninsula that are like Genesee County in socioeconomic, demographic, and health characteristics; or 2) a synthetic control (SC) method to construct weighted combinations of counties that had similar trends as that of Flint in the percentage of children under age 6 with elevated blood lead level (EBLL) in the period prior to the expansion.

In the *second* step, we will obtain the administrative claims data and residential census block group or census tract information for Medicaid children up to age 21 and pregnant women in the selected counties together with the data from the target population to estimate a propensity score (PS) for the likelihood of enrolling in the FME demonstration. The estimated PS will be combined with outcome regressions to estimate the average treatment effect on the treated using doubly robust estimation methods (Schuler & Rose, 2017; Zhong et al., 2021).

Details of the two-step procedure and the covariates for estimations are discussed in subsection (ii) of section 6) Analytic Methods.

2) *Target and Comparison Populations*

The FME Demonstration is intended to support individuals who were exposed to contaminated water from April 2016 through a date when the water is deemed safe. The groups targeted in the original FME demonstration were children up to age 21 and pregnant women. Thus, in the renewal evaluation, the same groups of beneficiaries will still be the *target population*.

We may further distinguish existing versus newly enrolled *individuals* in the renewal FME Demonstration. During the first waiver period, the evaluation team considered those at the higher income thresholds of 212-400% FPL would have been considered "newly eligible". These persons did not qualify for existing Medicaid coverage based on current restrictions. The FME demonstration was specifically designed to expand coverage to this group. However, when analyzing the available eligibility data, information regarding income levels was incomplete which compromised the ability to compare the "newly eligible" group to those that would have qualified at the non-FME demonstration levels. Discussions with MDHHS are in process to identify opportunities to obtain complete data to support these comparisons with sufficient rigor.

Additional patterns were noted in the FME demonstration enrollment data suggesting that some individuals could have voluntarily disenrolled from the FME demonstration benefit package but retained other Medicaid coverage. This anomaly is being reviewed with MDHHS representatives to determine if these observations represent errors in the data or potential operational edits. Examples of these patterns are noted in Table 2. Table 2 shows the beneficiaries' enrollment status in Medicaid (where "elig" and "no elig" indicate the person being in Medicaid or not, irrespective of specific FME demonstration enrollment) versus also in the initial FME demonstration (where "fme" indicates the person having at least one enrollment flag). For example, the first row represents individuals who enrolled in the demonstration ("fme") for at least one month in each period from 5/2016 to 4/2020; and among them, 20,307 (subgroup 1) were in Medicaid prior to 5/2016 and 2,619 (subgroup 2) were new to Medicaid starting sometime in 5/2016-4/2017 (e.g, no prior evidence of being a Medicaid beneficiary before 5/2016). The second row of the table represents individuals enrolled in the FME demonstration from 5/2016 to 4/2019, but did not enroll in 5/2019 to 4/2020; and among them, 368 were in Medicaid prior to 5/2016 and 31 were new to Medicaid starting from 5/2016. The rest of the rows of the table read similarly. In total, we found 31,494 existing (before 5/2016) beneficiaries (subgroup 1) and 11,028 new beneficiaries (subgroup 2) who had at least one month enrollment in the FME demonstration in the initial FME demonstration period (2016-2020). Depending on the potential sample sizes of the renewal demonstration, we may target the subgroup of new enrollees.

Ideally, we will assess the impact of the demonstration for those who became eligible through the higher income eligibility criteria as well as individuals already enrolled in Medicaid prior to

the demonstration. The feasibility will depend on the potential new information we may receive from MDHHS on program participation. Using current data, we found 916 (~4%) out of 22,765 enrolled children had income level greater than 212% FPL. The current sample sizes may not allow separate analyses of the impact of the FME Demonstration.

The general criteria for selecting the *comparison populations* will include: 1) children up to age 21 or pregnant women, 2) residing in one of the selected comparison counties using either K-means or synthetic controls method, 3) with estimated propensity scores that overlap with the propensity scores of the target population, and 4) in the appropriate subgroup of the target population defined by the outcome domain metric. Additional criteria for specific outcomes and the justification and limitation of these comparison groups are discussed in subsection (i) of the section 6) Analytic Methods.

Table 2. History of Flint Medicaid expansion (FME) enrollment among existing and new members who were children up to age 21 and pregnant women with a Flint ZIP code or at least one month enrollment in the demonstration after 5/2016.

5/2016 - 4/2017	5/2017 - 4/2018	5/2018 - 4/2019	5/2019 - 4/2020	Subgroup 1 (N=31,494)	Subgroup 2 (N=11,028)
fme	fme	fme	fme	20307	2619
fme	fme	fme	elig	368	31
fme	fme	fme	no elig	1722	282
fme	fme	elig	fme	100	14
fme	fme	elig	elig	351	47
fme	fme	elig	no elig	147	22
fme	fme	no elig	fme	248	64
fme	fme	no elig	elig	42	12
fme	fme	no elig	no elig	1906	615
fme	elig	fme	fme	67	8
fme	elig	fme	elig	16	2
fme	elig	fme	no elig	16	3
fme	elig	elig	fme	48	3
fme	elig	elig	elig	360	46
fme	elig	elig	no elig	87	17
fme	elig	no elig	fme	9	3

fme	elig	no elig	elig	12	5	
fme	elig	no elig	no elig	144	67	
fme	no elig	fme	fme	163	33	
fme	no elig	fme	elig	17	1	
fme	no elig	fme	no elig	64	19	
fme	no elig	elig	fme	6	8	
fme	no elig	elig	elig	24	0	
fme	no elig	elig	no elig	26	5	
fme	no elig	no elig	fme	112	39	**Subtotal**
fme	no elig	no elig	elig	35	9	**Subgroup 2a =**
fme	no elig	no elig	no elig	1977	773	**4747**
elig	fme	fme	fme	654	490	
elig	fme	fme	elig	78	17	
elig	fme	fme	no elig	116	54	
elig	fme	elig	fme	14	2	
elig	fme	elig	elig	88	19	
elig	fme	elig	no elig	21	7	
elig	fme	no elig	fme	11	10	
elig	fme	no elig	elig	6	4	
elig	fme	no elig	no elig	161	142	
elig	elig	fme	fme	226	39	
elig	elig	fme	elig	94	11	
elig	elig	fme	no elig	39	5	
elig	elig	elig	fme	251	46	
elig	elig	no elig	fme	27	9	
elig	no elig	fme	fme	42	4	
elig	no elig	fme	elig	3	0	
elig	no elig	fme	no elig	15	2	**Subtotal**
elig	no elig	elig	fme	8	1	**Subgroup 2b =**

elig	no elig	no elig	fme	61	3	**865**
no elig	fme	fme	fme	211	1027	
no elig	fme	fme	elig	24	60	
no elig	fme	fme	no elig	108	304	
no elig	fme	elig	fme	7	11	
no elig	fme	elig	elig	34	62	
no elig	fme	elig	no elig	17	35	
no elig	fme	no elig	fme	14	30	**Subtotal**
no elig	fme	no elig	elig	7	7	**Subgroup 2c =**
no elig	fme	no elig	no elig	147	461	**1997**
no elig	elig	fme	fme	23	151	
no elig	elig	fme	elig	7	25	
no elig	elig	fme	no elig	4	24	**Subtotal**
no elig	elig	elig	fme	33	147	**Subgroup 2d =**
no elig	elig	no elig	fme	3	13	**360**
no elig	no elig	fme	fme	181	1028	**Subtotal**
no elig	no elig	fme	elig	29	106	**Subgroup 2e =**
no elig	no elig	fme	no elig	71	354	**1488**
						Subtotal
no elig	no elig	elig	fme	26	152	**Subgroup 2f=**
no elig	no elig	no elig	fme	259	1419	**1571**

Footnote: “fme” means the beneficiary had at least one month enrollment in the demonstration program. “elig” means the beneficiary was in the Medicaid program. “no elig” means the beneficiary did not have any enrollment month in Medicaid.

3) *Evaluation Period*

In the initial evaluation, the critical time periods were May 1, 2013 – April 30, 2014, as ‘pre’ water switch period (T1), May 1, 2014 – April 30, 2016, as the ‘pre’ demonstration implementation period (T2), and all subsequent years since the demonstration began in May 2016 as the ‘post’ implementation period (T3). For the renewal evaluation, we will continue with the strategy using each 12-month period, starting from May 2016, as one study period and will include activity from 9/15/21 - 9/30/26.

Timeframe Code	Timeframe Description
T1	Baseline year prior to the water switch (May 1, 2013 – April 30, 2014).

T2	Post water switch, FME not implemented (May 1, 2014 – April 30, 2016).
T3	Post water switch, FME implemented (May 1, 2016 – present).

4) *Evaluation Measures*

As described in the Evaluation Questions and Hypotheses section, the evaluation measures fall in three domains: 1) Access to Services, 2) Eligibility Expansion, and 3) Improved Health Outcomes. We will provide the definitions of each outcome measure here. Summary tables of all measures by domain are available in Appendix A-1.

Domain 1 measures

Age-appropriate well-child exam: the Healthcare Effectiveness Data and Information Set (HEDIS) algorithms will be used to define the following measures.

- The HEDIS well child visits in the first 15 months of life measures "the percentage of children who had between one and six or more well-child visits by the time they turned 15 months of age." The corresponding procedure codes and principal diagnosis in the HEDIS value set will be used to construct the variables.
- The HEDIS well child visits in the third, fourth, fifth and sixth years of life measures "The percentage of members 3-6 years of age who had one or more well-child visits with a PCP (primary care practitioner) during the measurement year." The corresponding procedure codes and principal diagnosis in the HEDIS value set will be used to construct the variables.
- The HEDIS adolescent well-care visits measures "the percentage of enrolled members 12-21 years of age who had at least one comprehensive well-care visit with a PCP or an OB/GYN practitioner during the measurement year." The corresponding procedure codes and principal diagnosis in the HEDIS value set will be used to construct the variables.

Age-appropriate developmental screening: the HEDIS value set procedure codes will be used to construct the following variables.

- The percentage of children screened for risk of developmental, behavioral, and social delays using a standardized screening tool (CPT 96110) in the first three years of life.
- The percentage of children/adolescents 4-17 years of age who had at least one socio-emotional/behavioral screen (CPT 96127) with a primary care practitioner or an OB/GYN practitioner during the measurement year.

Age-appropriate lead testing and follow-up/retesting:

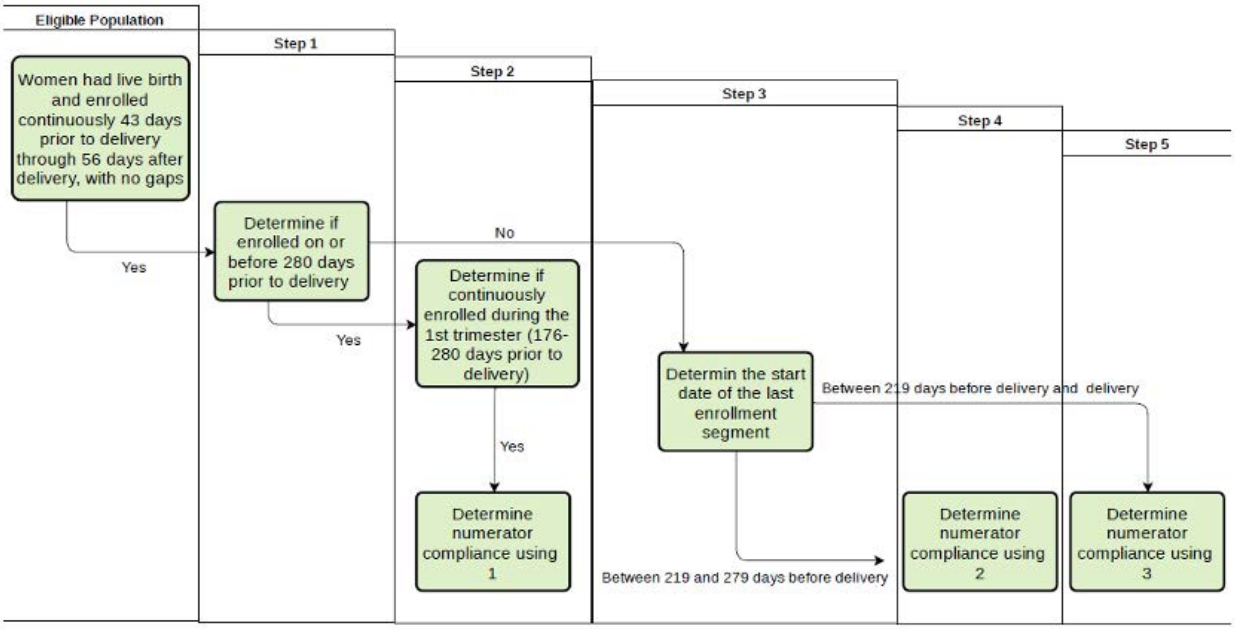
- The modified HEDIS lead screening in children measures "the percentage of children 6 years of age who had 1 or more capillary or venous lead blood test for lead poisoning by

their second birthday." We will use both claims coding and lab data to identify who had a lead test. We will use the Centers for Disease Control and Prevention guideline for the recommended timing for appropriate follow-up as of the evaluation period.

Pregnant enrollees with timely prenatal and postpartum care as defined in HEDIS specifications:

- The percentage of deliveries that received a prenatal care visit in the first trimester, on the enrollment start date or within 42 days of enrollment. Figure A shows the steps to identify the denominator and numerator for this measure.
- The percentage of deliveries that had a postpartum visit on or between 21 and 56 days after delivery. A postpartum visit for a pelvic exam or postpartum care on or between 21 and 56 days after delivery is identified using any of the following criteria: a postpartum visit (Postpartum Visits Value Set); a cervical cytology (Cervical Cytology Value Set); or a bundled service (Postpartum Bundled Services Value Set).

Figure A. The HEDIS procedure defines the percentage of deliveries that received a prenatal care visit in the first trimester, on the enrollment start date or within 42 days of enrollment.



1, Identifying Prenatal Care for Women Continuously Enrolled During the First Trimester
2, Identifying Prenatal Care for Women Not Continuously Enrolled During the First Trimester and find a visit on or between the last enrollment start date and 176 days before delivery
3, Identifying Prenatal Care for Women Not Continuously Enrolled During the First Trimester and find a visit on the enrollment start date or within 42 days after enrollment.

Pregnant enrollees with recommended lead testing:

- We will use the same claim codes and lab data identified for the child lead testing, but the time frame will be specific for pregnant women.

Pregnant enrollees participating in the Maternal and Infant Health Program (MIHP):

- Specific procedure codes for the MIHP in Michigan will be used to identify participants.

Enrollee attestation to improved health care access:

- Survey data questionnaire, for example: Since {Reference date}, the FME demonstration has made it easier to get the health care that I need.
    a. Strongly Agree
    b. Agree
    c. Neutral
    d. Disagree
    e. Strongly Disagree

Enrollee satisfaction with ability to access health care services:

- Survey data questionnaire, for example: Since {Reference date}, how satisfied have you been with your Supports Coordinator?
    a. Very Satisfied
    b. Somewhat Satisfied
    c. Somewhat Dissatisfied
    d. Very Dissatisfied

Evaluation of potential lead exposure at home:

- Environmental Reports from the community
- Survey data questionnaire, for example: Since {Reference date}, did you know that you could have your home evaluated for potential lead exposures? Did you have your home evaluated for potential lead exposures?
- Utilize a variety of analyses to map waterline replacement and associated neighborhood characteristics. We will geocode enrollee addresses and link their survey data with these characteristics, which include but are not limited to water age, previous lead levels in water, area socioeconomic characteristics, vacancy rates, physical disorder. From these connections, we will assess statistical relationships between enrollee health data and their neighborhood context. Subsequent maps will assist in visualizing patterns among these variables.

<u>Domain 2 measures</u>

Enrollee attestation to demonstration information leading to enrollment:

- Data from enrollee survey

Community partner awareness of demonstration enrollment processes:

- Data from community partner survey

Community partner attestation to enrollment processes:

- Data from community partner survey

Enrollee attestation to waiver providing new vs. replacement insurance coverage

- Data from enrollee survey

Domain 3 measures

Age-appropriate immunization status:

- The percentage of children 2 years of age who were fully immunized per the Advisory Committee on Immunization Practices: had four diphtheria, tetanus, and acellular pertussis (DTaP); three polios; one measles, mumps, and rubella (MMR); three haemophilus influenza type B (HiB); three hepatitis B (HepB), one chicken pox (VZV); four pneumococcal conjugates (PCV); one hepatitis A (HepA); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday. The children with all 10 immunization records will be counted as part of the numerator.
- The percentage of adolescents 13 years of age who had one dose of meningococcal conjugate vaccine, one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday. The measure calculates a rate for each vaccine and two combination rates. The adolescents with all 3 vaccines will be counted as part of the numerator.

Birth weights:

- Linked vital records data will be used to find the birth weights.
- Live births with birth weight < 2500 grams will be defined as low birth weight.

Increase in self-reported health status:

- Survey data questionnaire, for example: Since {Reference date}, how would you rate your overall health (both physical and behavioral/emotional)?
    a. Excellent
    b. Very Good
    c. Good
    d. Fair
    e. Poor

Chronic condition self-management confidence:

- Survey data questionnaire, for example: Since {Reference date}, I have access to more resources that help with self-management of my chronic condition(s)
    a. Strongly Agree
    b. Agree
    c. Neutral
    d. Disagree
    e. Strongly Disagree
- Since {Reference date}, I am more confident that I can manage my chronic condition(s) (such as asthma or diabetes).
    a. Strongly Agree
    b. Agree
    c. Neutral
    d. Disagree
    e. Strongly Disagree

Educational Delays:

- Since {Reference date}, have you been told by a doctor or nurse that your child has a behavioral or emotional problem?
    a. Yes
    b. No
    c. Don't know
- Since {Reference date}, has a daycare or school teacher or school nurse told you that your child has a behavioral or emotional problem?
    a. Yes
    b. No
    c. Don't know
    d. Child not school aged/not in school
- Has a daycare or school teacher or school nurse told you that your child has an educational delay requiring special support through an IEP?
    a. Yes
    b. No
    c. Don't know
    d. Child not school aged/not in school

Additional data for educational outcomes will be pursued through a potential partnership with the Genesee Intermediate School District.

5) *Data Sources*

The major data sources for the renewal evaluation will include:

(i) MDHHS (Michigan Department of Health and Human Services) Medicaid enrollment, utilization (claims/encounter) data, Lead Poisoning Prevention Program Data
(ii) TCM program information (administrative data and surveys)
(iii) Michigan Care Improvement Registry (MCIR)
(iv) Enrollee, non-enrollees, and community partner Surveys
(v) Publicly available data (Robert Wood Johnson Foundation County Health Rankings, and census block group and census tract data in American Community Survey)

Each data source and quality control measures are briefly described below.

(i) MDHHS Health Services Data Warehouse – Enrollment and Utilization

MDHHS maintains a data warehouse containing information at an individual level regarding a variety of health-related services and data points. IHP employs staff with the necessary permissions and expertise to access the MDHHS Health Services Data Warehouse (HSDW) and acquire the elements needed to support analyses through an honest broker arrangement. However, despite the storage of a variety of health-related program data in the HSDW, access to these data is controlled by each program.

Specific information contained within the data warehouse includes Medicaid eligibility/enrollment records, final paid Medicaid claims/encounter data, and blood lead program data. While much of the Medicaid claims/encounter data lack clinical care values, the Michigan Childhood Lead Poisoning Prevention Program (MCLPPP) does collect this information.

Reviews of routinely reported information are conducted by MDHHS program and warehouse staff to identify potential issues with data loading or when changes to warehouse tables are made. The evaluation team will not validate the data extracted from the warehouse with primary sources such as medical record reviews. Instead, periodically scheduled conversations between the IHP staff responsible for pulling data and state program and warehouse staff will ensure that relevant fields are captured, and coded variables are correctly interpreted. Data review will be an ongoing, iterative process and continue throughout the duration of the evaluation. Independent review and validation of code used to process data and conduct statistical analyses will be performed by evaluation team statisticians.

(ii) Targeted Case Management Program Information

The supplementary TCM benefit approved in the waiver necessitates additional data sources to support the evaluation beyond the claims/encounter information contained in the HDSW. While the provision of TCM services can be identified through specific procedure codes entered onto billing data, the data elements required to discriminate between specific services is not

available via this administrative data. Although in the initial evaluation, the evaluation team established a Business Associates' Agreement (BAA) with Genesee Health System (GHS) to access their records for purposes of this evaluation, the level of detail needed to support the evaluation was insufficient. The hope was that additional details regarding specific service delivery would be available from this source. Unfortunately, the existing documentation did not permit evaluators to discriminate between referrals to address needs associated with the water exposure versus referrals to address other pre-existing or concomitant social, physical, or behavioral needs. Thus, in the renewal evaluation we will not assess TCM referrals. Instead, enrollee surveys will provide additional data regarding the TCM benefit in Domain 1. More descriptions of the survey are in (iv), and details of the sampling design and analysis are in section 6) Analytic Methods.

(iii) Michigan Care Improvement Registry (MCIR)

In the renewal evaluation we will use MCIR data to complement the HSDW data to evaluate the participants' immunization status. A recent report showed that vaccine coverage declines among most children at milestone ages in May 2020 compared to previous May estimates (Bramer et al., 2020). We will use future MCIR publications as benchmarks to assess the coverage in enrollees.

(iv) Enrollee, non-enrollees, dis-enrollees, and community partner surveys

In the initial evaluation, we found that Flint community members preferred a web-based survey to the paper- or telephone-based survey. Initially, we adopted a longitudinal survey strategy and followed a random sample of enrollees over a 3-year period. However, the low response rates made longitudinal analyses difficult. In addition, the beneficiaries get in and out of Medicaid frequently (Table 2) and the COVID-19 pandemic will also affect the sampling frames. Thus, in the renewal evaluation, we will conduct repeated cross-sectional surveys each year.

MSU is working with MDHHS to clarify apparent voluntary disenrollment that was identified during the first evaluation cycle. If these patterns are confirmed, the following options will be pursued. To address these potential issues of non-enrollment and disenrollment, we will explore the potential of using Medicaid eligibility data to identify two additional groups for surveys. First, children up to age 21 in Medicaid who have at least one residential ZIP code in the list of Flint water service qualified ZIP codes, but no FME demonstration enrollment will be the basis for non- FME demonstration enrollees. Second, children up to age 21 who had at least one FME demonstration benefit flag in the year prior but do not have the benefit flag in the current evaluation year (e.g., the second row in Table 2 showing individuals who were enrolled for three years but not in year 4) will serve as the basis for FME demonstration disenrollees.

For details for the sampling frame, sampling procedure and analysis plan, see the subsection (iv) in section 6) Analytic Methods.

The focus on operational aspects of the FME demonstration for the impact on enrollment requires input from community partners who are involved with Medicaid eligibility verification and enrollment processes. These community partners will provide information through surveys and key informant interviews on topics such as awareness of revised eligibility for the demonstration and ease of processing enrollments.

(v) Publicly Available Data

American Community Surveys (ACS)

Recent literature on social determinants of health in general and the environmental correlates to elevated blood levels in Flint specifically suggests that social and built environments are important predictors for health outcomes (Sadler et al., 2017). Lacking individual-level data on these factors, we will link enrollees' addresses geocoded to the census tract or census block group level with the ACS to find proxies to the neighborhood socioeconomic backgrounds.

Childhood Opportunity Index (COI)

COI is a multidimensional depiction of the neighborhood beyond the population composition and socioeconomic conditions at the census tract level for 2010 and 2015. It captures "neighborhood resources and conditions that matter for children's healthy development" in a single metric. The index focuses on contemporary features of neighborhoods that are affecting children. It is based on 29 indicators spanning 3 domains: education, health and environment, and social and economic." (*Child Opportunity Index 2.0 Database*, n.d.)

Social Vulnerability Index (SVI)

SVI ranks census tracts on 15 social factors and groups them into four related themes: socioeconomic (income, poverty, employment, education), household composition and disability (age, single parenting, disability), minority status and language (race, ethnicity, English-language proficiency), and housing and transportation (housing structure, crowding, vehicle access). Each census tract receives a ranking for each theme, and an overall ranking within the state (*CDC/ATSDR Social Vulnerability Index 2018 Database Michigan.*, 2021).

County Health Rankings & Roadmaps (CHR&R)

CHR&R "provides data, evidence, guidance, and examples to build awareness of the multiple factors that influence health and support community leaders working to improve health and increase health equity". The Rankings are unique in their ability to measure the health of nearly every county in all 50 states, and are complemented by guidance, tools, and resources designed to accelerate community learning and action" (*How Healthy Is Your County?*, n.d.). The data elements will be used primarily in the first step of the comparison county selection procedure and listed under the "Covariates" section in 6).

Area Deprivation Index (ADI)

Researchers at the University of Wisconsin-Madison created the ADI using ACS (5-year data) at the block group level. It is "composed of 17 education, employment, housing-quality, and poverty measures originally drawn from long-form Census data … updated to incorporate more recent ACS data" (Kind & Buckingham, 2018).

Michigan Medicaid Statewide Weighted HEDIS Measures

Although the Michigan Medicaid summary HEDIS statewide report reflects statewide estimates rather than county level information, these reports will be reviewed to provide additional context to the results obtained through the renewal evaluation. However, the evaluation team is cognizant of the fact that several of the targeted measures reported by the statewide summary are based on hybrid (administrative and medical record review) reporting method by health plans. Hybrid rates are known to exceed administrative rates.

6) *Analytic Methods*

This section describes the identification strategies for the causal effects of interest in Domains 1-3 in the renewal evaluation plan. The analytic strategies depend on the period of comparisons (one year or longitudinal), the type of outcomes (continuous or discrete), the data source (administrative or survey), and the availability of a comparison group. The general hypothesis is driven by the intent of the FME Demonstration and services provided by the TCM. We will focus on the average treatment effect on the treated (ATT), which asks the question: "what would the difference in outcomes be had the FME Demonstration enrollees not participated in the program?" This section is divided into five subsections: subsection (i) describes whether there will be a potential comparison group for each outcome measure, subsection (ii) describes the two-step procedure to select potential comparison groups, subsection (iii) clearly lays out the assumptions and statistical methods that will be employed to identify and estimate the effects of interest, subsection (iv) presents the enrollee, non-enrollee, dis-enrollee survey sampling designs and analysis plans, and subsection (v) discusses potential sensitivity and robustness analyses.

Throughout this section we will refer to the renewal FME Demonstration as the program (first level intervention), the FME Demonstration enrollees as enrollees, the TCM services as the treatment (second level intervention), and the TCM recipients as the participants. Enrollees who do not use the TCM services will be called non-participants and the term non-enrollees will be reserved for beneficiaries who are potentially eligible for the FME Demonstration but do not enroll. The term comparison may refer to either comparison with enrollees or comparison with participants, depending on the context. The comparison group(s) for enrollees will be selected from other counties; and the comparison group(s) for participants will be selected from non-participants.

(i) Availability of Potential Comparison Groups

The causal inference problem is a missing data problem because the outcomes of the enrollees/participants if they had not enrolled in the program or received the treatment are never observable. To estimate the causal effect of any intervention, we must rely on the outcomes of an appropriate comparison group or multiple comparison groups as the counterfactual outcomes of the treated group.

The ideal comparison group should be comprised of individuals who are not exposed to the intervention, are like the enrollees in confounding factors (i.e., determinants of both enrollment and the outcome of interest), observed or unobserved, and "exposed to the same policy environment." (Contreary et al., 2018) However, the environment in Flint is unique due to the water crisis and the FME demonstration is only designed for individuals exposed to the crisis. All other Medicaid programs for children and pregnant women in Michigan have lower income limits (217% for children and 200% for pregnant women), thus the enrollees with income higher than these levels (approximately 5% of all enrollees in the initial FME demonstration period) will not have a natural comparison group.

Other Medicaid children and pregnant women with income higher than that allowed by non-FME demonstration programs may also have access to health care when their medical expenses equal or exceed their deductible (formerly known as spend-down) amount. The spend-down population may be closest to the high income (over 217%) enrollees in the FME demonstration. For the spend-down population we also may be missing some of their healthcare services through other insurance, which could also be true for enrollees. In addition, the initial FME demonstration enrollees whose income was higher than 200% federal poverty level (FPL) accounted for only approximately 5% of the total number of enrollees, and most of the initial FME demonstration enrollees had income levels similar to that of the selected comparison group in the initial evaluation.

Thus, the best strategy to approximate a 'same policy environment' is to first focus on some geographic areas with a larger policy environment like that of Genesee County (whose county seat and largest city is Flint). Genesee County is the 5th most populous county in Michigan, with approximately one-quarter enrolled in Medicaid each year. We chose a two-step procedure to select comparison groups when possible (see below).

Table 3 displays the outcomes of each domain by the availability of potential comparison groups. In general, outcomes measured using claims/encounter data may have a potential comparison group and outcomes assessed through surveys will not have a comparison group. When possible, the overarching criteria for a comparison group include: 1) children up to age 21 or pregnant women, 2) residing in one of the selected comparison counties using the two-step procedure, 3) with estimated propensity scores that overlap with the propensity scores of

the target population, and 4) in the appropriate subgroup of the target population defined by the outcome domain metric.

Table 3. Evaluation outcomes with or without a potential comparison group

Presence of comparison	Domain	Outcomes	Data sources
Yes	1	Age-Appropriate well-child exam	Enrollment and claims
		Age-appropriate developmental screening	Enrollment and claims
		Age-appropriate lead testing and follow-up/retesting	Enrollment, claims and lab tests
		Timely prenatal and postpartum care	Enrollment and claims
		Lead testing during pregnancy	Enrollment, claims and lab tests
		Participation in MIHP	Enrollment and claims
	3	Age-appropriate immunization status	Enrollment, claims and lab tests
		Birth weight	Enrollment, claims and vital records
No	1	Enrollee attestation of access	Survey
		Enrollee satisfaction	Survey
	2	Enrollee attestation of dissemination	Survey
		Community partner awareness	Survey
		Community partner attestation	Survey
	3	Self-reported health status	Survey
		Confidence in chronic disease management	Survey
		Education/behavior outcomes	Survey

(ii) Two-step Procedure for Selecting Comparison Groups

In the renewal evaluation we will continue the use of a pre- and post-period with two-group comparison design for changes of outcomes over time, and a two-group comparison design for cross-sectional outcomes, but the comparison populations in both designs will be refined. Previously, we used all pregnant women and children up to age 21 in Saginaw County as the comparison group. Saginaw County was selected using the K-means method. However, our experience revealed some limitations of this approach (detailed in the publication of an unrelated project) (Strutz et al., 2021). Thus, in the renewal evaluation for outcomes in Table 3 with enrollees as the target population, we will select up to 3 or 4 comparison counties from the Lower Peninsula and use individual- and census tract- or census block group-level data in the selected counties and the enrollees together to estimate propensity scores for enrolling in the FME demonstration. When the target population is the treated population (i.e., utilizing the TCM services) for outcomes in Table 3, we will compare the participants with non-participants estimating another propensity score.

As we outlined in the Evaluation Design section, the two-step procedure is as follows. In the *first* step, we will use 1) the K-means clustering method to select up to 3 or 4 counties in the Lower Peninsula that are like Genesee County in socioeconomic, demographic, and health characteristics; or 2) a synthetic control (SC) method to construct weighted combinations of counties that had similar trends as that of Flint in the outcomes in the period prior to the expansion. In the *second* step, we will obtain the administrative claims data and residential census block group or census tract information for Medicaid children up to age 21 and pregnant women in the selected counties together with the data from the target population to estimate a propensity score (PS) for the likelihood of enrolling in the FME demonstration. The estimated PS will be combined with outcome regressions to estimate the average treatment effect on the treated using double robust estimation methods. For different evaluation hypotheses we will consider different potential covariates (e.g., for age-appropriate immunization outcomes in children we may consider exact matching on age and sex; and for prenatal care measures we may consider matching on previous pregnancy history which can be identified through linked vital records). Below we provide some details of these steps.

The K-means clustering method

This is a common unsupervised learning method that we exploit to find other counties in Michigan like Genesee County in important socioeconomic, demographic, educational, physical environment, and health indicators. Traditionally, the K-means method aims at segregating a population into subgroups (clusters) such that the within cluster variation is minimized. The K-means solution is sensitive to the initial centroids of clusters and the final number of clusters, thus, we take advantage of these properties and use different initial centroids and different number of clusters many times (1,000 in each scenario) and find 3 or 4 counties in the Lower Peninsula that are most often clustered in the same subgroup as Genesee County.

The variables used in the K-means method are the key for success in this selection strategy. Table 4 shows health outcomes, health behavior, clinical care, social economic environment, and physical environment used by the CHR&R to rank counties in the US. We will choose relevant confounding characteristics that may influence the outcome of interest and the presence of potential programs (a total of 48 variables, but subject to change and selection in the renewal evaluation with updated years of data) under the assumption that counties similar in these characteristics as Genesee County will have a similar policy environment (Bradley et al., 2020).

Table 4. County Health Ranking measures and source data used in the initial evaluation*

Health Outcomes		
Measure	**Description**	**Source**
Poor or fair health	Percentage of adults reporting fair or poor health (age-adjusted)	Behavioral Risk Factor Surveillance System
Poor physical health days	Average number of physically unhealthy days reported in past 30 days (age-adjusted)	Behavioral Risk Factor Surveillance System
Poor mental health days	Average number of mentally unhealthy days reported in past 30 days (age-adjusted)	Behavioral Risk Factor Surveillance System
Low birthweight	Percentage of live births with low birthweight (< 2500 grams)	National Center for Health Statistics - Natality files
Infant mortality	Average infant death per 10,000 live births	Health Indicators Warehouse
Frequent physical distress	Percent population experiencing frequent physical distress	Behavioral Risk Factor Surveillance System
Frequent mental distress	Percent population experiencing frequent mental distress	Behavioral Risk Factor Surveillance System
Health Behaviors		
Measure	**Description**	**Source**
Food environment index	Index of factors that contribute to a healthy food environment, 0 (worst) to 10 (best)	USDA Food Environment Atlas, Map the Meal Gap
Teen births	Teen birth rate per 1,000 female population, ages 15-19	National Center for Health Statistics - Natality files
Food insecurity	Percent population with food insecurity	Map the Meal Gap
Access to healthy foods	Percent population with limited access to healthy foods	USDA Food Environment Atlas
Drug induced deaths	Number of deaths induced by drug overdose	Michigan Health Statistics
Insufficient sleep	Percent population with reported insufficient sleep	Behavioral Risk Factor Surveillance System
Clinical Care		
Measure	**Description**	**Source**
Uninsured	Percentage of population under age 65 without health insurance	Small Area Health Insurance Estimates
Primary care physicians	Ratio of population to primary care physicians	Area Health Resource File/American Medical Association

Dentists	Ratio of population to dentists	Area Health Resource File/National Provider Identification file
Uninsured adults	Percentage of population age 18 and above without health insurance	Small Area Health Insurance Estimates
Uninsured children	Percentage of population under age 18 without health insurance	Small Area Health Insurance Estimates
Health care costs	Average health care costs	Dartmouth Atlas of Health Care
Other primary care providers	Ratio of primary care physicians to per 10,000 population	CMS, National Provider Identification file
Social and Economic Environment		
Measure	**Description**	**Source**
High school graduation	Percentage of ninth-grade cohort that graduates in four years	EDFacts
Some college	Percentage of adults ages 25-44 years with some post-secondary education	American Community Survey
Unemployment	Percentage of population ages 16 and older unemployed but seeking work	Bureau of Labor Statistics
Children in poverty	Percentage of children under age 18 in poverty	Small Area Income and Poverty Estimates
Income	Median household income	Small Area Income and Poverty Estimates
Income inequality	Ratio of household income at the 80th percentile to income at the 20th percentile	American Community Survey
Children in single-parent households	Percentage of children that live in a household headed by single parent	American Community Survey
Children eligible for free lunch	Percent of children that are eligible for free lunch or lunch at the reduced price	National Center for Education Statistics
Violent crime	Number of reported violent crime offenses per 100,000 population	Uniform Crime Reporting – FBI and Michigan State Police
Homicide	Number of reported homicides per 100,000 population	CDC (Centers for Disease Control) WONDER mortality data
Property crime	Number of reported property-related crimes per 100,000 population	Uniform Crime Reporting – FBI and Michigan State Police
Physical Environment		
Measure	**Description**	**Source**

Air pollution - particulate matter	Average daily density of fine particulate matter in micrograms per cubic meter (PM2.5)	Environmental Public Health Tracking Network
Drinking water violations	Indicator of the presence of health-related drinking water violations. 1 - indicates the presence of a violation, 0 - indicates no violation	Safe Drinking Water Information System
Severe housing problems	Percentage of households with at least 1 of 4 housing problems: overcrowding, high housing costs, or lack of kitchen or plumbing facilities	Comprehensive Housing Affordability Strategy (CHAS) data
Demographics		
Measure	**Description**	**Source**
Population	Population Sizes	Census Population Estimates
Children	Percent population below 18 years of age	Census Population Estimates
Elderly	Percent population 65 and older	Census Population Estimates
Race-ethnicity	Percent population Non-Hispanic African American	Census Population Estimates
Race-ethnicity	Percent population American Indian and Alaskan Native	Census Population Estimates
Race-ethnicity	Percent population Asian	Census Population Estimates
Race-ethnicity	Percent population Native Hawaiian/Other Pacific Islander	Census Population Estimates
Race-ethnicity	Percent population Hispanic	Census Population Estimates
Race-ethnicity	Percent population non-Hispanic white	Census Population Estimates
Proficient in English	Percent population not proficient in English	American Community Survey
Female	Percent population females	Census Population Estimates
Rural	Percent population in rural areas	Census Population Estimates

* Information taken from County Health Ranking Reports https://www.countyhealthrankings.org

The K-means algorithm is as follows: 1) Randomly assign a number from 1 to K to each county where K is the assumed number of clusters; 2) compute the cluster centroid (defined by the feature means in each cluster) and reassign each county to the cluster whose centroid is closest using, say, the Euclidean distance to itself; and 3) iterate until the cluster assignments stop changing.

One issue of the K-means clustering method is that the resulting assignments depend on the random starting point. The K-means algorithm does not guarantee to lead to global minimum, so the starting points should be varied to examine the end partitioning. The second issue of the K-means algorithm is that sometimes a variable with high variability would dominate the cluster analysis. A common solution is to standardize variables, but there are multiple ways of standardizing variables and standardization could also hide the true groupings in the data (Schaffer & Green, 1996; Steinley, 2006). This is a case-by-case decision depending on the type of data and the nature of the groups. Finally, the optimal choice of the final number of clusters, K, is not always clear.

We will test solutions for 3 to 10 clusters for S iterations (say S=5,000) with randomly selected starting centroid values. We will use scree plots to visualize the curve of the within sum of squares (WSS) or its logarithm for all cluster solutions and a kink in the curve, if present, will be the number K. We will use the GAP statistics to estimate and confirm the optimal number of clusters (Tibshirani et al., 2001). If the scree plot does not produce any obvious kink point, or if the kink point suggested by the scree plot does not agree with the optimal solution based on the Gap statistic, we will use the number of clusters K* that passes the Gap statistic test. We will then generate S random starting values to run the K-means algorithm for K* clusters. Next, we count how many times a county is assigned to the same cluster as Genesee County out of the S iterations. The 3 or 4 counties most often clustered together with Genesee County will be chosen as the comparison counties. We will use the five standardization methods in addition to the z-score to calculate the distances between the selected and Genesee County using the Euclidean, L1, Canberra and 1-correlation distance measures based on the subset of relevant covariates from Table 3. If the majority of the distance measures suggest that the selected counties are closer to Genesee County than unselected counties, then the K means selection will be accepted (Schaffer & Green, 1996).

As an illustration, in the initial evaluation, the Gap statistic based on the z-score standardized features in Table 4 indicated the 68 Lower Peninsula counties were best grouped in 9 clusters. Using the 9-cluster solution, we ran the K-means algorithm with 5,000 random starting values and Saginaw County was clustered within the same group as Genesee County 4,405 times, followed by Muskegon and Calhoun with 4,183 and 4,124 times, respectively. Thus, Saginaw County was the chosen county in the initial evaluation.

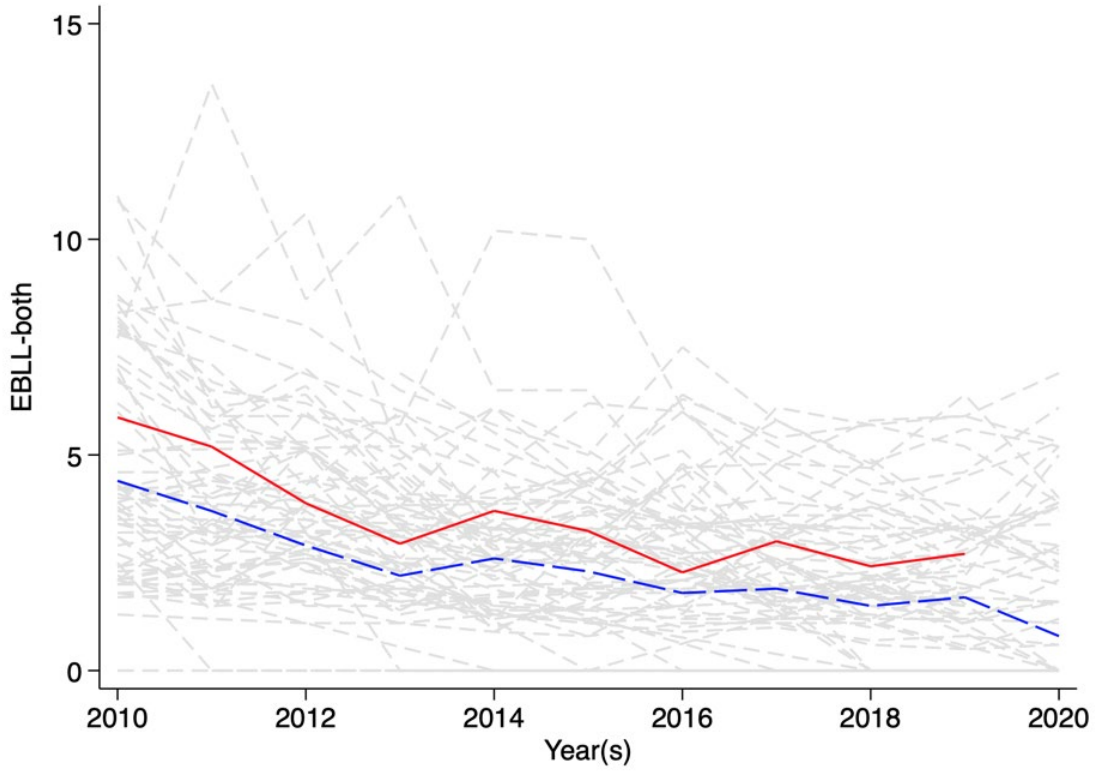
In K-means analyses, if all variables are standardized then clustering based on correlation (similarity) is equivalent to that based on squared distance (dissimilarity). Therefore, as a robustness check, we will run the K-means twice, with and without z score standardization of all features.

The Synthetic Control Method

The second approach the renewal evaluation will consider is the synthetic control (SC) method (Abadie et al., 2010). Since no single county is like Genesee County in all characteristics under consideration, we will explore using a weighted combination of counties as controls. The SC idea is to impute a counterfactual outcome of Genesee as a weighted average of other counties (not including the upper peninsula counties). The weights are computed by minimizing a vector distance between Genesee and other counties over a set of pre-treatment covariates that are predictive of the outcome.

The evaluation has numerous outcomes and the SC method, unlike the K-means method, needs to be conducted separately for each outcome to estimate the weights specific to that outcome. Here we use elevated blood lead levels (EBLL) for illustration. Even though this is not an outcome for the renewal evaluation, it may be informative as to what this approach can and cannot achieve and the required data elements and assumptions for the method to be valid. First, we extracted county-level and ZIP code-level data for the proportion of children < 6 years of age who were tested and had EBLL from 2010 to 2020, using the Michigan Childhood Lead Poisoning Prevention Program (MCLPPP) annual reports and data portal. Figure B shows the EBLL of children in the 11 ZIP code approved by the Flint waiver demonstration (red solid line), Genesee County (blue dashed line), and the rest of the 67 counties in the Lower Peninsula (light gray dashed lines, excluding the city of Detroit). We can see a more pronounced uptick of the trend in Flint than that in Genesee County in 2014.

Figure B. Percent children under age 6 with elevated blood lead level (EBLL) using either capillary or venous test. The red line is for children in Flint and blue dashed line is for children in Genesee County. (Note: The City of Detroit is excluded from the Wayne County data.)



We then use the 2010-2019 variables in Table 4 of the 68 counties in the Lower Peninsula of Michigan to construct an SC county for Flint (Genesee County is removed in this analysis and the county covariates are used for the 11 ZIP codes) using parametric and non-parametric SC methods (Cerulli, 2020). Table 5 shows that in 12 of the specifications of predictors and models, Saginaw was selected 10 times as one of the top 4 counties with the largest weights in the synthetic controls, followed by Wayne (6 times), Jackson (5 times) and St. Clair (5 times), Muskegon (4 times) and Monroe (4 times). Overall, the unstandardized predictors and non-parametric models had smaller biases and smaller root mean-squared prediction error (RMSPE).

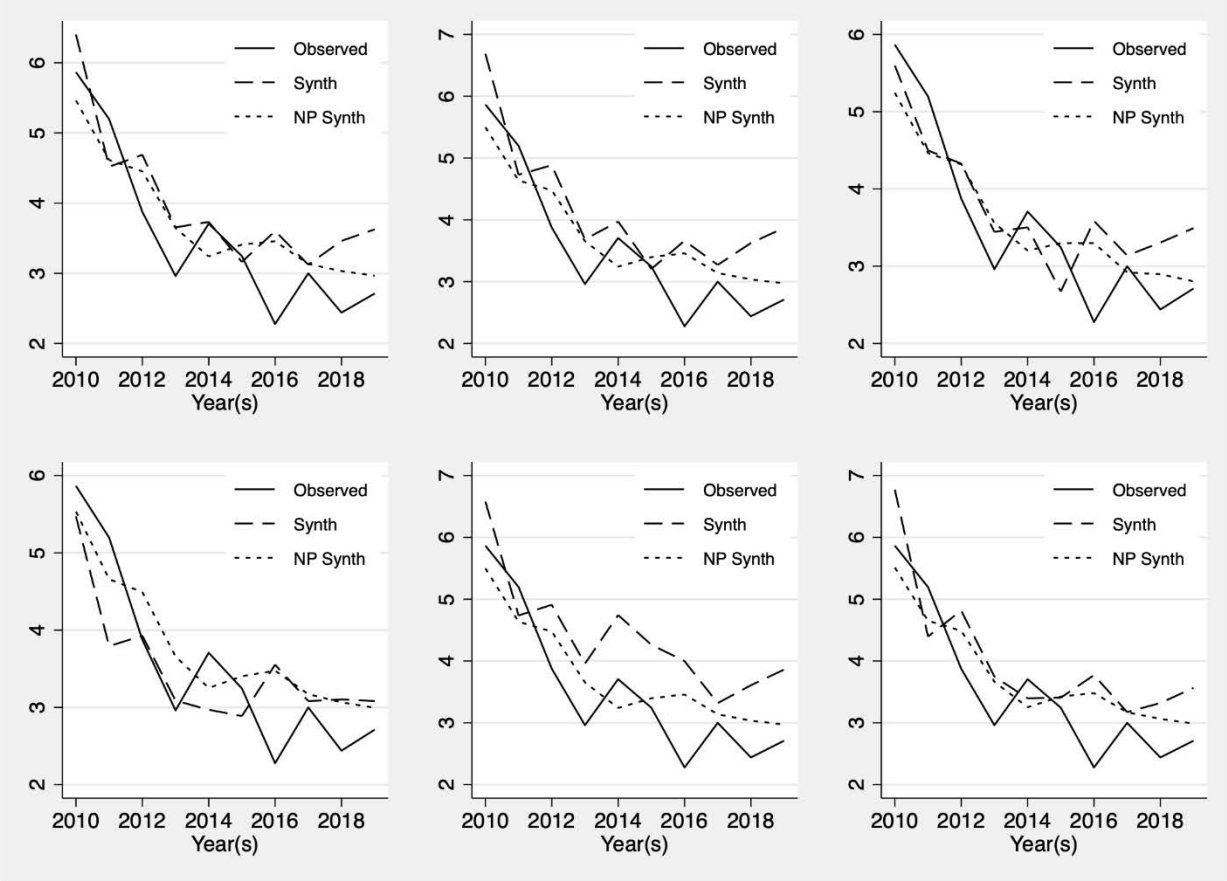
Figure C shows that the specifications in the top row and first column (unstandardized covariates and non-parametric model) tracks the Flint data the best prior to 2016; and all other specifications fall short in some aspect. The selected top counties in the best case are St. Clair, Saginaw, Jackson, and Monroe (row 2 of Table 5).

Table 5. The parametric and non-parametric* synthetic control models' root mean-squared prediction error (RMSPE), 4 counties with the highest weights, and average bias in the pre-treatment period. (Note: Wayne does not include the City of Detroit.)

Predictors***	Model	RMSPE	4 Highest weight counties	Bias in years prior to 2016
$unstd	Parametric	0.745	Saginaw, Wayne, Muskegon, St. Clair	-0.218
	Non-parametric	0.581	St. Clair, Saginaw, Jackson, Monroe	0.005
$std	Parametric	0.851	Saginaw, Muskegon, Wayne**	-0.385
	Non-parametric	0.581	Jackson, Monroe, St. Clair, Saginaw	-0.009
$unstd+$std	Parametric	0.668	Wayne, Muskegon, Cass**	0.135
	Non-parametric	0.548	Ottawa, Livingston, Oakland, Washtenaw	0.128
$unstd-pc10	Parametric	0.709	Wayne, Saginaw, Calhoun, St. Joseph	0.452
	Non-parametric	0.586	Saginaw, Monroe, Calhoun, Jackson	-0.025
$std-pc10	Parametric	1.032	Saginaw, Muskegon, Wayne, Lenawee	-0.724
	Non-parametric	0.581	Jackson, Monroe, St. Clair, Saginaw	-0.009
$unstd+$std-pc10	Parametric	0.828	Saginaw, St. Clair, St. Joseph, Wayne	-0.281
	Non-parametric	0.590	Jackson, Saginaw, Bay, Calhoun	-0.024

*Almost all counties have equal weights.
** Only 3 counties have non-zero weights
*** The list of variables in the unstandardized and standardized covariates are not the same.

Figure C. The parametric and non-parametric synthetic controls compared with the observed trends in Flint. The 6 panels from left to right and top to bottom are based on the following formats: 1) unstandardized variables, 2) standardized variables, 3) all variables, 4) first 10 principal components (PCs) of the unstandardized variables, 5) first 10 PCs of the standardized variables, 6) first 10 PCs of all variables.



The above illustration shows some disadvantages of the SC method. First, the method requires re-calibration of weights for each outcome because different counterfactual weights may be required to construct an SC that is similar in the respective hypothesis to be tested. Summary measures of the outcomes and time-varying covariates that are predictive of each outcome at the county level (and Flint) for each hypothesis many years prior to the FME demonstration expansion will be required. Extracting all the required data from the HSDW will be time-consuming and the predictive power of the covariates in the CHR&R may be weak. This is the main reason for which we prefer to use the K-means method or the nearest-neighbors method to find comparison counties in the first step of the evaluation.

Second, the SC method works best if the outcomes of interest have clear trends over time before and after the intervention. However, many of the outcomes in the renewal evaluation

have stable distribution and there is no compelling evidence of the change in the slope of the trends after the intervention.

Given these limitations, we will consider the SC method only as the secondary approach in selecting comparison counties.

Propensity Score (PS) Estimation Protocol

PS for Enrollment:

Once the comparison counties are selected, we will find children up to age 21 and pregnant women in these counties who meet the criteria in the appropriate subgroups of the target enrollees defined by the outcome measures. Their data will be combined with the data of the target enrollees to estimate a PS for the probability of enrollment in the FME demonstration.

We will use a logistic regression to estimate the PS when the number of covariates is not large as the literature shows that in this case a logistic regression performs as well as some machine learning algorithms (P. Austin et al., 2013). The covariates in the estimation of the PS have been traditionally selected using some statistical variable selection methods that are significant predictors of the intervention. However, more recent literature has shown that doing so may compromise causal effect estimation and inference. In addition, confounding variables should be the ones that can block the biasing pathways (e.g., the backdoor path from the intervention to the outcome), not just predictors of the intervention. Thus, we will not follow the traditional variable selection approach to estimate the PS. Instead, we will focus on examining covariate balance using the weighted standardized differences between enrollees and comparison persons using the inverse probability weighting (IPW) by the PS (P. C. Austin & Stuart, 2015). Note: because we are not using the PS matching estimators, we will not use the usual paired standardized differences to examine balance in covariates. It will be an iterative process until all weighted standardized differences are smaller than 0.1. If for some covariates this cannot be achieved, we will use them in outcome regression adjustment (ORA) to control residual confounding.

PS for Participation:

For hypotheses involving comparing FME demonstration enrollees who used the TCM services (i.e., participants) and FME demonstration enrollees who did not use the service (i.e., non-participants), we will estimate the PS for the probability of utilizing the TCM services with a logistic regression using data from all FME demonstration enrollees in the subpopulations relevant to the hypotheses. The protocol will be the same as the one above.

Covariates for PS and ORA models:

We will use individual-level and census tract- or census block group-level variables relevant to each hypothesis as covariates for the PS and ORA models for the double-robust estimation methods. For example, for age-appropriate well-child exam, we will use children's age, sex, race/ethnicity, and the COI at the census tract level as covariates; and for timely prenatal care, we will use women's age, race/ethnicity, pregnancy history in vital records, comorbidity index constructed using claims data, and the SVI at the census tract level or the ADI at the census block group level as covariates.

(iii) Identification Assumptions and Statistical Methods

The double-robust methods, incorporating both outcome and treatment mechanisms, can minimize the influence of model misspecification and outperform g-formula and IPW methods in both point and confidence interval estimation (Díaz, 2020; Le Borgne et al., 2021; Luque-Fernandez et al., 2018; Schuler & Rose, 2017; Zhong et al., 2021). With the assistance of machine learning techniques, these methods can further mitigate the influence of model misspecification (Kreif & DiazOrdaz, 2019). However, it is important to understand the underlying causal and statistical assumptions needed for these methods. All assumptions (conditional exchangeability for emulating randomization, sequential exchangeability for censoring and compliance, consistency, positivity, and stable unit of treatment value) are inherently untestable (Hernán & Robins, 2020). We will provide potential steps we may take to guard against violations of assumptions.

For the Pre-Post Two-Group (PPTG) Comparison Design:

This design will be used when the effect of interest is the change in outcomes over time. It is essentially the difference in differences (DID) design, which can be implemented using repeated cross sections or panel data, i.e., different individuals over time or the same individuals (Stuart et al., 2014). As Medicaid beneficiaries tend to go in and out of enrollment (churning), we will use repeated cross sections. In the initial evaluation, the critical time periods were May 1, 2013 – April 30, 2014, as 'pre' water switch period (T1), May 1, 2014 – April 30, 2016, as the 'pre' demonstration implementation period (T2), and all subsequent years since the demonstration began in May 2016 as the 'post' implementation period (T3). The two pre-periods, T1 and T2, will be used separately when feasible and the post-period will be the evaluation years. The "treated" population in the pre-periods will include individuals in the Flint area designated by the 11 zip codes and meeting the age restriction or pregnancy condition. We have extracted data from 2013 to 2021 for the initial evaluation. Very recent literature on DID methodologies suggests that having multiple pre-treatment periods may help satisfy the parallel trend assumption crucial to the analysis (Callaway & Sant'Anna, n.d.; Wooldridge, 2021). However, if we use T1 or T2 as the pre-period, we will not be able to take advantage of the multi-year data before the FME Demonstration.

For the Two-Group (TG) Comparison Design:

This design will be used when the effect of interest is the difference between the target population and the comparison population. This design is especially vulnerable to unmeasured confounding. We will perform sensitivity analysis and provide the E-values of the estimates and the confidence limits (VanderWeele & Ding, 2017). For both the PPTG and TG designs, we will appropriately consider the nesting of observations within individuals if present, and the nesting of individuals within clusters (census tract or census block group).

(iv) Enrollee, Non-enrollee, Dis-enrollee Survey Sampling Design and Analysis Plan

For each evaluation period, we will use the first 6-month FME demonstration enrollment data from MDHHS to identify FME demonstration enrollees who had at least one TCM benefit flag to form the sampling frame for the FME demonstration enrollee survey. Previously we used a longitudinal survey design but had poor response rates. In addition, the FME demonstration enrollees displayed the 'churning' phenomenon as in the general Medicaid population (as seen in Table 2). Thus, in the renewal evaluation, we will conduct repeated cross-sectional surveys and each sample will be representative of the FME demonstration enrollees of that year who had at least one month of enrollment (assuming the second 6 months enrollees are similar in characteristics). We will use a stratified (age, race, geography) unequal probability sample and the sample size will be based on 5% margin of error for the key question related to enrollment attestation and satisfaction.

We are interested in exploring the feasibility of surveying FME demonstration non-enrollees. For the non-enrollee survey, we would use the same first 6-month enrollment data from MDHHS to find the "potentially" eligible beneficiaries who 1) were up to age 21, 2) had one residential ZIP code in the list of 11 ZIP codes used by MDHHS to determine eligibility, 3) had no prior enrollment history, and 4) had income level >212%. These individuals would form the sampling frame of the FME demonstration non-enrollee survey. Since we have the age, race/ethnicity, and geographic information for these beneficiaries, we would use the same stratified unequal probability of sampling to select the survey samples and the sample size consideration will be based on the key question related to non-FME demonstration enrollment (e.g., main reason). However, we remain concerned about the traditional Medicaid income limits compromising the ability to identify sufficient individuals.

For the FME Demonstration dis-enrollee survey, we will use the previous year's enrollment data from MDHHS to identify individuals who had enrolled for at least 6 months in that year but had not enrolled in the first 6 months of the current evaluation year, and these individuals will form the sampling frame of the FME demonstration dis-enrollee survey. The sampling design and sample size consideration will be the same as in the two cases above.

For all three surveys, we will use Stata's svy prefixed commands for generalized linear models with proper sampling design features to estimate the parameters of interest.

(v) Potential Sensitivity and Robustness Analyses

Because we will employ double-robust estimation methodologies and not use statistical significance as a criterion to select covariates, we expect some degree of robustness of our statistical estimation. However, as we mentioned above, all observational studies suffer the potential bias for unmeasured confounding and endogenous selection, and we will perform quantitative bias analysis, i.e., sensitivity analysis, in these two categories. First, for binary outcomes, the E-value mentioned above is defined as "the minimum strength of association that an unmeasured confounder would need to have with both the treatment and the outcome to fully explain away a specific treatment-outcome association, conditional on the measured covariates" (VanderWeele & Ding, 2017). A large E-value implies that considerable unmeasured confounding would be needed to explain away an effect estimate. A small E-value implies little unmeasured confounding would be needed to explain away an effect estimate. Second, assessing selection bias is more difficult. We will use a negative-control idea to gauge the potential severity of the selection bias. We will use an outcome measure that is unlikely or assumed to have no reason to be affected by the program or the TCM services, e.g., say, accidental injury, and use the models for the analysis on this outcome. If our modeling strategy is sound and if the negative control outcome is not influenced by the program or the TCM services, then we should see zero treatment effects. On the contrary, if we found significant treatment effect on a negative control outcome, then we may suspect model misspecifications in some stage of our analysis, from selection of comparison sample to propensity score estimation, and to outcome regression modeling. If we find zero effect on the negative outcomes, then we will be more reassured of the evaluation results.

D. Limitations

Limitations associated with the planned evaluation include difficulty identifying individuals who would be eligible for the program at the higher income levels but have not come through the enrollment process. The FME Demonstration enrolled cohort further presents challenges due to missing data after enrollment if the FME demonstration enrollment is secondary coverage. We will attempt to document these participants who have other forms of health care coverage through documentation collected by the state for coordination of benefit processing which may give us additional strata for comparison. To better understand the participation process, we plan to use the survey mechanism and key-informant interviews.

The impacts of the COVID pandemic will continue to be felt during this renewal cycle as a full return to 'normalcy' has not yet been achieved. Nationally, ambulatory care visits dropped approximately 60% in 2020, according to some reports, although visits appeared to have rebounded in 2021 (Mehrotra et al., 2020). Care delivery shifted from an in-person model to one using telemedicine and virtual visits to a much greater degree. However, the key component of the demonstration, i.e., TCM, was not authorized for telemedicine delivery.

Evaluating changes in health care visits is a ripe topic for investigation. We will compare trends observed in our data against state and national estimates as those data become available through literature.

E. Attachments

1) *Independent Evaluator.*
The Michigan State University Institute for Health Policy (MSU-IHP) has been involved with health care quality improvement, program evaluation, and health services research for over two decades. MSU's College of Human Medicine maintains a community campus in Flint, Michigan, with associated clinical practices and faculty who may interact with MDHHS regarding Medicaid policies or reimbursement. The evaluation team at MSU-IHP, however, operates independently of the clinical practices and has no business interest in the expansion of Medicaid and the provision of services to the affected population. Thus, we believe no conflict of interest exists to conducting the evaluation and are willing to provide a "No Conflict of Interest" statement.

With specific regards to the FME demonstration, MSU-IHP was involved with the evaluation conducted on DYs 1-5. We are prepared to leverage the processes and tools that were successful in the first round and have identified lessons learned that will serve to augment the evaluation for the renewal period (DYs 6-10). The evaluation team includes expertise in Medicaid operations and Data Warehouse, Program Evaluation, Biostatistics and Epidemiology, Health Economics, Health Disparities, Nursing, Women and Children's Health, and Geospatial Epidemiology. Current members of the team include:

- Sabrina Ford, PhD, Institute for Health Policy & Department of Obstetrics and Gynecology, College of Human Medicine, MSU
- Nicole Jones, PhD, Division of Public Health, College of Human Medicine, MSU
- Joan Ilardo, PhD, LMSW; Office of Research, College of Human Medicine, MSU
- Zongqiang Liao, PhD, Institute for Health Policy, College of Human Medicine, MSU
- Zhehui Luo, PhD; Department of Epidemiology and Biostatistics, College of Human Medicine, MSU
- Kathleen Oberst, PhD, RN; Institute for Health Policy, College of Human Medicine, MSU
- Richard Sadler, PhD, MPH; Division of Public Health, College of Human Medicine, MSU

2) *Evaluation Budget.*
Budget submitted follows MDHHS fiscal year master agreement timelines. Start date of 01/01/22 reflects project start date in FY23 master agreement amendment. A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will

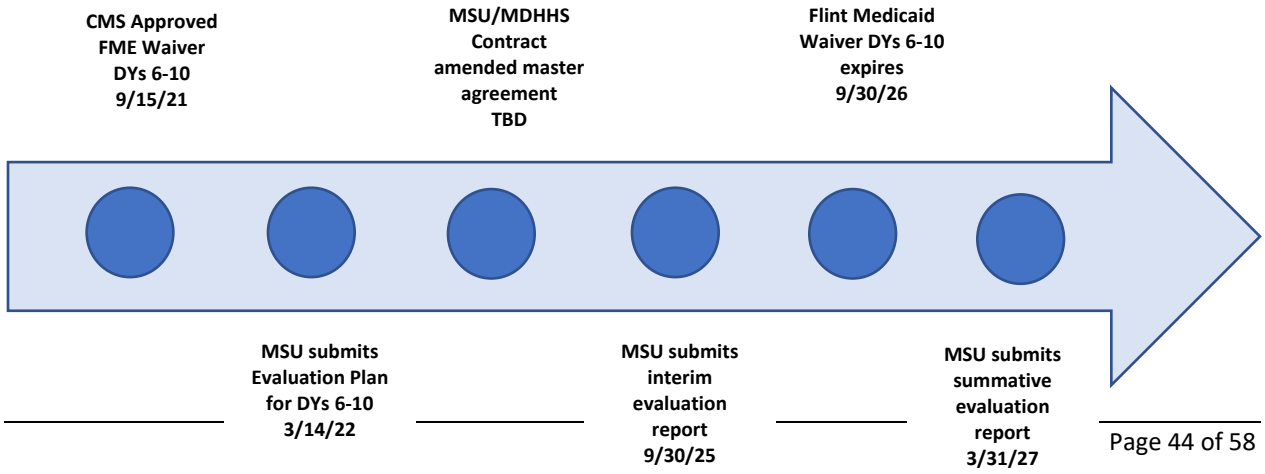
include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed. Refer to Table 6 below.

Table 6. Evaluation Budget

MSU Institute for Health Policy						
Flint Lead Waiver Renewal						
01/01/22-09/30/26						
	Year One	Year Two	Year Three	Year Four	Year Five	TOTAL
Salaries	180,309	245,221	250,125	255,128	260,338	1,191,121
Fringe Benefits	46,149	63,090	66,233	67,838	69,517	312,827
Supplies/Materials	6,200	6,200	6,200	6,200	6,200	31,000
Survey Expense	55,000	60,000	61,736	62,049	75,864	314,649
Graduate Assistant Tuition	24,000	24,720	25,462	26,226	26,226	126,634
Indirect Expense @ 20%	62,332	79,846	81,951	83,488	87,629	395,246
Total Expenses	373,990	479,077	491,707	500,929	525,774	2,371,477

Timeline and Major Milestones

- 9/15/21 - CMS approved Flint Medicaid Waiver DYs 6-10
- 3/14/22 - MSU submits Evaluation Plan for 9/15/21 - 9/30/26 to CMS
- TBD - MSU contract amended to MSU/MDHHS master agreement
- 9/30/25 - MSU submits Interim Evaluation Report
- 9/30/26 - Flint Medicaid Waiver DYs 6-10 expires
- 3/31/27 - MSU submits summative evaluation report



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Sub-hypotheses details for each Domain

Hypothesis 1 is made of 2 subgroups.

- H1.1 focuses on comparing enrollee services to non-enrollees (i.e. comparison group)
- H1.2 focuses on the impact of TCM services on enrollees adhering to recommended care, thus comparing TCM participants to non-participants *among those who are enrolled in the waiver*. The belief is that participants who take advantage of these services are better educated both as to the importance of preventive care and offered direct assistance and support in navigating the health care system. Thus, we repeat the targeted measures from H1.1 with further sub-categorization among all enrollees comparing TCM participants to non-participants. If sufficient data is available, we intend to explore whether a dose-response effect of TCM visits can be identified. Qualitative data from enrollees and TCM professionals will provide context to the findings.

Domain 1: Access to Services							
Hypothesis 1.1: "Enrollees will access services to identify and address physical or behavioral health issues associated with lead exposure at a rate higher non-enrollees with similar individual and neighborhood characteristics over the duration of the demonstration." *Hypothesis 1.2: "Enrollees who participate with TCM services will access medical, social, educational, and other services at a rate higher than enrollees with similar individual and neighborhood characteristics who do not participate with TCM services over the duration of the demonstration."*							
Characteristic	**Detail Description**	**Detail Description**	**Detail Description**	**Detail Description**	**Detail Description**	**Detail Description**	**Detail Description**
Measure Title	Well Child Visits in the First 15 months of Life	Well Child visits in the Third, Fourth, Fifth and Sixth Years of Life	Adolescent Well-Care Visits	Developmental Screening in the First Three Years of Life	Socio-emotional/Behavioral Screening for Children 4-17 years of age	Lead Screening in Children	Follow-up of elevated blood lead level
Measure Description	The percentage of children 15 months old who had the recommended number of well-child visits with a PCP during their first 15 months of life.	The percentage of children 3-6 years of age who had one or more well-child visits with a primary care provider during the measurement year.	The percentage of children/ adolescents 12-21 years of age who had at least one comprehensive well-care visit with a primary care provider or an OB/GYN practitioner during the measurement year.	The percentage of children screened for risk of developmental, behavioral, and social delays using a standardized screening tool in the first three years of life.	The percentage of children/ adolescents 4-17 years of age who had at least one socio-emotional/behavioral screen (CPT 96127) with a primary care provider or an OB/GYN practitioner during the measurement year.	The percentage of children 2 years of age who had 1 or more capillary or venous lead blood test for lead poisoning by their second birthday.	The percentage of children with elevated blood lead levels having retests according to recommended timeframes established by MDHHS Lead Policy.
NQF Number	1392	1516	n/a	1448	n/a	n/a	n/a
Measure Steward	National Committee for Quality Assurance	National Committee for Quality Assurance (Child Core Set)	National Committee for Quality Assurance (Child Core Set)	Oregon Health & Science University	n/a	National Committee for Quality Assurance	Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)-

							CMS/American Academy of Pediatrics
Numerator	This measure has 7 discrete numerators: • # Children who received 0 well-child visits • # Children who received 1 well-child visit • # Children who received 2 well-child visits • # Children who received 3 well-child visits • # Children who received 4 well-child visits • # Children who received 5 well-child visits • # Children who received 6 or more well-child visits	This measure has 1 discrete numerator: • At least one well-child visit with a primary care provider	This measure has 1 discrete numerator: • At least one comprehensive well-care visit with a PCP or an OB/GYN practitioner during the measurement year.	This measure has 4 discrete numerators: • # Children who had screening for risk of development, behavioral and social delays using a standardized screening tool that was documented by their first birthday. • # Children who had screening for risk of development, behavioral and social delays using a standardized screening tool that was documented by their second birthday. • # Children who had screening for risk of development, behavioral and social delays using a standardized screening tool that was documented by their third birthday. • # Children who had screening for risk of development, behavioral and social delays using a standardized screening tool that	This measure has 1 discrete numerator: • At least one socio-emotional/behavioral screen with a PCP or an OB/GYN practitioner during the measurement year.	# of children with at least one lead capillary or venous blood test on or before the child's second birthday.	# of children with elevated blood lead levels having re-testing with specified timeframes.

				was documented by their first, second, or third birthday. (Combination estimate)			
Denominator	Children 15 months old during the measurement period.	This measure has 1 discrete denominator: • Children 3-6 years of age during the measurement period.	This measure has 1 discrete denominator: • Children/ adolescents 12-21 years of age during the measurement period.	This measure has 4 discrete denominators (respectively): • # Children who turn 1 by the end of the measurement period. • # Children who turn 2 by the end of the measurement period. • # Children who turn 3 by the end of the measurement period. • # Children who turn 1 or 2 or 3 by the end of the measurement period.	This measure has 1 discrete denominator: • Children/adolescents 4-17 years of age during the measurement period.	# of children who turn 2 years old during the measurement period.	# of children with elevated blood lead levels during the measurement period.
Baseline Value(s)	DY 1-5 results	DY 1-5 results	DY 1-5 results	DY 1-5 results	DY 1-5 results	DY 1-5 results	DY 1-5 results
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data	No sampling – plan to use 100% available claims/encounter data	No sampling – plan to use 100% available claims/encounter data	No sampling – plan to use 100% available claims/encounter data	No sampling – plan to use 100% available claims/encounter data	No sampling – plan to use 100% available claims/encounter data matched with MCIR and Childhood Lead Prevention Program	No sampling – plan to use 100% available claims/encounter data
Anticipated Data Source	Administrative claims/encounters in the MDHHS data warehouse	Administrative claims/encounters in the MDHHS data warehouse	Administrative claims/encounters in the MDHHS data warehouse	Administrative claims/encounters in the MDHHS data warehouse	Administrative claims/encounters in the MDHHS data warehouse	Administrative claims/encounters, MCIR, and Childhood Lead Screening Data in the MDHHS data warehouse	Administrative claims/encounters in the MDHHS data warehouse linked to state lead

							screening and TCM monitoring data

Domain 1: Access to Services (continued)							
Hypothesis 1.1: "Enrollees will access services to identify and address physical or behavioral health issues associated with lead exposure at a rate higher non-enrollees with similar individual and neighborhood characteristics over the duration of the demonstration." *Hypothesis 1.2: "Enrollees who participate with TCM services will access medical, social, educational, and other services at a rate higher than enrollees with similar individual and neighborhood characteristics who do not participate with TCM services over the duration of the demonstration."*							
Characteristic	**Detail Description**	**Detail Description**	**Detail Description**	**Detail Description**	**Detail Description**	**Detail Description**	**Detail Description**
Measure Title	Timeliness of Prenatal Care	Postpartum Care	Lead screening in pregnancy	MIHP Participation	Enrollee Attestation for Improved Access to Care	Enrollee satisfaction with Medicaid expansion coverage	Evaluation of potential lead exposure in home
Measure Description	Percentage of Medicaid live birth deliveries between February 4 of the year prior to the measurement period and February 3 of the measurement period	The percentage of deliveries that had a postpartum visit on or between 21 and 56 days after delivery.	The percentage of pregnant women screened for elevated blood lead levels during pregnancy.	The percentage of deliveries participating with the Maternal Infant Health Program.	Surveyed enrollees will agree or strongly agree with a statement acknowledging the Medicaid program as one method for improving access to health care.	Surveyed enrollees ranking of their health care coverage using 0-10 scale (0=worst health care possible, 10=best health care possible)	Surveyed enrollees reporting accessing lead evaluation service offered through TCM
NQF Number	1517	1517	n/a	n/a	n/a	--	n/a
Measure Steward	National Committee for Quality Assurance	National Committee for Quality Assurance	American Congress of Obstetricians and Gynecologists	n/a	Agency for Healthcare Research and Quality – Consumer Assessment of Healthcare Providers and Systems (AHRQ-CAHPS) Question Modification	AHRQ CAHPS Question Modification	n/a
Numerator	Percentage of deliveries that received a prenatal care visit as a patient in the first trimester or within 42 days of enrollment.	Percentage of deliveries that had a postpartum visit on or between 21 and 56 days after delivery.	Percentage of deliveries that received 1 or more capillary or venous lead blood test during pregnancy.	Percentage of deliveries receiving 1 or more visit with MIHP during pregnancy or after birth.	Number of respondents who report they "agree "or "strongly agree" with a statement about Medicaid improving health care access. *Sample questions:* "In the last 6 months, how often was it easy to get the care, tests, or	Mean of health care scores provided by survey enrollees. *Sample question:* "Using any number from 0 to 10, where 0 is the	Proportion of households evaluated for potential lead exposure provided by survey enrollees.

					treatment you needed?" (never/sometimes/usually/always) "Overall, enrolling in the Medicaid expansion made it easier to get the health care that I needed" (strongly agree to strongly disagree)	worst health care possible and 10 is the best health care possible, what number would you use to rate all your health care"	
Denominator	Medicaid deliveries of live births between February 4 of the year prior to the measurement period and February 3 of the measurement period.	Medicaid live birth deliveries between February 4 of the year prior to the measurement period and February 3 of the measurement period.	Medicaid live birth deliveries between February 4 of the year prior to the measurement period and February 3 of the measurement period.	Medicaid deliveries of live births between February 4 of the year prior to the measurement period and February 3 of the measurement period.	Number of survey participants.	Number of survey participants.	Number of survey participants.
Baseline Value(s)	DY 1-5 results	DY 1-5 results	DY 1-5 results	DY 1-5 results	DY 1-5 results	DY 1-5 results	n/a
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data	No sampling – plan to use 100% available claims/encounter data	No sampling – plan to use 100% available claims/encounter data	No sampling – plan to use 100% available claims/encounter data	Random/weighted sampling	Random/weighted sampling	Random/weighted sampling
Anticipated Data Source	Administrative claims/encounters in the MDHHS data warehouse linked to Vital Records	Administrative claims/encounters in the MDHHS data warehouse linked to Vital Records	Administrative claims/encounters in the MDHHS data warehouse linked to Vital Records data	Administrative claims/encounters in the MDHHS data warehouse linked to MIHP visit and TCM Monitoring data	Enrollee survey	Enrollee survey	Enrollee survey

Domain 2: Expand Medicaid Eligibility			
Hypothesis 2: "The proportion of new enrollees between 212-400% FPL will increase over the duration of the demonstration representing an increase in the proportion of individuals having health care coverage."			
Characteristic	**Detail Description**	**Detail Description**	**Detail Description**
Measure Title	Enrollee attestation to demonstration leading to enrollment	Community partner awareness	Community partner attestation
Measure Description	Surveyed enrollees will agree or strongly agree with a statement acknowledging the waiver implementation provided information leading to enrollment.	Interviewed community partners … will agree or strongly agree with a statement acknowledging waiver eligibility, increased income limits, elimination of cost-sharing.	Interviewed community partners … will agree or strongly agree with a statement acknowledging that process to enroll individuals in the Flint Waiver is easy, they have contacts available if there are questions, the process is sufficiently automated for timely enrollment
NQF Number	n/a	n/a	n/a
Measure Steward	Agency for Healthcare Research and Quality – Consumer Assessment of Healthcare Providers and Systems (AHRQ-CAHPS) Question Modification	n/a	n/a
Numerator	Number of respondents who report they "agree" or "strongly agree" with the statement. *Sample questions:* I received information about the Flint Medicaid Waiver that told me how to find out if I qualify. The information I received about the Flint Medicaid Waiver was helpful to let me know that I could qualify for Medicaid. The information I received about the Flint Medicaid Waiver told me about special benefits only available to people enrolled in the waiver. The information I received about the Flint Medicaid Waiver told me about extra help that was available to help me get needed services.	Number of partners knowledgeable Sample questions: I/my agency received information about the Flint Medicaid Waiver eligibility guidelines. I/my agency received information about cost-sharing elimination so that I could inform potential enrollees.	Number of partners reporting positive experience with enrollment process Sample question: The information I/my agency received about the Flint Medicaid Waiver was helpful to understand the mechanisms to check eligibility and enroll new members, I am able to use existing systems with helpful prompts to check potential eligibility and enroll new individuals,
Denominator	Number of survey participants.	Number of partners interviewed	Number of partners interviewed
Baseline Value(s)	--	--	--
Sampling Methodology	Random/weighted sampling	n/a	n/a

Anticipated Data Source	Enrollee survey		Key informant interviews/surveys with Targeted partners		Key informant interviews/surveys with Targeted partners		
Domain 3: Improved Health Outcomes							
Hypothesis 3: "Enrollees will have improved health outcomes compared to non-enrollees with similar individual and neighborhood characteristics over the duration of the demonstration."							
Characteristic	**Detail Description**	**Detail Description**	**Detail Description**	**Detail Description**	**Detail Description**	**Detail Description**	**Detail Description**
Measure Title	Childhood Immunization Status	Immunizations for Adolescents	Low Birth Weight Rate	Enrollee Self-Reported Health Status	Enrollee Self-Reported Confidence of Chronic Condition Management	Enrollee Self-Report Cognitive and Education Status	Childhood Independent Educational Plan (IEP)
Measure Description	Percentage of children 2 years of age who had 4 diphtheria, tetanus and acellular pertussis (Tdap), polio (IPV); one measles, mumps and rubella (MMR); three H influenza type B (HiB): three hepatitis B (HepB); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (HepA); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	Percentage of adolescents 13 years of age who had the recommended immunizations (meningococcal vaccine and one tetanus, diphtheria toxoids and acellular pertussis vaccine (Tdap) or one tetanus, diphtheria toxoids vaccine (Td))) by their 13th birthday.	Low birth weight (<2500 gram) infants per 1,000 newborns (excluding transfers)	Surveyed enrollees' self-evaluation for overall health status.	Surveyed enrollees' self-evaluation for managing chronic conditions	Surveyed enrollees' self-evaluation of childhood educational delays.	MI Schools Dashboard school counts of IEP
NQF Number	0038	1407	0278	--	--	--	--
Measure Steward	National Committee for Quality Assurance	National Committee for Quality Assurance	Agency for Healthcare Research & Quality	AHRQ CAHPS/BRFSS Question Modification	--	--	State of Michigan Department of Education
Numerator	# children who received the recommended vaccines by their second birthday. Separate rates calculated for each	# adolescents 13 years of age who had one dose of meningococcal vaccine and one tetanus, diphtheria	# of newborns, among cases meeting inclusion/exclusion rules for the denominator, with	Number of respondents participating with at least 2 survey waves who have an increase in the level of self-	Number of respondents participating with at least 2 survey waves who report increase in confidence in managing chronic conditions.	Number of respondents participating in at least 2 survey waves who report childhood	Number of students who have official IEP for each age group.

	vaccine as well as 9 separate combination rates.	toxoids and acellular pertussis vaccine (Tdap) or one tetanus, diphtheria toxoids vaccine (Td) by their 13th birthday.	any-listed ICD-9-CM (ICD-10) diagnosis codes for birth weight less than 2,500 grams.	reported health status. *Sample questions:* "In general, how would you rate your overall health?" (excellent/very good/good/fair/poor) "In general, how would you rate your overall mental or emotional health?" (excellent/very good/good/fair/poor)	*Sample Tools:* Adult/Pediatric Asthma Control Test	cognitive and educational delays.	
Denominator	# children who turn 2 years of age during the measurement period.	# adolescents who turn 13 years of age during the measurement period.	# of newborns in region	Number of survey participants.	Number of survey participants.	Number of survey participants	Number of student counts for Flint City Schools
Baseline Value(s)	DY 1-5	DY 1-5	DY 1-5	DY 1-5	DY 1-5	DY 1-5	DY 1-5
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data	No sampling – plan to use 100% available claims/encounter data	No sampling – plan to use 100% available claims/encounter data	Random/weighted sampling	Random/weighted sampling	Random/weighted sampling	No sampling - plan to use 100% available student counts for Flint City Schools
Anticipated Data Source	Administrative claims/encounters in the MDHHS data warehouse	Administrative claims/encounters in the MDHHS data warehouse	Administrative claims/encounters in the MDHHS data warehouse linked to Vital Records	Enrollee survey responses	Enrollee survey responses	Enrollee survey responses	MI Schools Dashboard

STATE OF MICHIGAN
OFFICE OF THE GOVERNOR
LANSING

GRETCHEN WHITMER
GOVERNOR

GARLIN GILCHRIST II
LT. GOVERNOR

April 30, 2020

Ms. Seema Verma
Administrator
U.S. Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Verma,

The State of Michigan hereby submits a demonstration application, pursuant to Section 1115 of the Social Security Act, to extend the Flint Michigan Section 1115 Demonstration for a period of 10 years.

The waiver request includes: (1) expansion of Medicaid and Children's Health Insurance Program eligibility for select individuals (i.e. children up to age 21 and pregnant women) in the impacted area; (2) coordinating comprehensive benefits and resources through the provision of Targeted Case Management services; and (3) providing a mechanism for expanded lead abatement activities in the impacted area. Approval of this demonstration extension will continue providing access to health care, case management and other supportive services, and is necessary to minimize and further prevent any long-term adverse health effects associated with lead exposure.

We appreciate the assistance the Centers for Medicare & Medicaid Services have already provided and look forward to working together to achieve our mutual goal of improving the health and well-being of Michiganders.

Sincerely,

[redacted]

Gretchen Whitmer
Governor

Cc: James Scott
Thomas Long
Kimberly Beniquez
Nicole McKnight
Keri Toback

Michigan Application Certification Statement - Section 1115(a) Extension

This document, together with the supporting documentation outlined below, constitutes Michigan's application to the Centers for Medicare & Medicaid Services (CMS) to extend the Flint Michigan Section 1115 Demonstration (Project Number 11-W-00302/5) for a period of 10 years pursuant to section 1115(a) of the Social Security Act.

Type of Request (*select one only*):

___**X**____ **Section 1115(a) extension <u>with no</u> program changes**

This constitutes the state's application to the Centers for Medicare & Medicaid Services (CMS) to extend its demonstration without any programmatic changes. The state is requesting to extend approval of the demonstration subject to the same Special Terms and Conditions (STCs), waivers, and expenditure authorities currently in effect for the period of 2016-2021.

The state is submitting the following items that are necessary to ensure that the demonstration is operating in accordance with the objectives of title XIX and/or title XXI as originally approved. The state's application will only be considered complete for purposes of initiating federal review and federal-level public notice when the state provides the information as requested in the below appendices.

- **Appendix A:** A historical narrative summary of the demonstration project, which includes the objectives set forth at the time the demonstration was approved, evidence of how these objectives have or have not been met, and the future goals of the program.
- **Appendix B:** Budget/allotment neutrality assessment, and projections for the projected extension period. The state will present an analysis of budget/allotment neutrality for the current demonstration approval period, including status of budget/allotment neutrality to date based on the most recent expenditure and member month data, and projections through the end of the current approval that incorporate the latest data. CMS will also review the state's Medicaid and State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) expenditure reports to ensure that the demonstration has not exceeded the federal expenditure limits established for the demonstration. The state's actual expenditures incurred over the period from initial approval through the current expiration date, together with the projected costs for the requested extension period, must comply with CMS budget/allotment neutrality requirements outlined in the STCs.
- **Appendix C:** Interim evaluation of the overall impact of the demonstration that includes evaluation activities and findings to date, in addition to plans for evaluation activities over the requested extension period. The interim evaluation should provide CMS with a clear analysis of the state's achievement in obtaining the outcomes expected as a direct effect of the demonstration program. The state's interim evaluation must meet all of the requirements outlined in the STCs.
- **Appendix D:** Summaries of External Quality Review Organization (EQRO) reports, managed care organization and state quality assurance monitoring, and

any other documentation of the quality of and access to care provided under the demonstration.

- **Appendix E:** Documentation of the state's compliance with the public notice process set forth in 42 CFR 431.408 and 431.420.

_____ **Section 1115(a) extension <u>with</u> minor program changes**

This constitutes the state's application to the Centers for Medicare & Medicaid Services (CMS) to extend its demonstration with minor demonstration program changes. In combination with completing the Section 1115 Extension Template, the state may also choose to submit a redline version of its approved Special Terms and Conditions (STCs) to identify how it proposes to revise its demonstration agreement with CMS.

With the exception of the proposed changes outlined in this application, the state is requesting CMS to extend approval of the demonstration subject to the same STCs, waivers, and expenditure authorities currently in effect for the period [insert current demo period].

The state's application will only be considered complete for purposes of initiating federal review and federal-level public notice when the state provides the information requested in Appendices A through E above, along with the Section 1115 Extension Template identifying the program changes being requested for the extension period. Please list all enclosures that accompany this document constituting the state's whole submission.

1. Section 1115 Extension Template
2. Cover letter
3. Application
4. Consultation summary
5. 10-year projections
6. Public notice (short)
7. Public notice (full)
8. Tribal notice
9. Interim evaluation

The state attests that it has abided by all provisions of the approved STCs and will continuously operate the demonstration in accordance with the requirements outlined in the STCs.

Signature: [redacted] **Date:** <u>April 30, 2020 (4:22pm)</u>

[Governor]

CMS will notify the state no later than 15 days of submitting its application of whether we determine the state's application meets the requirements for a streamlined federal review. The state will have an opportunity to modify its application submission if CMS determines it does not meet these requirements. If CMS reviews the state's submission and determines that any proposed changes significantly alter the original objectives and goals of the existing demonstration as approved, CMS has the discretion to process this application full scope pursuant to regular statutory timeframes for an extension or as an application for a new demonstration.

History, Purpose, Goals, and Objectives

History

In 2016, the Centers for Medicare & Medicaid Services (CMS) approved Michigan's application to establish a five-year Medicaid demonstration entitled "Flint Michigan Section 1115 Demonstration," (Project Number 11-W-00302/5) in response to the public health emergency of lead exposure related to the Flint water system. Implementation of the waiver expanded coverage to low-income children up to age 21 years and pregnant women served by the Flint water system during a state-specified time period and who would not be otherwise eligible for Medicaid. This population included children in households with incomes from 212 percent of the federal poverty level (FPL) up to and including 400 percent of FPL and pregnant women in households with incomes from 195 percent of FPL up to and including 400 percent of the FPL.

The demonstration population received care primarily through Medicaid managed care plans and receives all state plan benefits including, for children, Early and Periodic Screening, Diagnostic, and Treatment (EPSDT). Individuals receiving benefits under the demonstration are exempt from cost sharing and premiums. Targeted Case Management (TCM) services and home lead investigation services are available to children and pregnant women serviced by the Flint water system during the defined period who have been determined eligible for Medicaid.

Goals Met

The demonstration has successfully promoted the objectives of Medicaid and helped achieve the state's initial goals by improving access to services, expanding Medicaid eligibility, and creating better health outcomes.

Consistent with the approved waiver, the MDHHS provided eligibility protocol that expanded eligibility to any pregnant woman or child up to age 21 with a household income up to and including 400 percent of the Federal Poverty Level (FPL) served by the Flint water system during the specified time period. Eligibility also applies to any children born to a pregnant woman during the specified time period. Exemptions from premiums are granted to families with children under age 19 covered by MIChild and those subject to premiums and cost sharing under Michigan's Freedom to Work program, provided their income is below 400 percent of FPL.[1] As of February 2019, a total of 40,943 cumulative pregnant women and children have been enrolled in the program.[2]

The program also added TCM services as part of the comprehensive benefits available to pregnant women and children served by the Flint water system. TCM services include:

[1] MSA 16-11

[2] For reporting purposes, children are defined as individuals under the age of 21 and pregnant women are identified using indicators in the Michigan Department of Health and Human Services' data warehouse. To avoid any duplication, pregnant women are excluded from the children enrollment group.

- Face-to-face comprehensive assessment, history, reassessment, and identification of a course of action to determine the specific needs of a beneficiary and develop an individual plan of care
- Planning, linking, coordinating, follow-up, and monitoring to assist the beneficiary in gaining access to services
- Coordination with the beneficiary's primary care provider, other providers, and Medicaid Health Plans as applicable

TCM services are available to all eligible beneficiaries up to age 21 and pregnant women up to 60 days post-delivery.[3] As of February 2019, 90 percent of cumulative enrollees had utilized the services of a primary care provider, for a total of 112,106 primary care provider visits, and a cumulative 621 enrollees were actively receiving ongoing TCM services since the start of the program.

Enrollment

Enrollment into the Flint Medicaid wavier program began on May 9, 2016. The Michigan Department of Health and Human Services (MDHHS) used an electronic administrative renewal process to annually redetermine eligibility, based on verification of income and residency, in order to facilitate enrollment and retention.

Demonstration enrollment activity is detailed in this section of the extension application. Enrollment data was derived from the MDHHS Data Warehouse. For reporting purposes, the Children enrollment group is defined as demonstration enrollees under the age of 21. Pregnant women are identified using pregnancy indicators in the MDHHS Data Warehouse. To avoid duplication, pregnant women are excluded from the Children enrollment group. Demonstration years in the following tables are aligned with the definition for demonstration years in the demonstration special terms and conditions (i.e. demonstration year 1 spans March 1, 2016 – February 28, 2017). Since the following data was retrieved in late January 2020, enrollment for demonstration year 4 is not complete.

The following table shows an unduplicated aggregate count of beneficiaries enrolled in Medicaid or CHIP for each year of the current demonstration approval period. The Children and Pregnant Women enrollment groups are a subset of the total Medicaid/CHIP population. For this reason, adding these two enrollment groups together will not add up to the total Medicaid/CHIP population. The Cumulative Enrollment row shows the total distinct number of Medicaid/CHIP enrollees over the demonstration period.

Medicaid/CHIP Enrollment by Demonstration Year			
Demonstration Year	**Enrollment Group**		**Total Medicaid/CHIP Enrollment**
	Children	**Pregnant Women**	
1	1,265,574	117,935	2,898,870
2	1,255,784	113,813	2,912,025

[3] MSA 16-10

3	1,246,670	108,516	2,893,218
4	1,213,802	100,594	2,810,810
Cumulative Enrollment	1,625,601	243,859	3,763,368

The following table shows an unduplicated aggregate count of beneficiaries whose coverage is affected by the demonstration for each year of the current demonstration approval period. The Cumulative Enrollment row shows the total distinct number of Flint waiver enrollees over the demonstration period.

Flint Demonstration Enrollment by Demonstration Year			
Demonstration Year	**Enrollment Group**		**Total Flint Demonstration Enrollment**
	Children	**Pregnant Women**	
1	29,985	1,813	31,798
2	32,990	1,735	34,725
3	31,047	1,254	32,301
4	29,681	1,195	30,876
Cumulative Enrollment	39,375	4,046	43,421

The following table shows an unduplicated aggregate count of the beneficiaries who were disenrolled for any period by demonstration year. The Cumulative Disenrollment row shows the distinct number of individuals that disenrolled from the Flint waiver over the course of the demonstration period.

Flint Demonstration Disenrollment by Demonstration Year			
Demonstration Year	**Enrollment Group**		**Total Flint Demonstration Disenrollment**
	Children	**Pregnant Women**	
1	6,223	1,103	7,326
2	8,310	3,629	11,939
3	7,168	927	8,095
4	7,540	862	8,402
Cumulative Disenrollment	23,029	3,975	27,004

Building on Success

The Flint Medicaid waiver will build on success already achieved by first preserving coverage for the thousands of beneficiaries enrolled. There has also been a steady increase in developmental and behavioral screenings, indicating an opportunity for further improving access and awareness. As the full impact of lead exposure and subsequent healthcare needs become more visible in the population, the number of individuals seeking assistance will continue to

grow. Further, as trust in state institutions and operations is slowly regained, participation can grow as well. Based on this, the state does not plan to change its program administration.

A projection of the program's impact shows continued enrollment of full-coverage and TCM-only beneficiaries into 2029, with the overall number of individuals receiving full-coverage rising steadily. A detailed 5-year projection and explanation of limitations is discussed in the section related to fiscal impact. The full 10-year projection of expenditures and enrollment by demonstration year is attached.

Building on Core Objectives

Extending the Flint Waiver will continue promoting core objectives of the Medicaid program, including improved access to care and health outcomes for beneficiaries. The waiver has already improved access for many, as shown by the clear increase in blood lead tests for children, increase in blood lead screenings for pregnant women, and consistently high level of access for prenatal care. A majority of beneficiaries also reported that the waiver made it easier to get the care they needed, or access care for a child.

Improved healthcare outcomes have also been realized since implementation of the waiver, with a majority reporting themselves to be in good health overall since enrolling and very few reporting poor physical health.

Implementation

Expenditure Authority

Michigan is requesting the same authorities as those approved in the current demonstration for the same purpose, as approved for the requested extension period. Specifically, MDHHS seeks the continuation of the following waivers of state plan requirements contained in §1902 of the Social Security Act, subject to the Special Terms & Conditions for the FME §1115 Demonstration:

- *Provision of Medical Assistance §1902(a)(8); 1902(a)(10)* – To the extent necessary to permit the state to limit the provision of medical assistance (and treatment as eligible) for individuals described in the eligibility group under 1902(a)(10)(A)(ii)(XX) and the state plan, to children up to age 21 and pregnant women who were served by the Flint water system at any time from April 2014 to the state-specified date, including any child bonito a pregnant woman served by the Flint water system from April 2014 to the state-specified date. For this purpose, an individual was served by the Flint water system if, for more than one day, the individual consumed water drawn from the Flint water system and: 1) resided in a dwelling connected to this system; 2) had employment at a location served by this system; or, 3) received child care or education at a location connected to this system.
- *Comparability §1902(a)(17) or § 1902(a)(10)(B)* – To the extent necessary to enable the state to not charge premiums to individuals who resided in the area served by the Flint water system from April 2014 up to the date specified in accordance with paragraph"l8 of the special terms and conditions (STCs). Also, to the extent necessary to enable the state

to provide evaluation of potential lead exposure in the home only for individual~ who meet these nonfinancial criteria.

- *Freedom of Choice §1902(a)(23*) – To the extent necessary to enable the state to restrict freedom of choice of provider for children and pregnant women with respect to targeted case management and evaluation of potential lead exposure in the home. Also, to the extent necessary to enable the state to limit beneficiary choice of providers for beneficiaries enrolled in a Managed Care Entity (MCE) and a Prepaid Inpatient Health Plan (PIHP) under the demonstration to those providers that are within the MCE and PIHP networks. No waiver of freedom of choice is authorized for family planning providers.

Additionally, MDHHS seeks the continuation of the CMS-approved expenditure authority that enables Michigan to implement the Flint Medicaid Section 1115 demonstration:

- Expenditures for evaluation of potential lead exposure in the homes of eligible children under age 21 and eligible pregnant women who resided in the area served by the Flint water system between April 2014 and the date specified in accordance with paragraph 18 of the Special Terms and Conditions, without regard to whether there has been documentation of an elevated blood lead level of an eligible household member.

Quality Assessment Process

Michigan assesses quality, accessibility, and efficiency for the Flint Waiver from both a broad and narrow perspective. MDHHS annually conducts a statewide assessment of its managed care delivery systems by working with the state's 11 contracted Medicaid Health Plans (MHPs) to facilitate valid reporting of the Healthcare Effectiveness Data and Information Set (HEDIS) measures. Two HEDIS measures, "Child & Adolescent Care" and "Pregnancy Care," match the Flint Waiver's extended eligibility categories. Measures in access and utilization also help evaluate the overall delivery of care in Michigan. In addition, the state conducts monthly evaluations, quarterly reports, and annual reviews of enrollment, changes in enrollment status, service utilization, and other measures. These evaluations are key to measuring access to services and targeted case management.

Quality Assessment Summary

Internal reviews of enrollment and the interim assessment conducted by Michigan State University indicate increased enrollment, service utilization, and health outcomes. As of 2020, 43,421 cumulative pregnant women and children have been enrolled in the program.[4] The program also added TCM services as part of the comprehensive benefits available to pregnant women and children served by the Flint water system. TCM services include:

[4] For reporting purposes, children are defined as individuals under the age of 21 and pregnant women are identified using indicators in the Michigan Department of Health and Human Services' data warehouse. To avoid any duplication, pregnant women are excluded from the children enrollment group.

- Face-to-face comprehensive assessment, history, reassessment, and identification of a course of action to determine the specific needs of a beneficiary and develop an individual plan of care
- Planning, linking, coordinating, follow-up, and monitoring to assist the beneficiary in gaining access to services
- Coordination with the beneficiary's primary care provider, other providers, and Medicaid Health Plans as applicable

TCM services are available to all eligible beneficiaries up to age 21 and pregnant women up to 60 days post-delivery.[5] As of February 2019, 90 percent of cumulative enrollees had utilized the services of a primary care provider, for a total of 112,106 primary care provider visits, and a cumulative 621 enrollees were actively receiving ongoing TCM services since the start of the program.

External quality reviews of the state's Medicaid Health Plans (MHP) show improvements to quality of and access to care. MHP performance levels for child and adolescent care ranked above national averages, with significant growth in terms of adolescent well-care visits. Lead screening in children under the age of 2 years old increased from 79.55 percent in 2016 to 80.55 percent in 2018. Testing rates for five of the six MHPs serving Flint's county of Genesee ranged from 76.64 percent to 85.16 percent.[6] Similarly, performance measures showed an increase in the percentage of deliveries that received a prenatal care visit in the first trimester or within 42 days of joining an MHP rose from 78.63 percent in 2016 to 80.23 percent in 2018.

Changes to Quality Assessment

The state intends to maintain its current quality assurance monitoring program.

Costs, Fiscal Impact, and Funding Sources

Member Months and Expenditures

In order to report on past enrollment and expenditures, as well as make projections, the population is separated into two groups: "Full Coverage" beneficiaries and "TCM-Only" beneficiaries. "Full Coverage" beneficiaries are defined as all individuals under 21 years of age and pregnant women (of any age) under 400 percent federal poverty level (FPL) but higher than the FPL for their enrollment category (between 212 and 400 FPL for children under 20, between 133 and 400 for those age 20, and between 195 and 400 for pregnant women). "TCM-Only" beneficiaries are defined as all individuals that were Medicaid-eligible prior to the waiver but receive the additional targeted case management (TCM) services as a result of the demonstration.

Again, demonstration years in the following tables are aligned with the definition for demonstration years in the demonstration special terms and conditions (i.e. demonstration year 1

[5] MSA 16-10

[6] Although it follow the specifications, HAP Empowered was not included because the plan's population in Genesee county was too small (<30) to report a valid rate.

spans March 1, 2016 – February 28, 2017). Since the following data was retrieved in late January 2020, enrollment for demonstration year 4 is not complete.

	DY 2016	DY 2017	DY 2018	DY 2019
Total Member Months	**220,725**	**341,171**	**325,798**	**312,804**
TCM-Only Benes	215,908	332,516	315,998	302,506
Full Coverage Benes	4,817	8,655	9,800	10,298
Total Utilization	**$1,520,887**	**$3,221,038**	**$3,730,902**	**$3,863,461**
TCM-Only Benes	$650,859	$1,646,424	$1,952,738	$2,078,898
Full Coverage Benes	$870,028	$1,574,615	$1,778,164	$1,784,563

Enrollment and Expenditure Projections

Projecting the next five years of cost associated with the waiver entails population projection followed by utilization. Historic enrollment and costs were analyzed for the two enrollment groups. A “per member per month” (PMPM) cost was then calculated for each group, with trends applied to estimate the future costs. This PMPM was then multiplied by the member months expected by year for the two enrollment groups as a projected total waiver utilization.

	DY2020 (Projected)	DY 2021 (Projected)	DY 2022 (Projected)	DY 2023 (Projected)	DY 2024 (Projected)
Total Member Months	**305,452**	**298,502**	**293,280**	**289,788**	**288,020**
TCM-Only Benes	294,054	286,180	280,034	275,618	272,926
Full Coverage Benes	11,398	12,322	13,246	14,170	15,094
Total Utilization	**$4,185,264**	**$4,496,131**	**$4,820,518**	**$5,160,882**	**$5,521,010**
TCM-Only Benes	$2,164,074	$2,267,412	$2,376,775	$2,494,407	$2,623,871
Full Coverage Benes	$2,021,190	$2,228,720	$2,443,743	$2,666,475	$2,897,139

The state is not requesting any changes to the program. Based on current projections, there would be a large number of individuals in both categories that would lose coverage if the waiver were discontinued.

	DY2020 (Projected)	DY 2021 (Projected)	DY 2022 (Projected)	DY 2023 (Projected)	DY 2024 (Projected)
Annual Members Impacted	**25,454**	**24,875**	**24,440**	**24,149**	**24,002**
TCM-Only Benes	24,505	23,848	23,336	22,968	22,744

Full Coverage Benes	950	1,027	1,104	1,181	1,258

These projections reflect an average number of distinct beneficiaries per year based on the overall member months.

Funding Sources

The state's intended source for financing the non-federal share of expenditures under the demonstration is the state general fund.

Evaluation

Interim & Proposed Evaluation

A copy of the interim evaluation and accompanying proposal for evaluating the waiver extension are available online at https://www.michigan.gov/mdhhs/0,5885,7-339-71547-376862--,00.html.

MDHHS will continue working with Michigan State University to extend the current evaluation beyond 2021, utilizing the model, research questions, and hypotheses outlined in the interim report. Because the report only covers a limited time period, it is important that the State be afforded the opportunity to track longer-term trends and monitor previously identified targets. As additional data sources and methodologies for collection are developed, the State may consider pursuing data use agreements with other agencies or departments. One key limitation was the time-consuming process of defining and compiling all data sources, as well as conducting community outreach and soliciting participation from data outside of MDHHS. Now that many of these barriers have been identified and worked through, the evaluation of the program can be conducted without impediment.

State Public Notice and Input Process prior to Submission

Public Notice Mechanisms

The following methods were used by the state to provide notice to the public and solicit input from interested parties:

- Public meeting & open comment held by Medical Care Advisory Council on 8/14/19
- Public meeting & open comment held by Medical Care Advisory Council on 11/14/19
- Notice (L 19-44) sent to Tribal Chairs and Health Directors on 12/2/19
- Notice (L 20-08) sent to Stakeholders on 2/20/26
- Abbreviated public notice sent to state newspapers on 2/19/20
- Full public notice posted on department website on 2/20/20
- Public meeting & open comment held in Flint, MI on 2/25/20
- Public meeting & open comment held by Medical Care Advisory Council on 2/26/20

Full Public Notice (2)

A copy of the full public notice can be found attached.

Abbreviated Public Notice

A copy of the abbreviated public notice can be found attached.

Tribal notice

A copy of the tribal notice can be found attached.

Link to Website

The public notice documents and public input procedures can be found online at the following website: https://www.michigan.gov/mdhhs/0,5885,7-339-71547-376862--,00.html

Public comments

A copy of the consultation summary can be found attached.

Press Release

A copy of the press release can be found here: https://www.michigan.gov/mdhhs/0,5885,7-339-73970_71692_71696-520380--,00.html

Flint, Michigan Section 1115 Demonstration

#11W 00302/5

2018/2019 Cumulative Interim Report

Submitted 1/15/20

Table of Contents

Executive Summary

In April 2014, Flint, Michigan experienced a public health crisis related to its water supply. The City of Flint switched the water sources from Lake Huron and Detroit River to the Flint River to reduce costs. This switch and its water treatment process caused lead and other toxins to leach from pipes that delivered water into homes. As a result, many residents experienced serious health problems. Chief among them was lead exposure in pregnant women and children. Health providers discovered that Flint children's blood lead levels (BLL) increased significantly from 2.4% to 4.9% after the water source change.[1] Those neighborhoods with aging lead pipes and infrastructure experienced a 6% increase in lead levels in the drinking water.[2]

Lead is a neurotoxin and high BLLs can affect the developing brain and neural systems. Lead exposure in utero and young children has the potential to cause serious physical and developmental delays. Most notably, these neurodevelopmental effects can impact intelligence, behavior, and a healthy life trajectory. Likewise, in unborn children lead crosses the placenta as a toxin and may cause miscarriage, low-birth weight, and affect major organs. These effects are difficult to ameliorate and often sustain into adulthood.

In 2016, the federal government declared the Flint Water Crisis an emergency and leveraged funds to assist residents facing immediate effects of the contaminated water. To address the sustained public health crisis directly, the Centers for Medicare and Medicaid Services (CMS) administered funds via the Michigan Department of Health and Human Services (MDHHS) to expand eligibility and access to healthcare for pregnant women and children under 21 years. The Flint Medicaid Expansion (FME) went into effect on May 1, 2016 (expansion date), two years after the water switch date (April 1, 2014). This Medicaid Section 1115 Waiver expanded eligibility and services in two ways: 1) increased the income eligibility from a maximum of 212% FPL to 400% FPL, and 2) included Targeted Case Management of specialized services.

MDHHS engaged Michigan State University's Institute for Health Policy (IHP) to evaluate the expansion of Medicaid services in four domains: 1) access to care; 2) access to targeted case management; 3) improved health outcomes; and 4) lead hazard investigation. The evaluation plan was approved August 2017. In this cumulative interim report, evaluation activities and progress from 1/1/2018 to 12/31/19 are described. The four domains offer specific hypotheses to guide the evaluation.

Predominant activities during calendar year 2018 included acquisition of data, data preparation, securing resources to implement the evaluation, engaging key stakeholders, and preliminary analyses. Activities during calendar year 2019 included expansion of available results as well as implementation of enrollee and provider surveys.

The results describe enrollment and utilization data acquired from the MDHHS Health Services Data Warehouse. Reported utilization is through an effective date of 4/30/2019 due to allowances for claims processing. Data sources targeted for the upcoming year include medical record data from the Genesee Health System and public data sources such as *MI Schools* and *Lead Safe Home*.

Evaluation of administrative data sets along with enrollee survey responses suggest that the waiver has had a degree of success in meeting the overarching goal. With respect to the four domains referenced in the waiver application, currently available data suggest positive impacts have been realized in some of the measures for three of the domains. The remaining domain has not yet been evaluated and no interim opinion can be rendered.

The first domain, Access to Care, has been supported by the information provided directly by enrollees. Most respondents documented the waiver made it easier for them to access care and services. However, based on administrative health care data, only several measures suggested rate increases since the water switch (e.g. developmental/behavioral screening, retesting of children having elevated BLL and lead testing in pregnant women).

The second domain, Access to TCM, has been shown in preliminary analyses to have limited impact predominantly due to the low uptake and participation. Administrative and TCM Provider data show rates less than 5% while survey participants do not report participation in excess of 10%. Despite the lower than anticipated penetration, those who have participated report satisfaction with the benefit.

The third domain, Improved Health Outcomes, has been predominantly supported by the data collected during the beneficiary survey as well. Most participants report health status rankings as good, very good or excellent. However, a discrepancy is observed between physical health status and behavioral/emotional health status with behavioral health status being rated significantly worse. Beneficiaries further report increased confidence and resources to manage chronic conditions since enrollment.

Preliminary analyses on the last domain, Lead Hazard Investigation remain in progress and are unavailable currently. External community reports indicate positive trends in water lead values and number of environmental investigations completed through 2017.

The full impact of the approved Flint Waiver cannot yet be appreciated as the evaluation period is scheduled to continue through April 2021. Early results suggest the waiver has been partly successful in achieving the state's overarching goal to "*identify and address any physical or behavioral health issues associated with actual or potential exposure to lead hazards."* An unanticipated positive finding arising from the evaluation activities was the interest and participation in web-based surveys by enrollees.

General Background Information

In 2016, the Michigan Department of Health and Human Services (MDHHS) received a 1115 waiver from the Centers for Medicare and Medicaid Services (CMS) to expand Medicaid coverage and benefits to individuals affected by the Flint Water Crisis.

The Flint Water Crisis occurred when the city's water source was changed in April 2014 to the Flint River. This water did not receive appropriate treatment and subsequently caused lead to leach from pipes, increasing the incidence of elevated lead levels in tap water and in children's blood. Over 100,000 residents were affected and among those were approximately 25,000 infants and children.[3] In January 2016, President Obama declared an emergency in Flint, leveraging federal aid to support state and local response efforts. The Flint Medicaid Expansion (FME) Waiver provided and continues to provide expansion of health services to address potential health risks and diseases possibly incurred during exposure to lead during the Flint Water Crisis. As of January 13, 2020, lead exposure is still a threat since all the water supply lines have not yet been replaced. Because lead is a known neurotoxin,[2] MDHHS applied for the waiver to expand Medicaid coverage to individuals who may have been exposed, but not eligible for Medicaid due to income limitations. Given the known adverse impact on neurological development,[5] the target populations identified in the application included infants and children as well as pregnant women.

The 1115 Waiver entitled the *Flint, Michigan Section 1115 Demonstration #11W 00302/5* was approved in March 2016 with an approval period through February 2021. The overarching goal of the MDHHS waiver application was to "*identify and address any physical or behavioral health issues associated with actual or potential exposure to lead hazards."* The demonstration waiver expanded eligibility of all Medicaid benefits for low-income children (up to age 21 including children born to eligible pregnant women) and pregnant women (through two months post-delivery) served by the Flint water region from 4/1/2014 through the date when the water is deemed safe. As of 1/13/20, the water had not yet been deemed safe although lead levels were below national thresholds. The specific eligibility modifications included:

- Increase income threshold to offer coverage to children in households with incomes from 212% federal poverty level (FPL) up to and including 400% FPL.
- Increase income threshold to offer coverage to pregnant women in households with incomes from 195% FPL up to and including 400% FPL.
- Eliminate cost sharing and Medicaid premiums for eligible children and pregnant women served by the Flint water system.
- Permit eligible children and pregnant women above the 400% FPL and served by the Flint water system to buy into Medicaid benefits by paying premiums.

The demonstration also added a Targeted Case Management (TCM) benefit to all low-income children (up to age 21 including children born to eligible pregnant women) and pregnant women (through two months post-delivery) served by the Flint water system as of 4/1/2014. The activities included in the TCM benefit were to:

- Assist enrolled eligible children and pregnant women served by the Flint water system to gain access to needed medical, social, educational, and other service(s).

A condition of this waiver authorization was the requirement for an independent evaluation. Michigan State University's Institute for Health Policy (IHP) collaborated with CMS on the evaluation goals and activities resulting in final approval August 2017. Contracting between MDHHS and IHP was effective January 2018. The evaluation team includes faculty and staff from IHP as well as faculty from the College of Human Medicine's Department of Epidemiology and Biostatistics, Division of Public Health, and the Office of Research. Additionally, faculty and staff from the College of Social Science, Office for Survey Research are members of the evaluation team. The team includes:

- Hong Su An, PhD; Institute for Health Policy, College of Human Medicine
- Karen Clark, BA; Office for Survey Research, Institute for Public Policy & Social Research
- Debra Darling, BSN, RN, CCP; Institute for Health Policy, College of Human Medicine
- Julie DuPuis, MPA; Institute for Health Policy, College of Human Medicine
- Sabrina Ford, PhD; Institute for Health Policy, College of Human Medicine
- Mona Hanna-Attisha, MD, MPH, FAAP; Department of Pediatrics, College of Human Medicine and Hurley Medical Center
- Joan Ilardo, PhD, LMSW; Office of Research, College of Human Medicine
- Nicole Jones, MS, PhD, Division of Public Health, College of Human Medicine
- Christine Karl, RN, BA; Institute for Health Policy, College of Human Medicine
- Zhehui Luo, PhD; Department of Epidemiology and Biostatistics, College of Human Medicine
- Kathleen Oberst, PhD, RN; Institute for Health Policy, College of Human Medicine
- Debra Rusz, MA; Office for Survey Research, Institute for Public Policy & Social Research;
- Richard Sadler, PhD; Division of Public Health, College of Human Medicine
- Lin Stork, MA; Office for Survey Research, Institute for Public Policy & Social Research

The evaluation findings contained in this report are preliminary and reflect the activities conducted by the evaluation team during calendar years 2018 and 2019. The full evaluation

timeframe is scheduled through April 2021. The interim findings are provided to support the waiver renewal process.

Evaluation Questions and Hypotheses

The Waiver application referred to four domains in which the expanded Medicaid offerings would support attainment of the overall waiver goal. Described below are Domains, related hypotheses and progress thus far based on the evaluation activities occurring during calendar years 2018 and 2019. A summary matrix of all measures by domain and steward is available in Appendix 1. A copy of the approved evaluation plan is provided in Appendix 2.

- Domain 1: Access to Care
- Domain 2: Access to Targeted Case Management
- Domain 3: Improved Health Outcomes
- Domain 4: Lead Hazard Investigation

Domain 1: Access to Care

The approved demonstration provided Medicaid coverage and access to health care services to a cohort of individuals who were exposed to the lead contaminated water and potentially at risk for physical and behavioral issues. Data sources to address the hypotheses included data acquired from MDHHS Health Services Data warehouse (enrollment and claims) and the enrollee surveys. Enrollee survey materials and Wave 1 summary are provided in Appendix 3.

Hypothesis 1: "Enrollees will access services to identify and address physical or behavioral health issues associated with lead exposure at a rate higher than others with similar levels of lead exposure." Nine (9) sub-hypotheses made up this domain and several of the sub-hypotheses included multiple discrete measures. The overall objectives were to evaluate the use of specified services including: well-child visits, developmental screening assessments, testing and retesting of blood lead levels in pregnant women and children, prenatal and postpartum care, maternal infant health program (MIHP) participation, and improved care and satisfaction.

Children: Access to Care

1. A greater proportion of enrollees will obtain age-appropriate well-child exams compared to others with similar lead exposures.
2. A greater proportion of enrollees will receive age-appropriate developmental screening/assessments compared to others with similar lead exposures.
3. A greater proportion of enrollees will receive age appropriate lead testing compared to others with similar lead exposures.
4. A greater proportion of enrollees with high blood lead levels will receive re-testing at the appropriate intervals compared to others with similar lead exposures.

Pregnant Women: Access to Care

5. Enrollees who are pregnant will have more timely prenatal and postpartum care compared to others with similar lead exposures.
6. A greater proportion of enrollees who are pregnant will have recommended lead testing compared to others with similar lead exposures.
7. A greater proportion of enrollees will participate with Maternal Infant Home Program services compared to others with similar lead levels.

Improved Care & Satisfaction

8. The majority of enrollees will attest to improved access to health care as a result of the expanded coverage.
9. The majority of enrollees will report improved satisfaction with their ability to access health care as a result of the expanded coverage.

Domain 2: Access to Targeted Case Management

The approved demonstration provided expanded benefits, specifically Targeted Case Management (TCM) to facilitate needed medical, social, educational and other services to a cohort of individuals exposed to the contaminated water and potentially at risk for physical or behavioral health consequences. Required elements of TCM have been described in MDHHS policy and included assessments, planning, linkage, advocacy, coordination, referral, monitoring and follow-up activities. In response to enrollee feedback, TCM was relabeled as Family Supports Coordination (FSC). In the interest of consistency for this report and alignment with the Waiver application and approval materials, the services will continue be referred to as TCM throughout this evaluation document. The potential data sources to test these hypotheses included administrative health care data, TCM provider electronic medical record data, enrollee survey data as well as TCM provider survey data.

Hypothesis 2: *"Enrollees who access TCM services will access needed medical, social, educational, and other services at a rate higher than others with similar levels of lead exposure."* Hypothesis 2 encompassed four sub-hypotheses. The first two reflected operational aspects of the new benefit while the remaining two assessed for selected improvement in receipt of specific health care services.

1. Referral source and participation levels with TCM will be tracked among enrollees.
2. All TCM participants will have an annual assessment conducted.
3. A greater proportion of TCM participants will have age-appropriate well child exams compared to TCM non-participants.

4. A greater proportion of TCM participants will have completed age-appropriate developmental screening compared to TCM non-participants.

In addition to accessible Medicaid data, collaboration and cooperation with Genesee Health System (GHS) related to TCM data was necessary. GHS was the designated provider for TCM services. Additionally, the Greater Flint Health Coalition (GFHC) also provided TCM services and regularly submitted data to GHS for reporting purposes. As of December 2018, a Business Associate Agreement (BAA) was executed between IHP and GHS permitting IHP to obtain and use GHS TCM data contained within the electronic medical record. These data remain under investigation and were expected to provide information on TCM referral and screening processes and include available data of those children referred for neuropsychological testing at the Neurodevelopmental Center of Excellence (NCE).

TCM specific questions were included in the enrollee survey previously described and presented in Appendix 3. This was done in order to obtain information regarding self-reported use and satisfaction with the TCM services.

In addition to information documented by the TCM providers as part of an enrollee's medical record, qualitative information was obtained from the professional social workers employed at both organizations as TCM Support Coordinators. The TCM Provider Key Informant Interview summary report and discussion guide documents are available as Appendix 4.

Domain 3: Improved Health Outcomes

Hypothesis 3: "*Enrollees will have improved health outcomes compared to others with similar levels of lead exposure*." Domain 3 included three primary sub-hypotheses to examine: status and rates of age-appropriate immunization, greater birth weights, and improved health status rating during enrollment in relation to a comparison group. These primary sub-hypotheses were selected for the ability to report on them using administrative health care data which was already available to the evaluation team. The evaluation activities also included plans for enrollee surveys which were identified as the data source for the health outcome questions.

There were three provisional sub-hypotheses that were descriptive of neurocognitive, behavioral, and educational outcomes of eligible children. These outcomes were deemed provisional due to several concerns. The first was concern regarding the inclusion of children enrolled in the Serious Emotional Disturbance (SED) waiver as an appropriate comparison group. Next, access to the education data necessary for evaluation are protected by the Family Educational Rights and Privacy Act (FERPA) and concerns regarding the availability of such data to the evaluation team were raised. The State of Michigan's Department of Education (MDE) requested permission from the federal Department of Education to share individual-level data

for purposes of the waiver evaluation. The request was denied thus prohibiting the state from sharing these data. The evaluation team thus had to rely on publicly available school system data which was less robust and had no ability to accurately categorize children as a waiver enrollee versus member of a potential comparison group. Within the provisional hypotheses, the specific metrics associated with behavioral and educational outcomes included measuring the proportion of occurrence of severe emotional disturbance and developmental disabilities; the number of children suspended or expelled from school; and the number of children receiving special education services.

After learning of the FERPA denial, questions pertaining to the provisional hypotheses were added to the enrollee survey. The evaluation team also sought out guidance from additional MSU faculty having experience with publicly available MDE summary reports. The evaluation team will explore how these may provide context to findings during the remainder of the evaluation period.

Primary Hypotheses:

1. Enrollees will have higher completed age-appropriate immunization statuses compared to others with similar lead exposures,
2. Enrollees who are pregnant will deliver infants with higher birth weights compared to others with similar lead exposures, and
3. Enrollees report an increase in their self-reported health status over the duration of their enrollment.

Provisional Hypotheses:

1. *We will conduct a descriptive analysis of the proportion of children diagnosed with severe emotional disturbance and other developmental/learning disabilities including comparing rates to others with similar lead exposures,*
2. *Descriptive analysis of behavioral health conditions among enrolled children (i.e. rate/proportion of children suspended or expelled), and*
3. *Descriptive analysis of educational delays among enrolled children (i.e. rate/proportion of children receiving special education services, i.e. individual education plans "IEPs", early preschool performance, and reading and math scores at end of grades 3, 4, and 5).*

Domain 4: Lead Hazard Investigation

Hypothesis 4: *"The lead hazard investigation program will reduce estimated expected ongoing or re-exposure to lead hazards in the absence of this program."* Hypothesis 4 included two sub-hypotheses to address: 1) ongoing monitoring of the blood lead levels (BLLs) of all eligible children who were living in Flint at the time of the water crisis regardless of BLL status at the

time of crisis and 2) ongoing surveillance of the beneficiaries who may have had continued exposure to lead (e.g. water pipes, lead in the home).

The evaluation team originally identified administrative health care records as the source to test these hypotheses. In response to difficulty framing the data pulls and the existence of pertinent data outside of the Medicaid program, questions were again added to the enrollee survey.

Methodology

Evaluation Design

The approved evaluation plan located in Appendix 2 proposed a pre-post design to evaluate the degree to which the FME met the overarching goal to identify and address any physical or behavioral health issues associated with actual or potential exposure to lead hazards. The timeframes were originally anchored around April 1, 2014 as that date coincided with the date of the water switch. This date was originally selected so that the annual reporting of administratively derived measures regarding enrollee characteristics could reach back to a twelve-month time period prior to the water switch and then follow over time accordingly after exposure to the contaminated water. As the evaluation team moved forward to assessing FME services, the anchor point was adjusted to May 1, 2016 to coincide with the implementation of the approved waiver. Thus, critical timeframes for the purposes of the evaluation were revised to May 1, 2013 – April 30, 2014 as "pre" water switch time period and each subsequent year following this time period starting May 1, 2014 considered "post" water switch with FME benefit implementation effective May 1, 2016. The timeframe of May 1, 2015 – April 30, 2016 was considered "pre" FME implementation and each subsequent year since the start of the FME benefit considered "post" FME implementation.

Target and Comparison Populations

Another design strategy of the evaluation proposal was to test a variety of comparison groups in addition to the pre-post design. The evaluation team considered a variety of potential comparison groups. The target population of the FME included those individuals known to be at risk for adverse outcomes related to lead exposure via the Flint Water system and included:

- Any pregnant woman and/or child up to age 21 with a household income up to and including 400% of the Federal Poverty Level (FPL) who has been served by the Flint water system on or between 4/1/2014 and the date water is deemed safe (Date to be determined).
- Any child born to a pregnant woman served by the Flint water system during the specified time period. The child will remain eligible until age 21.
- Exposure was defined as consumed water drawn from the Flint water system during the specified time period and
    - resides or resided in a dwelling connected to Flint water system service lines;
    - is employed and/or had employment at a location served by the system; or
    - is receiving or received child care and/or education at a location connected to this system.

The Eligibility Protocol further clarified the criteria to include individuals who were incarcerated or who resided in a health care facility at a location served by the Flint water system. Four potential comparison groups were identified in the original proposal:

1. Medicaid beneficiaries residing in the target Flint area based on water exposure map in the year prior to the water switch.
2. Commercially insured individuals in Michigan.
3. Communities known to have similarly elevated lead exposures.
4. Beneficiaries covered through Michigan's Serious Emotional Disturbances (SED) waiver.

Each of these was associated with limitations. The main concern for Comparison Group 1 was that even if these beneficiaries had similar water lead exposure prior to the water switch, they would not have similar exposure after the water switch. The main concern for Comparison Group 2 was inability to acquire commercial insurance data. The main concern for Comparison Group 4 was the relatively small number of beneficiaries enrolled in the SED waiver and the significantly greater need for services these individuals are known to require. Enrollment criteria for the SED is an important factor in causing this group to not be a suitable comparison group. Specifically, SED waiver enrollment requires an individual to meet criteria for admission to the state inpatient psychiatric hospital. Upon reflection of the cohort in Comparison Group 4, the evaluation team concluded the groups were more dissimilar than similar which compromised their ability to serve as comparators. Thus, we focused on exploring communities potentially having similar elevated lead exposures identified as Comparison Group 3. A more robust description of the procedure and analyses for selecting the comparison group is described in the Preliminary Results section.

Evaluation Period

The FME approval was for the time period 3/3/16 - 2/28/21 with a state identified begin date of 5/9/16. Upon CMS approval of the evaluation proposal 8/8/17, the evaluation team began preparing to commence the evaluation during the contracting period. Formal evaluation activities began January 2018. The evaluation timeframe runs 1/1/2018 through 4/30/2021 allowing a sixty-day period to finish up a final report after the waiver period expires. This cumulative interim report is provided upon request as an element of a waiver extension application. Results described should not be interpreted as final. Additionally, not all hypotheses have been formally addressed as of the date of this report. Generally, data collection protocols for administrative health care data were established during calendar year 2018 while enrollee, TCM provider and MDHHS key informant survey protocols were implemented during calendar year 2019.

Due to the prescribed pre-post design and the predominant reliance on administrative datasets for many of the evaluation sub-hypotheses, the full time period of health care claims/encounter and blood lead testing data reached back to 5/1/13 or one year prior to the water switch to provide baseline estimates. While this allowed one month of "post water switch" to be included in the baseline timeframe, the impact on measure reporting was negligible.

Evaluation Measures

Again, the overarching goal of the FME was to identify and address any physical or behavioral health issues associated with actual or potential exposure to lead hazards. Thus, specific evaluation measures were selected for their relevance to known impacts of lead as a neurotoxin on developing physiological systems. In addition, recommended measures of preventive and screening services were included. The waiver also authorized individuals at higher income levels to qualify, offering a chance to measure uptake in targeted services across socioeconomic levels. The summary matrix of all measures by domain and steward is available in Appendix 1.

The specific evaluation measures associated with Hypothesis 1, "*Enrollees will access services to identify and address physical or behavioral health issues associated with lead exposure at a rate higher than others with similar levels of lead exposure*", included specific Health Plan Employer Data Information Set (HEDIS) measures endorsed by the National Quality Forum (NQF).[4] The selected measures included:

- Age-appropriate well-child exams;
- Age-appropriate developmental screening;
- Age-appropriate blood lead testing;
- Appropriate re-testing for individuals with elevated blood lead levels;
- Timely prenatal and postpartum care for pregnant women; and
- Recommended blood lead testing for pregnant women.

The remaining measures included items that were specific to Michigan. For instance, participation in a program intended to support positive birth outcomes, the Maternal Infant Health Program (MIHP) was added. It was expected that individuals receiving TCM supports would be more likely to receive referrals and participate in MIHP.

The evaluation team felt it was important to solicit feedback directly from FME participants to ascertain whether the expanded eligibility and TCM services supported them in accessing services. An enrollee survey was designed to address the final two measures:

- Beneficiary attestation to improved access to health care; and

- Beneficiary report of improved satisfaction with ability to access health care.

Hypothesis 2 focused on the additional TCM service added as a new benefit with the waiver. The hypothesis was "*Enrollees who access TCM services will access needed medical, social, educational, and other services at a rate higher than others with similar levels of lead exposure."* The intention of this benefit was to facilitate needed medical, social, educational and other services for those who were exposed to the contaminated water. TCM provided an opportunity for enrollee education and support as well as assistance navigating the health care system and helping to mitigate barriers to care. Therefore, the measures associated with the sub-hypotheses were selected for their significance to the operational and implementation aspects of the benefit. As such, these measures were specific to Michigan.

- Use of referral services by TCM participation level;
- Proportion receiving annual TCM assessment;
- Proportion of TCM participants having well-child exams will exceed proportion by non-TCM participants; and
- Proportion of TCM participants having developmental screenings will exceed proportion by non-TCM participants.

Hypothesis 3 in the waiver application addressed improved health outcomes. This reflected the overall goal of the FME waiver, "*Enrollees will have improved health outcomes compared to others with similar levels of lead exposure*." Because the full impact of lead exposure on a child's developing nervous system cannot be assessed for several years, three process measures were identified as proxies for clinical outcomes.[3] Process measures validated by national organizations were used to measure clinical outcomes based on known associations between these metrics and general health status.[4]

- FME enrollees will have greater age-appropriate immunization completion;
- Pregnant FME enrollees will deliver infants with greater birth weights; and
- Self-reported improvement in health status.

As the enrollee survey was designed, the potential for TCM providers to impact enrollees holistically with their health care needs was realized. The TCM providers were acknowledged to have opportunities to ensure appropriate referrals and services for a host of health conditions including chronic conditions. Thus, several additional questions regarding chronic disease and self-management capacity were included in the enrollee survey to inform evaluation questions regarding changes in health status.

This domain also included three *provisional* hypotheses regarding educational measures and performance. These measures were developed in-house. The following measures were deemed

provisional due to concerns regarding the appropriateness of children enrolled in the Severe Emotional Disturbance (SED) waiver as a comparison and/or the availability of the necessary data to fully investigate them.

- *Proportion of children diagnosed with SED;*
- *Proportion of children suspended or expelled; and*
- *Proportion of children receiving special education services.*

Information regarding prevalence of behavioral health conditions and educational delays was collected from parents/guardians of children enrolled in the waiver. The enrollee survey was the vehicle used to obtain these self-reported data.

The evaluation team has conducted preliminary reviews of the publicly available education dashboards. The appropriateness of these aggregated data as proxy measures has not yet been finalized. Investigation continues into specific metrics available through related local, district and state educational reporting sources.

Hypothesis 4 referenced the Lead Hazard Investigation that was expanded through the FME waiver, "*The lead hazard investigation program will reduce estimated expected ongoing or re-exposure to lead hazards in the absence of this program."* Mitigation or abatement efforts to home sites with lead hazards were not funded through this expansion. The FME waiver did authorize the use of funding to conduct screening and assessment of environments to assist with case finding. Prior to the waiver, documentation of an elevated BLL was necessary in order to refer a property for lead exposure investigation. This requirement was relaxed by the FME waiver so that home sites could be assessed even in the absence of an elevated BLL. The details of environmental assessments and mitigation efforts are supported and documented by governmental agencies outside of Medicaid compromising the evaluation team's ability to quantify levels of lead exposure. Thus, developed metrics took into consideration the effect of additional Medicaid funds' in facilitating additional screening and case finding. The enrollee survey was again targeted to provide some information regarding ongoing lead exposures.

- Prevalence of lead hazard assessment/investigation; and
- Prevalence of those at risk for ongoing lead exposure receiving referrals for additional environmental investigation.

Data Sources

Major sources of data identified as necessary to address the evaluation measures thus far have included: 1) the MDHHS Health Services Data Warehouse, 2) TCM program information, 3) Beneficiary surveys, 4) Provider Key Informant Interviews, 5) Michigan Childhood Lead

Poisoning Prevention Program Data Report, and 6) Michigan Care Improvement Registry data. MDHHS maintains a data warehouse containing information at an individual level regarding a variety of health-related services and data points. IHP employs staff with the necessary permissions and expertise to access the MDHHS Health Services Data Warehouse and acquire the elements needed to support analyses. However, despite the storage of a variety of health-related program data in the Health Services Data Warehouse, access to these data are controlled by each program. IHP staff having access to Medicaid claims/encounter data did not have access to the Lead Poisoning Prevention or Care Improvement registry data on the onset of the evaluation. During the first two years, access to the Lead Poisoning data has been granted however remained pending for the Care Improvement program.

MDHHS Health Services Data Warehouse – Enrollment and Utilization

Specific targets contained within the data warehouse included Medicaid eligibility/enrollment, final paid Medicaid claims/encounter data, blood lead program data and immunization data. While much of the Medicaid claims/encounter data lack clinical care values, the blood lead program data does collect this information. The State of Michigan further maintains a master person index to facilitate matching of individuals between different programs so that individuals covered through Medicaid will be linked to their blood lead testing dates and values when present. Moreover, the lead program data is not restricted to include only those covered through Medicaid, thus it may provide opportunities to shed light on conditions of potential comparison groups. The Michigan Care Improvement Registry (MCIR) collects immunization data that is required reporting by health care providers. Like the lead program data, the evaluation team would theoretically be able to link an individual's immunization record to their Medicaid data via the master person index given appropriate access. Also, data on individuals covered through other forms of insurance or receiving immunizations funded through programs besides Medicaid will be present in MCIR as the team explores potential comparison groups. Evaluation team members already had access to the eligibility, enrollment and health care claims data. Approval was needed for the blood lead program as well as the MCIR data. To date, access to the blood lead program has been granted and MCIR data will continue to be pursued in the upcoming year.

Ongoing review of routinely reported information is conducted by MDHHS program and warehouse staff to identify potential issues with data loading or when changes to warehouse tables are made. The evaluation team did not validate the data extracted from the warehouse with primary sources such as medical record reviews. Instead, conversations between the IHP staff responsible for pulling data and state program staff occurred and continue to occur to ensure that relevant fields are captured, and coded variables are correctly interpreted. For example, an issue with the completeness of the blood lead program was identified resulting in a repull of the data once IHP had been advised of the correction. Data review is an ongoing, iterative process and continues throughout the duration of the evaluation. Independent review

and validation of code used to process data and conduct statistical analyses was performed by evaluation team statisticians.

Targeted Case Management Program Information

The supplementary TCM benefit approved in the waiver necessitated additional data sources to support the evaluation beyond the claims/encounter information contained in the MDHHS Health Services Data Warehouse. While the provision of TCM services were identified through specific procedure codes entered onto billing data, the ability to discriminate between specific services was not available via this administrative data. For example, the TCM provider could assist a beneficiary to schedule a medical appointment or arrange for transportation. The allowable procedure codes would not permit the evaluation team to monitor which of these two services was most needed. This level of detail was only available through electronic medical record documentation among visit summaries or progress notes. Therefore, the evaluation team established a Business Associates' Agreement (BAA) with Genesee Health System (GHS) to authorize access to their electronic medical records (EMR) for purposes of this evaluation. The data contained in this source continues to be evaluated for the level of detail desired. GHS was successful in working with their EMR vendor to set up summary reporting for the evaluation team. However, the detailed progress notes have been found to not be amenable to extraction in a format readily suited for analyses. Ongoing efforts to use these data elements will be explored in the remaining evaluation period.

An additional data source regarding the TCM benefit was a key informant interview conducted with individual(s) employed to serve as TCM providers. These data were obtained through a telephone survey implemented during the second quarter of 2019. A discussion guide was established to facilitate consistency of information and one registered nurse staff member from IHP conducted all the telephone interviews. The draft summary report was shared with the informants to ensure accurate representation of their information. Refer to Appendix 4 for the TCM Key Informant Interview summary and associated documentation.

Beneficiary Survey and Reporting

Enrollee survey data represented the last major source of data to inform the evaluation. Key measures of the evaluation such as inquiries regarding improvements in access to care or health outcomes required input from those enrolled in the FME waiver. The original survey plan was to conduct three survey waves approximately twelve months apart to capture trends over time. Modifications to the original survey plans were necessary due to the time period involved with evaluation plan approval and contracting. This original design was modified to maintain three waves but have each wave spaced approximately nine months apart. Methods for survey participation were further expanded from the original design based on feedback from Flint community members. The original survey design called for a paper or phone-in survey. A web-

based component was added in time for the first wave's dissemination based on community feedback. The evaluation team requested and received approval to offer a small monetary incentive to complete the survey. Flint community residents have been inundated with academic and non-academic projects and programs operating in the area; therefore, the evaluation team was concerned that survey fatigue could adversely affect participation.

Wave 1 was conducted from December 2018 through March 2019. All paper surveys were blind double data entered. Surveys completed by telephone were subjected to monitoring by supervisory staff. Web-based responses to the survey were directly entered by the respondent. In addition to using a two-factor authentication process for a selected respondent to access the online survey, the web survey allowed only one response per unique credential. This prevented respondents from completing more than one survey. The online survey was further protected from non-FME enrollee participation by restrictions imposed on the ability of internet search engines to locate the survey. Refer to Appendix 3 for copies of the wave 1 survey tools.

Analytic Methods

Tests of significance (Chi-square and t-tests, etc.) to ascertain group differences and change over-time are planned to monitor the measures that are being tracked on an annual basis. Future comparisons of measures will be tested using identified cluster-robust methods accounting for the potential nesting of observations within the same individual. Because the expansion criteria have the potential to change the population composition of enrolled individuals over time, the evaluation team monitors the population composition.

Beneficiary Survey Sample Selection

The population eligible to participate in the initial survey wave were those enrollees who had at least six months of continuous enrollment in the FME waiver and were enrolled as of November 1, 2018. This inclusion criteria resulted in 24,082 unique beneficiaries being identified. The sample was selected in two stages to identify a sample pool of 11,453 for Wave 1. In the first sampling stage, the sampling frame was divided into three groups based on the beneficiary's residence. These residential categories were selected upon the evaluation team's recognition that the FME waiver enrolled individuals were more geographically dispersed than what had been hypothesized. The categories established included:

- Only Genesee County – included beneficiaries who only appeared to only reside somewhere in Genesee County based on the available enrollment record history.
- Partial Genesee County – included beneficiaries who resided both in and out of Genesee County based on the available enrollment record history.

- Never Genesee County – included beneficiaries who had no enrollment data to suggest they ever resided in Genesee County. However, these individuals were flagged as being enrolled in the FME waiver and therefore were included.

We applied stratified random sampling by residence category resulting in 11,453 potential participants for Wave 1 (refer to Table 1). Among those in the Only Genesee category, we randomly selected 10,000 beneficiaries. In the second stage, we applied the probability proportional to size (PPS) sampling based on the size of the age category. However, due to the small number of enrollees in the Partial Genesee Category, the team elected to oversample and retain all individuals identified regardless of Age Category (n=384). We further included all beneficiaries in the Age Category 23-64 years as of November 1, 2018 regardless of residence category due to the small number of individuals (n=87). For the Never Genesee category, the team randomly selected 1,000 beneficiaries for survey participation. The total number of beneficiaries selected for survey inclusion were then equally split into four batches to manage the mailing process.

Table 1. Number of beneficiaries selected for survey sample out of total eligible population

		Residence Category			
	Age Category (Years)	**Always in Genesee N (%)***	**In and Out of Genesee N (%)**	**Never in Genesee N (%)**	**Total N (%)**
Population Count	0-6	7,657 (31.8)	163 (0.7)	855 (3.6)	8,675 (36)
	7-17	11,791 (49.0)	181 (0.8)	1,051 (4.4)	13,023 (54.1)
	>=18	2,136 (8.9)	40 (0.2)	208 (0.9)	2,384 (9.9)
	Total	*21,584 (89.6)*	*384 (1.6)*	*2,114 (8.8)*	*24,082*
Sample Selection Count	0-6	3,559 (31.1)	163 (1.4)	404 (3.5)	4,126 (36.0)
	7-17	5,480 (47.8)	181 (1.6)	497 (4.3)	6,158 (53.8)
	>=18	1,029 (9.0)	40 (0.4)	100 (0.9)	1,169 (10.2)
	Total	*10,068 (87.9)*	*384 (3.4)*	*1,001 (8.7)*	*11,453*

*Proportions reflect sub-category representation among the Total Count of all Enrollees

The nearly 50% sampling frame was applied because of the longitudinal nature of the survey. The evaluation team was concerned with retaining sufficient numbers for analysis at the end of Wave 3. The time period required to implement all three waves was eighteen months. A larger than normal sample was also deemed necessary based on concerns regarding the level of participation among these individuals who have been inundated with survey requests by a multitude of organizations. The evaluation team received anecdotal reports that some attorneys recommended area residents against participating with surveys due to possible future civil litigation. The impact of these recommendations on survey response rate was unable to be quantified.

Beneficiary Survey Response Rate

Wave 1 results can be considered baseline results for comparison to forthcoming survey waves. Of the 11,453 surveys that were sent out in four batches, 2584 or 22.5% of participants responded. The association between mailing batch and rate of survey response was not statistically significant (p=0.07). Since there was no batch effect for mode of response, all batches were combined to create a single cohort of respondents. Of the 2584 returned surveys, 2359 (91.3%) were child and 225 (8.7%) were adult. Ultimately, 2356 of the child surveys had usable data for reporting.

Table 2. Number of Survey Participants out of Total Sample Selected

		Residence Category			
	Age Category (Years)	**Always in Genesee N (%)**	**In and Out of Genesee N (%)**	**Never in Genesee N (%)**	**Total N (%)**
Sample Selection Count	0-6	3,559 (31.1)	163 (1.4)	404 (3.5)	4,126 (36.0)
	7-17	5,480 (47.8)	181 (1.6)	497 (4.3)	6,158 (53.8)
	>=18	1,029 (9.0)	40 (0.4)	100 (0.9)	1,169 (10.2)
	Total	*10,068 (87.9)*	*384 (3.4)*	*1,001 (8.7)*	*11,453*
Survey Participants	0-6	808 (31.3)	31 (1.2)	88 (3.4)	927 (35.9)
	7-17	1,276 (49.4)	43 (1.7)	113 (4.4)	1,432 (55.4)
	>=18	198 (7.7)	6 (0.2)	21 (0.8)	225 (8.7)
	Total	*2,282 (88.3)*	*80 (3.1)*	*222 (8.6)*	*2,584*

*Proportions reflect sub-category representation among the Total Count of Sampled Enrollees

The response by online method was the most frequent. During the initial planning, the prevailing belief was that these beneficiaries would not be able to access internet-based surveys. Also, the evaluation team believed that implementation of full online modality without email addresses would potentially limit distribution. However, in response to community suggestions, the online modality was added as an initial option with the opportunity for respondents to provide email addresses for future waves. In fact, over 70% of these who participated in Wave 1 provided an email address for Wave 2. To date, those who were notified and provided the survey internet link by email exceeds 50%.

Additional Considerations

IHP engaged in discussions with MDHHS and CMS regarding evaluation tasks and activities during the evaluation approval and contracting process. Upon execution of the contract, the evaluation team submitted the project to the MSU Institutional Review Board for review. The project was determined to not meet the definition of research on 1/22/18 and is considered exempt (refer to Appendix 5).

The evaluation team communicated and met regularly in formed work groups to ensure progress and efficiency. All evaluation team members are members of the Full Workgroup with topical workgroups established to focus attention and activities on discrete elements of the FME workplan (see Table 3). In addition, activities of the evaluation team included day-to-day communication to troubleshoot and resolve questions as they arise. Drs. Oberst and Ford remain responsible for project supervision.

Table 3: Flint Medicaid Evaluation Workgroups

Workgroup Title	Frequency	Purpose
Full	Monthly	Full team meets regarding progress and communication between the other workgroups.
Survey	Bi-Weekly	Design and administration of the beneficiary surveys. Communication with Flint community partners to avoid duplication and beneficiary surveys. Design and administration of TCM key informant interviews.
Data	Bi-Weekly	Updates on data preparation, data management and analyses. Creating data files to include target variables.
Community Asset Inventory	*Disbanded*	Create and maintain inventory of all community entities and key stakeholders that provide services related to Flint Water Crisis. Communication with major key stakeholders to inform the evaluation.
Education	As Needed	Ongoing communication with Flint Community Schools, Genesee Intermediate School District, GHS, Neurodevelopmental Center of Excellence (NCE), and other key stakeholders. Utilize MI Schools Data to address educational progression and NCE data for behavioral/developmental outcomes.

Community Asset Inventory

The project team identified a partial inventory of community partners and resources that provided support to those affected by the water crisis. At the onset of the recognition of the water crisis, community agencies and private and public non-profit organizations offered services and supports and were positioned for more rapid response than governmental agencies. Many volunteers and community-based organizations served at various points without formal acknowledgement. The federal declaration enabled governmental agencies to work with the affected community after many of these other organizations were already operational. Federal resources were likely to be formally documented while the bulk of community-based volunteer activities were not. The evaluation team had hoped to identify and categorize this information.

During calendar year 2019, the Community Asset Inventory workgroup identified community fatigue with respect to revisiting the efforts of the many organizations that had entered the region after the water crisis was made public. Specifically, individuals expressed concern that accurate and reliable information was unavailable. The evaluation team fielded questions regarding the relevance of this information obtained so remotely from the initial insult as well as concerns regarding increasing anxiety levels by revisiting the immediate responses. In deference to the community's concerns, the Community Asset Inventory group was disbanded during calendar year 2019 in favor of using existing information (press releases, announcements, etc.) that might be sourced through major media to provide examples of the types of organizations that could have supported individual community member needs. This work was intended only to provide possible context for observed trends. The evaluation team agreed that hypothesis testing activities would not be unduly limited by the lack of these data.

Education Data

Several meetings were held with representatives from the MDE. Adverse impacts of lead can be identified through learning delays and behavioral problems. Thus, discussions were held regarding permissions to link children covered through the Medicaid waiver to MDE data. MDE representatives clarified FERPA restrictions and explained that an exemption from the federal government would be required to access data at the individual level. Unfortunately, the federal Department of Education declined to provide this exemption.

Due to the inability to link at the individual level to existing Medicaid data, the evaluation team pivoted to evaluate the potential to use publicly available summary reports. A process to utilize MDE data in aggregate to include the MI Schools Dashboard/Database to track developmental and educational outcomes was identified and will be implemented in 2020.

A secondary source of education-related data was incorporated through the beneficiary survey. Acknowledging the limitation of self-reported information, the evaluation team included several questions on the child version of the survey inquiring about school grade level and whether children had been identified as having learning problems or behavioral/emotional problems. The goal of these questions was to provide at least a suggestion regarding the impact of the lead exposure on educational performance.

Timeline Modification

The timeline proposed in the original evaluation plan submission required initial modification to adjust for the time required for evaluation plan approval and contracting activities. As the activities unfolded during 2018 and 2019, further adjustments were necessary as additional information regarding potential data sources became available. Although some activities were

deferred to later years, the groundwork established over the first 24 months is expected to support the bulk of planned activities within the remaining timeframe. The evaluation's timeframe was based on calendar year to coincide with federal reporting timelines and as a result, activities may span more than one state fiscal year reflected as the contracting year in Table 4. A revised Evaluation Timeline is presented below along with activity status as of December 31, 2019.

As of 12/31/19, the following activities were finalized:

- Final report summarizing Wave 1 Beneficiary Survey Responses.
- Wave 2 Beneficiary Survey modifications completed, and mailing begun to the approximately 2600 Wave 1 respondents.
- Final report summarizing the TCM Provider Key Informant Interviews.
- An additional activity, Administrative Costs MDHHS Key Informant Interviews, was added and the final report summarizing these interviews was completed.

Year 3 activities are expected to continue the tasks that support the annual reporting of hypotheses established for the four Flint Waiver Expansion evaluation domains.

- MDHHS data acquisition requires annual pulls allowing appropriate time for claims run-out to ensure data completeness.
- Wave 2 Beneficiary surveys will be completed and summarized with attention to trends over time between the waves.
- Wave 2 TCM Key Informant Interviews will be completed and summarized with attention to trends over time between the waves.
- Wave 3 Beneficiary surveys will be initiated.

Table 4: Revised Timeline for Evaluation Activities

Revised Time Period	Activities	Status *(as of 12/31/19)*
Eval Contract Year 1: 1/1/2018 – 9/30/2018	• Identify key contacts for targeted data sources • Participate with Flint Registry Advisory Committee • Draft beneficiary survey • Implement Wave 1 beneficiary survey (~33 months post-enrollment target: December 2018) • Draft TCM Provider Survey/Key Informant Interview • Implement Wave 1 TCM Provider Survey/Key Informant Interviews (~34 months post TCM implementation: January 2019) • Draft community asset inventory tool • Program administratively derived measures and report for pre-exposure year (4/1/13 – 3/31/14), year 1 (4/1/14 – 3/31/15) and year 2 (4/1/15 – 3/31/16)	• Completed • Ongoing • Completed • Deferred to Year 2 • Completed • Deferred to Year 2 • *Eliminated* • Completed

Revised Time Period	Activities	Status *(as of 12/31/19)*
	• Assemble and test different methods to generate comparison groups	• Ongoing
	• Identify and test data sources for TCM (needs assessments, plans of care, screenings, referrals, etc.)	• Ongoing
	• Identify and test data sources and methods for linkage with Department of Education information (will be using publicly reported school data)	• Ongoing
	• Identify research co-occurring studies and evaluation for possible incorporation into evaluation	• Ongoing
	• Generate quarterly updates	• Ongoing
Eval Contract Year 2: 10/1/2018 – 9/30/2019	• Implement Wave 1 beneficiary survey (*From Year 1:* ~33 months post-enrollment target: December 2018)	• Completed (Dec 2018 - April 2019)
	• Wave 1 Beneficiary Survey analysis and report findings	• Completed
	• Implement Wave 2 Beneficiary Survey to Wave 1 participants (~40 months post-enrollment: Sept 2019 – January 2020)	• Ongoing
	• Implement Wave 1 TCM Provider Survey/Key Informant Interviews (~ 32 months post TCM implementation: Jan 2019)	• Completed (Jan 2019 – April 2019)
	• Wave 1 TCM Provider Survey/Key Informant Interviews analysis and report findings	• Completed
	• Ongoing community asset inventory surveillance	• *Eliminated*
	• Ongoing monitoring of community-based co-occurring studies and evaluation for possible incorporation into evaluation	• *Eliminated*
	• Run TCM measures and conduct data analysis for timeframe 5/1/16 – 4/30/17 (year 1 delivery)	• Completed
	• Run annual administrative measures and conduct analysis and trending for timeframe 5/1/16 – 4/30/17	• Completed
	• Monitor increase in enrollment and services for cost evaluation for timeframe(s)	• Completed
	• *Drafted and implemented Key Informant Interview for Administrative Cost Summarization (Added to Year 2)*	• *Deferred to Year 3*
	• *Administrative Cost Key Informant Interview analysis and report findings (Added to Year 2)*	• *Deferred to Year 3*
	• Assemble and test different methods to generate comparison groups (*From Year 1)*	• Ongoing
	• Generate quarterly updates	• Ongoing
	• Generate interim annual report (Calendar Year 2018)	• Completed (March 2019)
Eval Contract Year 3: 10/1/2019 – 9/30/2020	• Implement Wave 2 (Follow-Up) TCM Provider Survey/Key Informant Interviews (~42 months post TCM implementation: Jan 2020)	• Pending

Revised Time Period	Activities	Status *(as of 12/31/19)*
	• Research and report potential commercial comparison group estimates for expanded financial limit cohort	• Pending
	• Continue Wave 2 (Follow-Up) Beneficiary Survey (~39 months post-enrollment: Sept 2019 – March 2020)	• Ongoing (will extend through March 2020 due to timing of Wave 1 responses)
	• Wave 2 Beneficiary Survey analysis and report findings	• Pending
	• Summarize Wave 2 TCM Provider Survey/Key Informant Interviews and report findings	• Pending
	• Implement Wave 3 (Follow-Up) Beneficiary Survey (~48 months post-enrollment: June 2020)	• Pending
	• Ongoing community inventory surveillance	• *Eliminated*
	• Ongoing monitoring of community-based co-occurring studies and evaluation for possible incorporation into evaluation	• *Eliminated*
	• Run TCM measures and conduct data analysis for timeframe 5/1/17 – 4/30/18	• Ongoing
	• Run annual administrative measures and conduct data analysis/trending for timeframe 5/1/17 – 4/30/18	• Ongoing
	• Monitor change in enrollment and services for cost evaluation (*From Year 2)*	• Ongoing
	• Generate quarterly updates	• Ongoing
	• Generate cumulative, interim evaluation report (Calendar Years 2018-2019)	• Ongoing (January 2020)
Eval Contract Year 4: 10/1/2020 – 4/30/2021	• Continue Wave 3 Beneficiary Survey (~48 months post-enrollment: June-Oct 2020) • Summarize Wave 3 Beneficiary Survey analysis and report findings • Implement Wave 3 TCM Provider Survey/Key Informant Interviews (~54 months post TCM implementation: Jan 2021) • Summarize Wave 3 TCM Provider Survey/Key Informant Interviews and report findings • Ongoing community inventory surveillance • Ongoing monitoring of community-based co-occurring studies and evaluation for possible incorporation into evaluation • Run TCM measures and conduct data analysis for timeframe 5/1/18 – 4/30/19 and 5/1/19 - 4/30/20 • Run annual administrative measures and conduct data analysis/trending for timeframe 5/1/18 – 4/30/19 and 5/1/19 - 4/30/20 • Monitor increase in enrollment and services for cost evaluation • Generate quarterly updates	*All Items Deferred*

Revised Time Period	Activities	Status *(as of 12/31/19)*
	• Generate final evaluation report (4/30/2021)	

Methodological Limitations

The major activities in calendar years 2018 included organization of administrative data sources already available to the team as well as planning activities to implement the various surveys needed to supplement the health care claims/encounter data. The evaluation team faced issues early on regarding proposed methods to distinguish beneficiaries potentially eligible for the FME waiver regardless of enrollment as well as how to handle problematic cases (i.e. missing or incomplete data). The execution of three main surveys, beneficiary, TCM Provider and MDHHS waiver staff were a focus during 2019 as well as expanding the scope of the programming needed to report on the measures based on administrative health care data.

The evaluation team further dealt with the observation that enrollees were more geographically distributed than originally expected. The original assumption was that all potential FME enrollees would come from City of Flint residents. However, lead exposure was based on the Flint Water System delivery network of service lines which did not fully align with the city's geographic boundaries. This caused the team to adjust the planned approach for acquiring data from the MDHHS Data Warehouse for enrollees and potential comparison groups. The sampling strategy for the beneficiary survey also needed adjustment to incorporate a stratified method in order to accommodate this observation.

Another limitation was the inability to secure a federal Department of Education waiver to permit MDE to share education data at the individual level for linking with health care data. The evaluation team identified other data sources in response to this barrier. The evaluation team reached out to MSU faculty involved with school based public reporting. These data may provide context to the impact of the lead exposure on the educational attainment of students in the community schools however the team will be unable to quantify the impact of the waiver's offerings. The team may also utilize anecdotal data from key stakeholders of the Flint Schools and Neurodevelopmental Center for Excellence as well as related published studies to again provide context to findings. The beneficiary survey was the final data source identified as potentially useful for obtaining education related information. Several questions were designed to inquire about learning and emotional/behavioral problems for the child survey. While self-report is not without limitations, the evaluation team chose to pursue all available options.

Another limitation the evaluation team faced was the practice of individualized program data management. Several state-sponsored health related registries were not housed in MSA due to their inclusion of populations outside of Medicaid enrollees. This included both the lead screening and the MCIR data. Separate data access request and approvals were needed to acquire these data elements. Access to the lead screening data was granted during 2019 while access to MCIR data remains pending.

As the evaluation team began meeting with organizations involved in serving Flint community residents, they became aware of entities involved in FME waiver service delivery beyond what was initially identified. Thus, the evaluation was expanded to include certain data elements such as TCM provider input. Additionally, we encountered timing barriers affecting our plans to implement the beneficiary survey. The extended approval and contracting timeframe shortened the original timeline of proposed activities.

The hypotheses as written in the waiver application referenced comparing individuals enrolled in the FME waiver to others with similar BLLs. The evaluation team still intends to link available blood lead values to individuals enrolled in the waiver, yet it was acknowledged that available data may not accurately reflect actual BLLs during the exposure period. In fact, current water testing is showing lead levels below accepted national standards, but the water system still has not yet been deemed “safe” as of January 2020. This designation cannot be granted until all affected (corroded) water service lines have been replaced. Thus, there may be ongoing exposure occurring in the population which is difficult to quantify.

The implementation of this evaluation project to date had several strengths. Gained partnerships and communications with key stakeholders to inform the evaluation were invaluable in identifying alternatives for data or methods to acquire data. Particularly, the close collaboration with the CDC funded Flint Registry project has provided supplemental information and access to interactions with a cohort of affected Flint residents. One example of the direct impact of this relationship on the evaluation operations was noted in the beneficiary survey. Members of a Flint Registry Parent Advisory Group provided information on the willingness and ability to complete web-based surveys which caused the evaluation team to reconsider planned survey methods. As the Wave 1 survey had not yet been distributed, an online version was included and positively received by those invited to participate.

Preliminary Results

Results presented as part of this interim evaluation include data available to the evaluation team and summarized as of December 31, 2019 based on evaluation activities occurring between January 2018 – December 2019. The findings are presented by Evaluation Domain and relevant hypotheses. Where available, administrative health care claims or enrollment data as far back as May 2015 was obtained in order to provide estimates for the year prior to the waiver implementation which occurred May 2016. Because of time needed to allow claims processing to occur, the most recent utilization data available for this interim report ends April 2019.

Comparison Group Considerations

In many of the measures identified for the hypotheses, they were worded in such a manner to propose that FME enrollees will have better access *compared with others with similar levels of lead exposure*. The reference to others reflects on the selection of an appropriate comparison group. As described in the Target and Comparison Populations section, each of the four potential comparison populations suffered from limitations. The most significant of which is the inability to accurately quantify the level of lead exposure from what is most frequently a one-time blood draw. Despite this issue which the team acknowledged to persist among all the potential comparison groups, a decision was made to focus on the third group described as *communities known to have similarly elevated lead exposures*.

The evaluation team considered two approaches in selection of this comparison group. In the first approach, we considered the K means method to find a lower-peninsula county similar to Genesee county in health outcomes, health behavior, clinical care, social economic environment, and physical environment. These factors are used by the Robert Wood Johnson Foundation and the University of Wisconsin Population Health Institute to rank counties in the U.S. by these vital health factors. We chose these confounding characteristics (a total of 48 variables) under the assumption that counties with similar characteristics affecting lead exposures would have similar levels of lead exposures. We used the Gap statistic to first estimate the number of clusters in the data and then used 10,000 random starting values to run the K means algorithm to count how many times a county was assigned to the same cluster as Genesee County.[8] The county that was most often clustered together with Genesee county was chosen as the comparison county. The preliminary result indicated the 68 lower-peninsula counties were best grouped in four clusters and the county most often clustered together with Genesee county was Saginaw county.

The second approach the evaluation team considered was the synthetic control method.[9] Since no single county was as like Genesee county in all characteristics under consideration, we

planned to explore using a weighted combination of counties as controls. The key data for this approach was the Michigan Childhood Lead Poisoning Prevention Program Data Report series from 2005 to 2015.

Both approaches were limited by the availability of data and comparisons would have been ideal at the city level. The cities of Pontiac and Saginaw were considered as they were similar in size, racial composition, socioeconomic distress, initial development, economic trajectory, and current housing landscape as Flint. Thus, risk factors for lead exposure were similar across all three communities. Pontiac was additionally suitable as a comparison community because, like Flint, it has been served by the Great Lakes Water Authority (formerly the Detroit Water & Sewerage Department). These communities further share the existence of a spread of wealthier suburbs surrounding them which may offer comparison opportunities. Additional potentially suitable communities included the smaller metropolitan areas of Jackson, Muskegon, and Kalamazoo. However, city-level characteristics data were difficult to obtain which made it difficult to quantify the similarities. Thus, we restricted our choice of geographic comparison group to the county level. Once a county comparison approach is finalized using the K-means approach or a weighted combination of counties using the synthetic control approach is determined and constructed, the evaluation team will further explore person-level characteristics to comparison persons like the FME enrollees.

Since the evaluation team continues to finalize the choice of comparison group(s), the results presented in this interim report focus on the experience of the FME enrollees and their patterns over time. Direct comparisons to control group estimates will be provided in the final evaluation report.

Potentially Eligible Waiver Population Characteristics

The expansion effective date was set at 5/1/2016. Residency in the City of Flint or Genesee County was not required for enrollment into the FME waiver. Initial methods to identify potentially eligible individuals using a list of seven Flint zip codes was found to be incomplete when compared to the City's water service distribution network. Therefore, the State of Michigan added four zip codes representing areas that existed outside of the City of Flint's geographic boundaries yet were exposed to the affected water. This full list of eleven zip codes represented the Flint Water Service Area (FWSA) and was used to identify potentially eligible individuals. The eleven zip codes were all contained within the geographic boundaries of Genesee County. The evaluation team also noted potentially eligible individuals relocating to other geographic areas since the water crisis. Based on data contained in enrollment records, individuals relocated since the water switch outside of the FWSA and even outside of Genesee County to elsewhere in the state. We theorized that individuals who relocated may have had

different levels of resources than those who remained in the same location. This will be empirically tested upon acquisition of all the data.

Upon meeting potential eligibility criteria, enrollment in the FME waiver further required evidence of exposure to the contaminated water. We identified individuals officially enrolled in the waiver using a combination of Modified Adjusted Gross Income (MAGI) and Medicaid Benefit Plan codes available through the MDHHS Health Services Data Warehouse. Enrollees were identified by a MAGI code beginning with "F" along with a current benefit plan of "TCMF". Pregnant women eligible and enrolled in the Waiver were identified through a combination of eligible MAGI codes along with Medicaid Scope and Coverage codes and claims related to live births. These coding algorithms were reviewed with MDHHS colleagues for accuracy.

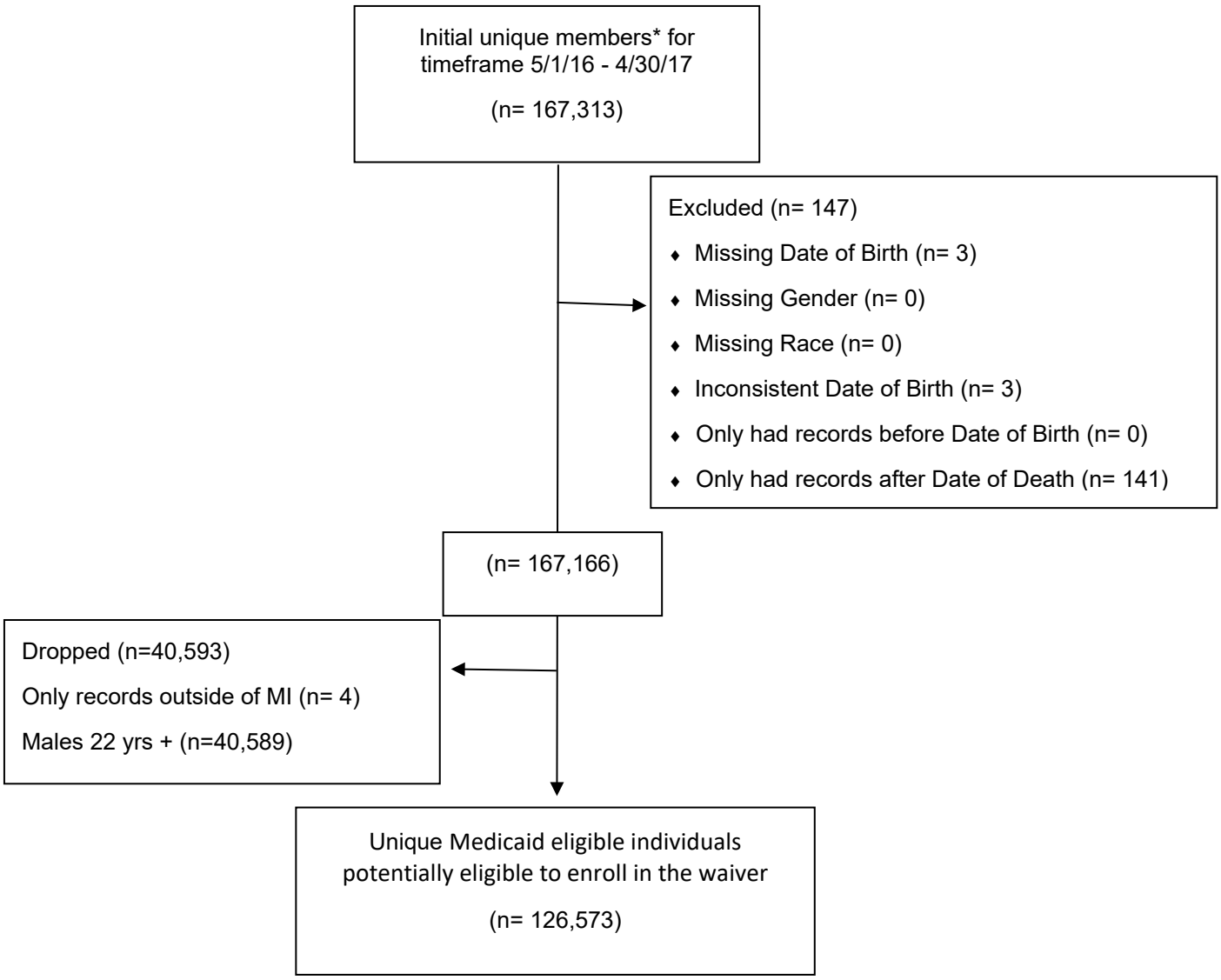
Using Medicaid eligibility and FME waiver enrollment data contained in the MDHHS Health Services Data Warehouse, Table 5 described the potentially covered population and selected data cleaning steps performed on the original cohort. Table 5 further quantified the number of individuals being dropped from analyses due to potentially problematic/erroneous data. This process is also displayed in Figure 1.

Table 5: Potentially covered population identified* for 12 months preceding and three years following FME Waiver Start (5/2016)

Timeframe	Pre FME	Post FME		
	5/1/15—4/30/16	5/1/16—4/30/17	5/1/17—4/30/18	5/1/18—4/30/19
Initial unique potentially eligible members identified	169,713	167,313	168,958	166,662
Missing date of birth	8	3	0	0
Missing gender	0	0	0	0
Missing race	0	0	0	0
Inconsistent year of birth	20	2	0	0
Inconsistent month of birth	4	1	0	0
Only had eligibility records before recorded date of birth	1	0	5	0
Only had eligibility records after recorded date of death	177	141	166	188
Only had eligibility records outside Michigan	7	4	37	19
Males age 22 and older as of 10/1 of the target year	40,746	40,589	41,653	40,834
Total potentially eligible members retained	128,750	126,573	127,097	125,621

*Potentially covered population includes anyone with history residing in Genesee County, meeting FME waiver age and pregnancy criteria only plus anyone else formally enrolled in the FME waiver.

Figure 1: Sample eligibility cleaning process applied



*Potentially covered population includes anyone with history residing in Genesee County meeting FME waiver age and pregnancy criteria only plus anyone else formally enrolled in the FME waiver.

The potential eligible cohort definition used by the evaluation team exceeded the number estimated by the State of Michigan in the FME waiver application (n=15,000 newly eligible plus n=30,000 existing Medicaid beneficiaries). This was because the evaluation team was originally interested in using others in a similar geographic region as potential controls. Figure 2 identified FME enrollment statistics reflecting the proportion of the potential eligible cohort that ultimately enrolled. The figure further described the proportion of those enrolled that would have been identified using only the FWSA definition, 89.3%. This suggested the remaining 10%

of those successfully enrolled in the FME waiver did not necessarily live in the FWSA area potentially affecting access to other, non-Medicaid community formal and informal supports.

Figure 2: Year 1 FME Enrollment Among Potentially Eligible Cohort (n=126,572)

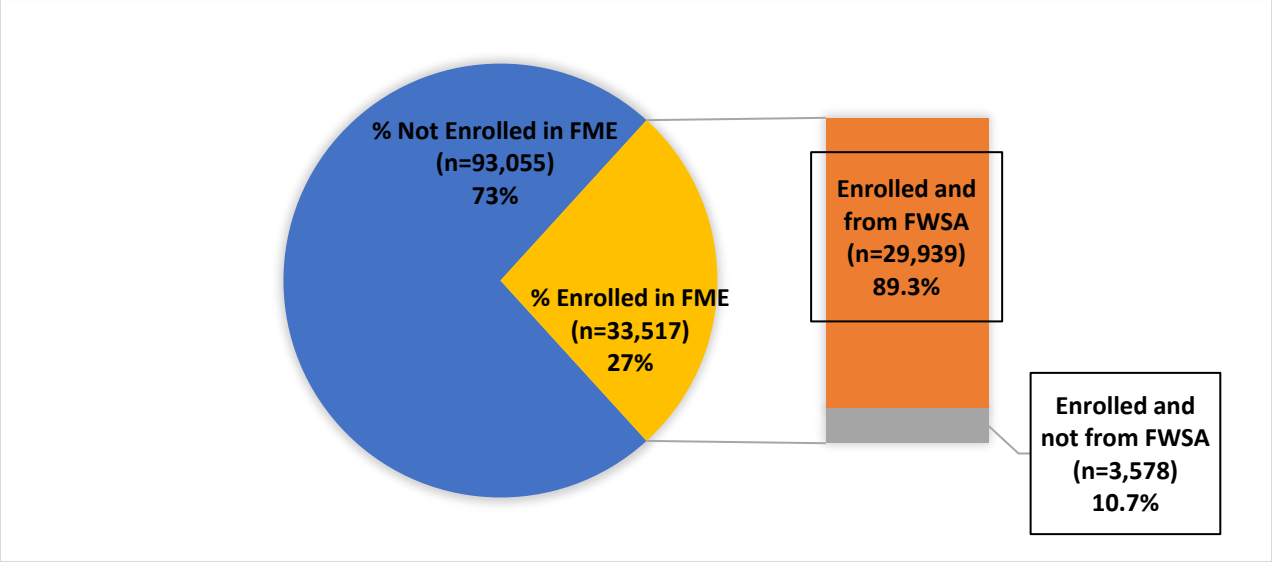


Table 6 displayed the socio-demographic characteristics of the potentially eligible cohorts, those in Genesee County, those residing in the FWSA and those who enrolled in the FME waiver. Minimal variation was observed between the two timeframes (pre-post FME start) for population characteristics of the potentially eligible cohort residing in Genesee County. As we restricted to the FWSA geographic region which included the City of Flint, little variation was noted among the age and gender proportions. However, the proportion of non-Hispanic, African American beneficiaries identified as potentially eligible increased nearly 10% with a corresponding decrease noted in the number of non-Hispanic, White beneficiaries. This observation was consistent with the racial make-up of the City of Flint.

Table 6: Population characteristics of Potentially Eligible before and after May 1, 2016.

	Medicaid Eligible in Genesee County plus Statewide FME Waiver Enrollees		Medicaid Eligible in FWSA*		FME Waiver Enrollees (5/1/16 – 4/30/17)	
	Pre FME Waiver 5/1/15—4/30/16	Post FME Waiver 5/1/16—4/30/17	Pre FME Waiver 5/1/15—4/3/16	Post FME Waiver 5/1/16—4/30/17	Total	FWSA Subgroup
Count of unique Medicaid beneficiaries	N=128,750	N=126,572	N=107,520	N=106,123	N=33,516	N=29,939
Age (Years, as of October 1 of each year)						
0-6	22.0%	22.1%	22.6%	22.5%	39.8%	39.5%
7-16	25.0%	24.9%	24.2%	24.4%	41.2%	41.7%
17-21	11.6%	11.4%	11.5%	11.1%	14.9%	14.7%
22-64	37.8%	37.9%	38.6%	38.7%	4.1%	4.0%
65+	3.5%	3.6%	3.1%	3.2%	(22+)**	n/a
Gender						
Male	29.6%	29.4%	29.3%	29.1%	47.9%	48.2%
Female	70.4%	70.6%	70.7%	70.9%	52.1%	51.8%
Race/Ethnicity						
non-Hispanic white	55.2%	55.0%	43.3%	43.2%	31.9%	29.5%
non-Hispanic black	34.6%	34.8%	47.6%	47.8%	59.6%	62.4%
Hispanic/Other	4.1%	4.2%	4.0%	4.0%	4.3%	4.2%
Unknown	6.1%	6.0%	5.1%	5.0%	4.3%	4.0%
Residence Category						
Always Genesee County	55.2%	55.0%	99.0%	98.3%	90.7%	95.8%
Partial Genesee County	34.6%	34.8%	1.0%	1.7%	4.2%	4.1%
Never Genesee County	4.1%	4.2%	0.0%	0.1%	5.1%	0.1%
FME Waiver Enrollment						
Proportion having any FME enrollment	n/a	26.5%	n/a	37.7%	100%	100%
Pregnancy Indicator	2.6%	3.0%	2.8%	3.2%	4.8%	4.6%
Federal Poverty Level Category (% FPL)						
FPL 0 - 99%	81.5%	79.1%	83.9%	81.1%	76.9%	77.6%
FPL 100 - 199%	17.3%	19.3%	15.2%	17.4%	19.8%	19.4%
FPL 200 - 299%	1.2%	1.4%	0.8%	1.2%	2.6%	2.4%
FPL 300% +	0.1%	0.2%	0.1%	0.2%	0.6%	0.6%

**FWSA defined by full listing of 11 Zip codes serviced by Flint Water System*

***Categories collapsed due to small cell sizes*

Table 7 shows some sociodemographic changes when reviewing the most recent enrollment year (5/1/18 – 4/30/19). Turning attention to the characteristics of the FME enrolled population, we observed the proportion of the younger age categories substantially increased as designed by the waiver criteria. The gender distribution remained relatively unchanged. Another 10% increase in the non-Hispanic, African American segment of FME waiver enrollees was observed. Ten percent of those enrolled in FME resided outside of Genesee County at some point during their coverage. This highlighted the importance of the water exposure screening criteria allowing for individuals to access the services even if they did not live in the City of Flint. FME also appeared to be successful in reaching out to pregnant women for coverage. According to enrollment data, it appeared the FME was having success at recruiting and covering individuals at the higher income levels permitted under the waiver.

Table 7: Population characteristics of Potentially Eligible before May 1, 2016 and after 5/1/18.

	Medicaid Eligible in Genesee County plus Statewide FME Waiver Enrollees		Medicaid Eligible in FWSA*		FME Waiver Enrollees (5/1/18 – 4/30/19)	
	Pre FME Waiver 5/1/15—4/30/16	Post FME Waiver 5/1/18—4/30/19	Pre FME Waiver 5/1/15—4/3/16	Post FME Waiver 5/1/18—4/30/19	Total	FWSA Subgroup
Count of unique Medicaid beneficiaries	N=128,750	N=125,621	N=107,520	N=104,275	N=31,805	N=26,135
Age (Years, as of October 1 of each year)						
0-6	22.0%	21.9%	22.6%	16.5%	35.4%	35.0%
7-16	25.0%	25.3%	24.2%	18.4%	45.6%	46.2%
17-21	11.6%	11.3%	11.5%	8.2%	16.3%	16.3%
22+	41.3%	41.5%	41.7%	56.9%	2.8%	2.5%
Gender						
Male	29.6%	29.5%	29.3%	47.1%	49.2%	49.5%
Female	70.4%	70.5%	70.7%	52.9%	50.8%	50.5%
Race/Ethnicity						
non-Hispanic white	55.2%	54.4%	43.3%	43.6%	33.1%	29.0%
non-Hispanic black	34.6%	35.3%	47.6%	46.8%	58.3%	63.0%
Hispanic/Other	4.1%	4.4%	4.0%	4.1%	4.3%	4.2%
Unknown	6.1%	5.9%	5.1%	5.5%	4.3%	3.8%
Residence Category						
Always Genesee County	55.2%	96.8%	99.0%	99.1%	87.4%	96.4%
Partial Genesee County	34.6%	0.9%	1.0%	0.9%	3.5%	3.5%
Never Genesee County	4.1%	2.3%	0.0%	0.0%	9.0%	0.1%
FME Waiver Enrollment						
Proportion having any FME enrollment	n/a	25.3%	n/a	25.1%	100.0%	100.0%
Pregnancy Indicator	2.6%	2.9%	2.8%	2.3%	3.3%	3.0%
Federal Poverty Level Category (% FPL)						
FPL 0 - 99%	81.5%	79.4%	83.9%	84.3%	76.1%	76.7%
FPL 100 - 199%	17.3%	18.7%	15.2%	14.4%	19.5%	19.1%
FPL 200 - 299%	1.2%	1.6%	0.8%	1.1%	3.4%	3.3%
FPL 300% +	0.1%	0.3%	0.1%	0.2%	1.0%	0.9%

FME Waiver Enrollment

Table 8 displays the change in socio-demographic characteristics among those who were enrolled in the FME waiver regardless of residence since the start of the FME waiver from May

2016 to April 2019. An increasing number of beneficiaries who enrolled in FME now reside outside Genesee county. The observation of a decline in overall enrollment since waiver approval confirmed the pattern anticipated by Medical Services Administration (MSA) informants. The waiver authorized individuals at higher FPL to qualify for the benefit and for those exceeding the 400% threshold, to buy into the program in order to secure access to TCM. The use by individuals at these higher income thresholds continues to be small.

Over the three years, a total of 40,543 unique beneficiaries had at least one FME enrollment month, among whom 25,641 (63%) enrolled for all three years. Approximately 6%, (n=2,486) of unique beneficiaries newly enrolled during the 2018/19 timeframe.

Table 8: Total Medicaid statewide FME waiver enrollees from May 1, 2016 to April 30, 2019

	FME Waiver Enrollee (5/1/16-4/30/17)	FME Waiver Enrollee (5/1/17-4/30/18)	FME Waiver Enrollee (5/1/18-4/30/19)
Count of unique Medicaid beneficiaries	N=33,516	N=33,921	N=31,801
Age (Years, as of October 1 of each year)			
0-6	39.8%	38.0%	35.4%
7-16	41.2%	42.6%	45.6%
17-21	14.9%	16.1%	16.3%
22+	4.1%	3.3%	2.7%
Gender			
Male	47.9%	48.6%	49.2%
Female	52.1%	51.4%	50.8%
Race/Ethnicity			
non-Hispanic white	31.9%	32.8%	33.1%
non-Hispanic black	59.6%	59.0%	58.4%
Hispanic/Other	4.3%	4.3%	4.3%
Unknown	4.3%	4.0%	4.3%
Residence Category			
Always Genesee County	90.7%	88.6%	87.4%
Partial Genesee County	4.2%	4.0%	3.5%
Never Genesee County	5.1%	7.3%	9.0%
Federal Poverty Level Category (% FPL)			
FPL 0 - 99%	75.6%	76.0%	76.1%
FPL 100 - 199%	20.9%	20.0%	19.5%
FPL 200 - 299%	2.8%	3.2%	3.4%
FPL 300% +	0.7%	0.8%	1.0%

Domain 1: Access to Care

The main hypothesis for Domain 1 focused on access to care: *"Enrollees will access services to identify and address physical or behavioral health issues associated with lead exposure at a rate higher than others with similar levels of lead exposure*." Nine specific sub-hypotheses were identified to provide measures of access for both targeted populations, children and pregnant women. Sub-hypotheses 1.1 through 1.5 were chosen for their applicability to a pediatric population while items 1.5, 1.6 and 1.7 were relevant for pregnant women. These seven sub-hypotheses used administrative health care claims for evaluation. Baseline information was calculated for the pre-water switch timeframe (May 2013 – April 2014) through the most recent completed available data year (May 2018 – April 2019). The last two sub-hypotheses acquired the necessary data through the beneficiary survey process.

Sub-hypotheses 1.1: Improved Access to Care

- 1.1: *A greater proportion of enrollees will obtain age-appropriate well-child exams compared to others with similar lead exposures*.

The Well-Child Check HEDIS Measure was defined in terms of three age groups. The first metric included the percentage of children 15 months old who had the recommended number of well-child visits with a PCP during their first 15 months of life. The second metric focused on children 3-6 years of age having a well-child visit during the year. The last metric reported on adolescents from 12-21 years of age.

Table 9 reflects the proportion of continuously eligible children who received at least one well-child check. The evaluation team restricted to children that were continuously enrolled to ensure that complete claims/encounter data was available through the Medicaid Health Services Data Warehouse when assessing service use. Imposing the requirement for continuous eligibility retained a majority (>80%) of all possible beneficiaries for the age group up to 15 months. The retention of beneficiaries for reporting increased to at least 90% for both older groups. When the team compared the reporting rates between those who were ever enrolled (i.e. not continuously enrolled) with those who were continuously enrolled, the results were approximately within five percent with the "ever enrolled" consistently being lower. This was not unexpected as there would be no way to document health services delivered and paid for by other insurance or programs during periods of Medicaid ineligibility. When a comparison group is identified, results may prove to be more informative.

Table 9. Well-Child Visits for all Age Groups Eligible 5/1/2013 – 4/30/19

	5/1/2013—4/30/2014	5/1/2014—4/30/2015	5/1/2015—4/30/2016	5/1/2016—4/30/2017*	5/1/2017—4/30/2018*	5/1/2018—4/30/2019*
Well-Child Visits in the First 15 Months of Life						
N	N=11573	N=11090	N=10719	N=6108	N=6279	N=6127
Had any visits	8170 (70.6%)	7814 (70.5%)	7525 (70.2%)	4317 (70.7%)	4490 (71.5%)	4559 (74.4%)
Well-Child Visits at Age 3, 4, 5, and 6 Years						
N	N=11573	N=11090	N=10719	N=6108	N=6279	N=6127
Had any visits	8170 (70.6%)	7814 (70.5%)	7525 (70.2%)	4317 (70.7%)	4490 (71.5%)	4559 (74.4%)
Adolescent Well-Care Visits Age 12 -21 years.						
N	N=11573	N=11090	N=10719	N=6108	N=6279	N=6127
Had any visits	8170 (70.6%)	7814 (70.5%)	7525 (70.2%)	4317 (70.7%)	4490 (71.5%)	4559 (74.4%)

*FME continuous enrollee results

Sub-hypotheses 1.2: Improved Access to Care

- 1.2: *A greater proportion of enrollees will receive age-appropriate developmental screening/assessments compared to others with similar lead exposures.*

It is known that lead is a neurotoxin and that children exposed to high levels of lead may experience poor developmental and behavioral health. Thus, developmental and behavioral screening is necessary to assess problems early for timely treatment to mitigate poor outcomes. Thus, to address sub-hypotheses 1.2, observed rates based on administrative claims data for any number of developmental and behavioral screening visits in the first three years of life are presented in Table 10. As with 1.1, rates reported are based on continuous eligibility from 5/1/2013 to 4/30/2019 for children age 1, 2 or 3 years old. For 2013-2014, before the water crisis, 7% of children had developmental screening visits. This rate increased to 19.8% during the first year of the water crisis, 2014 – 2015 and 25% in 2015-2016 before the waiver was administered. The proportion having at least one developmental screening visit for those enrolled in the waiver continues to increase over time.

Table 10. Developmental/Behavioral Screening visits in the First Three Years of Life (eligible 5/1/2013-4/30/2019

	5/1/2013—4/30/2014	5/1/2014—4/30/2015	5/1/2015—4/30/2016	5/1/2016—4/30/2017*	5/1/2017—4/30/2018*	5/1/2018—4/30/2019*
Developmental screening in the first 3 years of life						
N	N=11782	N=11936	N=11777	N=5646	N=5621	N=4297
Had any visits	829 (7.0%)	2358 (19.8%)	2961 (25.1%)	1784 (31.6%)	2053 (36.5%)	1775 (41.3%)

*FME continuous enrollee results

Sub-hypotheses 1.3: Improved Access to Care

- 1.3: *A greater proportion of enrollees will receive age appropriate lead testing compared to others with similar lead exposures*.

Examining lead screening using administrative claims and lab data for children continuously eligible from 5/1/2013-4/30/2019 showed steady increases for all years until 2018-2019. In 2013-2014 reported claims revealed a lead screening rate of 35.2%. In the year of the water crisis, 2014-2015, screening jumped to 70.6% and 72.2% in 2015-2016. Screening in the first year of the waiver implementation (2016-2017) was 81.3% for waiver enrollees. This trend leveled off most recently (2018-2019) to 71.3% for waiver enrollees.

Table 11. Lead Screening in Children using claims or lab data. Eligible 5/1/2013-4/30/19.

	5/1/2013—4/30/2014	5/1/2014—4/30/2015	5/1/2015—4/30/2016	5/1/2016—4/30/2017*	5/1/2017—4/30/2018*	5/1/2018—4/30/2019*
N	N=3624	N=3836	N=3774	N=1849	N=1824	N=1778
Had any BLL testing (N, %)	1274 (35.2%)	2710 (70.6%)	2723 (72.2%)	1503 (81.3%)	1430 (78.4%)	1268 (71.3%)

*FME continuous enrollee results

Sub-hypotheses 1.4: Improved Access to Care

- 1.4: *A greater proportion of enrollees with high blood lead levels will receive re-testing at the appropriate intervals compared to others with similar lead exposures*.

For some children, high BLL can be elevated and given the recent elevated lead content in Flint supplied water re-testing for those children is critical. Affected children documented to have elevated blood lead values need to be re-tested to monitor impacts of treatment. In 2013-2014, BLL re-testing was 8.3% before the water crisis and 11.9% during the water crisis. For the year the waiver was implemented, 32.5% for enrollees needing to be re-tested were re-screened. Rates were similar in 2017-18 at 34.3% and increased to 42.5% for the most recent reporting year (2018-2019).

Table 12. Blood lead level re-testing with children with elevated BLL, 5/1/2013-4/30/19.

	5/1/2013—4/30/2014	5/1/2014—4/30/2015	5/1/2015—4/30/2016	5/1/2016—4/30/2017*	5/1/2017—4/30/2018*	5/1/2018—4/30/2019*
N	N=205	N=226	N=351	N=246	N=143	N=80
Had any BLL retesting (N, %)	17 (8.3%)	27 (11.9%)	83 (23.6%)	80 (32.5%)	49 (34.3%)	34 (42.5%)

*FME continuous enrollee results

Sub-hypotheses 1.5: Improved Access to Care

- 1.5: *Enrollees who are pregnant will have more timely prenatal and postpartum care compared to others with similar lead exposures*.

Prenatal and postpartum care is essential especially during environmental crises whereby the mother and baby may be at physical (lead exposure, miscarriage) and behavioral risks (toxic stress, postpartum depression). To address sub-hypothesis 1.5 claims data was examined to assess timeliness of prenatal care according to accepted HEDIS specifications (e.g., percentage of deliveries that received a prenatal care visit in the first trimester, on the enrollment start date or within 42 days of enrollment in the organization). As the HEDIS specification for identifying prenatal and postpartum care requires the practitioner type to be "an OB/GYN or other prenatal care practitioner or PCP", whereas the administrative claims data does not fully document the billing and rendering provider information, the evaluation team chose to present three algorithms for identifying prenatal and postpartum care. In algorithm #1, we used only the procedure (CPT) and diagnosis (DX) codes related to prenatal care (bundled to stand alone visits); in algorithm #2, we considered either the CPT/DX codes or the provider taxonomy codes to capture the most records; and in algorithm #3, we used both the CPT/DX codes and the provider taxonomy codes, which most the most stringent criteria, but subject to missing provider information. Table 13 shows that although there was a steady decline in the number of births, the proportion of timely prenatal and postpartum care remained relatively high using the first two algorithms.

Table 13. Timeliness of Prenatal Care 5/1/2013-4/30/19

	5/1/2014—4/30/2015	5/1/2015—4/30/2016	5/1/2016—4/30/2017*	5/1/2017—4/30/2018*	5/1/2018—4/30/2019*
N	2,871	2,567	1070	762	432
Algorithm #1 (CPT/DX)					
Had prenatal care visit (N, %)	1839 (64.1%)	1848 (72.0%)	762 (71.2%)	535 (70.2%)	299 (69.2%)
Algorithm #2 (CPT/DX or taxonomy)					
Had prenatal care visit (N, %)	2043 (71.2%)	1983 (77.1%)	812 (75.9%)	573 (75.2%)	333 (77.1%)
Algorithm #3 (CPT/DX and taxonomy)					
Had prenatal care visit (N, %)	1750 (61.0%)	1613 (62.8%)	353 (33.0%)	271 (35.6%)	165 (38.2%)

*FME continuous enrollee results. Due to additional requirements for prenatal and postpartum care measures, the sample size in Tables 12 and 13 are slightly different.

Sub-hypotheses 1.6: Improved Access to Care

- 1.6: *A greater proportion of enrollees who are pregnant will have recommended lead testing compared to others with similar lead exposures*.

Lead screening for pregnant women is important to mitigate adverse birth outcomes associated with the exposure to high levels. This sub-hypothesis reported lead screening in pregnant women having a live birth. Prior to the water crisis, 5/1/2013-4/30/2014, very few data points were identified as evidence for this screening. However, in 2015-2016, during the time when pregnant women were mostly likely exposed to lead and the crisis was public, lead screening increased to 10.2% of the eligible beneficiaries. These rates continued to increase even higher for women enrolled in the waiver.

Table 14. Lead Screening in pregnant women with live birth using claims and lab data, 5/1/2013-4/30/19

	5/1/2013—4/30/2014	5/1/2014—4/30/2015	5/1/2015—4/30/2016	5/1/2016—4/30/2017*	5/1/2017—4/30/2018*	5/1/2018—4/30/2019*
N	N=3354	N=3220	N=2938	N=1119	N=866	N=545
Had any BLL testing (N, %)	2 (0.1%)	7 (0.2%)	300 (10.2%)	780 (69.7%)	638 (73.7%)	428 (78.5%)

*FME continuous enrollee results. Due to additional requirements for prenatal and postpartum care measures, the sample size in Tables 12 and 13 are slightly different.

Sub-hypotheses 1.7: Improved Access to Care

- 1.7: *A greater proportion of enrollees will participate with home visiting services compared to others with similar lead levels*.

In Michigan, enhanced prenatal services are available through a home visiting service called the Maternal Infant Health Program (MIHP). This program is intended to address high risk pregnancies with an increase of specialized services. The program may also offer transportation and birthing classes along with professional visits. Since the interest in this measure was to evaluate active program engagement, the team restricted on professional visits. Administrative health care data assessing for MIHP services was reviewed. Prior to the water crisis, 27.4% of live births showed evidence of MIHP participation. This rate was essentially unchanged during the two years of the initial water crisis. Waiver enrollees appeared to have a slight increase in participation followed by a downward trend. Reasons for this decline are not well-understood. The evaluation team plans to reach out to MIHP program staff to learn whether larger scale program participation changes have been documented. The results of those discussions will inform the final evaluation report.

Table 15. MIHP participation with Medicaid deliveries of live births (5/1/2013-4/30/2019).

	5/1/2013—4/30/2014	5/1/2014—4/30/2015	5/1/2015—4/30/2016	5/1/2016—4/30/2017*	5/1/2017—4/30/2018*	5/1/2018—4/30/2019*
N	N=3354	N=3220	N=2938	N=1119	N=866	N=545
Had any MIHP (profv) visit (N, %)	918 (27.4%)	878 (27.3%)	835 (28.4%)	338 (30.2%)	234 (27.0%)	121 (22.2%)

*FME continuous enrollee results.

Sub-hypotheses 1.8: Improved Access to Care

The beneficiary survey was the primary vehicle to obtain data regarding enrollee rating of the success of the waiver in improving their health care as specified in sub-hypotheses 1.8 and 1.9. For this interim report, the first wave was completed and analyzed. Refer to Appendix 4 for the full report. The second wave remains in process.

- 1.8: *Enrollees will attest to improved access to health care as a result of the expanded coverage.*

Although most respondents reported that they were already enrolled in Medicaid for both the child (85%) and adult (80%) survey participants, over 400 individuals presumably experienced this as a new form of coverage. Table 16 shows the proportion of respondents selecting each answer option.

Table 16. Reasons for Enrollment in Medicaid

Question	Child N=2356	Adult N=225	Total N=2581
What were the reasons you enrolled (your child) in the Flint Medicaid Waiver? ***Check all that apply***	N (%)	N (%)	N (%)
Already enrolled in Medicaid	1994 (84.5)	179 (79.6)	2173 (84.2)
To get health services	574 (24.4)	70 (31.1)	644 (25.0)
For targeted case management/family supports services	247 (10.5)	20 (8.9)	267 (10.3)
Help with behavioral or emotional issues	236 (10.0)	25 (11.1)	261 (10.1)
To lower health costs	162 (6.9)	16 (7.1)	178 (6.9)
Other reason	117 (5.0)	8 (3.6)	125 (4.8)

Two questions were posed to respondents asking about the ease of obtaining health care services related to enrollment in the waiver. The first question asked generally about the level

of difficulty obtaining services. A follow-up question specifically asked respondents whether the level of difficulty had decreased.

When asked about the ease of getting health care since enrollment in the Medicaid program, more than half of all survey participants (53%) reported that it was *easy* and an additional 29% reported it was *fairly easy*. Respondents answering on behalf of children were more likely to rate getting health care since enrollment *easy* compared to adult respondents (Table 17).

Table 17: General Ease of Getting Health Care

Question	Child N=2330	Adult N=221	Total Respondents N=2551
Since enrolling in the Flint Medicaid waiver, how easy was it to get the medical care, tests, or treatment you (your child) needed?	N (%)	N (%)	N (%)
Easy	1269 (54.4)	94 (42.5)	1363 (53.4)
Fairly Easy	672(28.8)	80 (36.2)	752 (29.5)
Not Easy, Not Difficult	306 (13.1)	38 (17.2)	344 (13.5)
Difficult	68 (2.9)	6 (2.7)	74 (2.9)
Very Difficult	15 (0.6)	3 (1.4)	18 (0.7)

More than half (60%) of both survey cohorts (child and adult) *strongly agreed* or *agreed* with the statement that the Flint Medicaid waiver made it easier to get the health care they or their child needed. Results for these items are displayed in Table 18.

Table 18. Specific Flint Medicaid Waiver Makes it Easier to Get Health Care

Question	Child N=2337	Adult N=222	Total N=2559
Being in the Flint Medicaid waiver made it easier to get the health care I (my child) needed.	N (%)	N (%)	N (%)
Strongly Agree	550 (23.5)	52 (23.4)	601 (23.5)
Agree	782 (33.5)	81 (36.5)	863 (33.7)
Neutral	855 (36.6)	74 (33.3)	930 (36.3)
Disagree	106 (4.5)	10 (4.5)	116 (4.5)
Strongly Disagree	44 (1.9)	5 (2.2)	49 (1.9)

Sub-hypotheses 1.9: Improved Access to Care

- 1.9: *Enrollees will report improved satisfaction with their ability to access health care as a result of the expanded coverage.*

Beyond simply offering the opportunity for expanded access and coverage, another aspect related to uptake was the overall satisfaction beneficiaries reported with their waiver experiences. The expanded coverage was offered through the health plans that operate in the affected geographic region. Thus, waiver participants had the benefit of existing health plan relationships with a variety of health care and community providers.

Several questions were asked on the survey targeting specific aspects of the waiver coverage. A general rating question was asked of participants. Respondents to the child survey rated the coverage slightly better than the adult survey respondents (7.4 vs. 6.9) as displayed in Table 19.

Table 19. Satisfaction with Flint Medicaid Waiver

Question	Child N=2312 Mean (SD)	Adult N=224 Mean (SD)	Total N=2536 Mean (SD)
Choosing a number from 0 to 10, where 0 is the worst and 10 the best, what number would you use to rate your overall Flint Medicaid waiver experience?	7.4 (3.1)	6.9 (2.3)	7.4 (3.0)

An additional satisfaction question targeted health care providers generally. Regarding health care providers working in the beneficiary's best interest, approximately 64% *strongly agreed* or *agreed* with the statement (Table 20).

Table 20. Satisfaction with Health Care Providers Working in Beneficiary Interest

Question	Child N=2333	Adult N=222	Total N=2555
Since enrolling in the Flint Medicaid waiver, I feel that the health care providers are working in my (child's) best interest.	N (%)	N (%)	N (%)
Strongly Agree	590 (25.3)	49 (22.1)	639 (25.0)
Agree	910 (39.0)	89 (40.1)	999 (39.1)
Neutral	704 (30.2)	67 (30.2)	771 (30.2)
Disagree	98 (4.2)	11 (5.0)	109 (4.3)
Strongly Disagree	31 (1.3)	6 (2.7)	37 (1.4)

Sub-hypotheses 1.8-1.9: Improved Access to Care – Wave 1 to Wave 2 Variation

Wave 2 of the enrollee survey is currently in process. For those questions included in both waves, the evaluation team explored changes over time between the two waves. These results are *preliminary* and only represent one-third of the Wave 1 participant cohort. They are presented only to provide some indication of patterns that have emerged to date.

Between Wave 1 and Wave 2, the proportion of available respondents acknowledging the waiver made it *easy* to get care increased. The shift appeared to be a result of the decline in those that originally reported having a neutral opinion.

Table 21: General Ease of Getting Health Care

Question	Child		Adult		Total Respondents	
	Wave 1 N =2330	**Wave 2 N=786**	**Wave 1 N=221**	**Wave 2 N=64**	**Wave 1 N=2551**	**Wave 2 N=850**
Since enrolling in the Flint Medicaid waiver, how easy was it to get the medical care, tests, or treatment you/your child needed?	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Easy	1269 (54.4)	492 (62.6)	94 (42.5)	20 (31.3)	1363 (53.4)	512 (60.2)
Fairly Easy	672 (28.8)	226 (28.8)	80 (36.2)	28 (43.8)	752 (29.5)	254 (29.9)
Not Easy, Not Difficult	306 (13.1)	48 (6.1)	38 (17.2)	8 (12.5)	344 (13.5)	56 (6.6)
Difficult	68 (2.9)	17 (2.2)	6 (2.7)	7 (10.9)	74 (2.9)	24 (2.8)
Very Difficult	15 (0.6)	3 (0.4)	3 (1.4)	1 (1.6)	18 (0.7)	4 (0.5)

However, essentially no variation has been observed thus far in the overall satisfaction rating between the waves.

Table 22. Satisfaction with Flint Medicaid Waiver

Question	Child Mean (SD)		Adult Mean (SD)		Total Mean (SD)	
	Wave 1 N=2312	Wave 2 N=770	Wave 1 N=224	Wave 2 N=64	Wave 1 N=2536	Wave 2 N=834
Choosing a number from 0 to 10, where 0 is the worst and 10 the best, what number would you use to rate your overall Flint Medicaid waiver experience?	7.4 (3.1)	7.5 (2.4)	6.9 (2.3)	6.9 (2.1)	7.4 (3.0)	7.3 (2.3)

Domain 2: Access to Targeted Case Management

A variety of data sources contributed to the evaluation activities for Domain 2, "*enrollees who access TCM services will access needed medical, social, educational, and other services at a rate higher than others with similar levels of lead exposure".* Data was reported by GHS obtained through tracking they instituted during the operational period of TCM services. Also, administrative and survey data from enrollees and TCM providers garnered additional information. Four sub-hypotheses were identified for testing. Currently available results reflected the total cohort of TCM participants. Access to a comparison group matched on BLL is in progress.

Sub-hypotheses 2.1-2.2: Improved Access to TCM

- 2.1: *Referral source and participation levels with TCM will be tracked among enrollees.*
- 2.2: *All TCM participants will have an annual assessment conducted.*

Table 23 provides information on the number of beneficiaries that GHS screened for eligibility and enrollment into the Flint Waiver and TCM services. The count of individuals decreased over time as expected with the bulk of referrals occurring at the time of waiver approval. The reported counts also included clients served by GFHC. GHS staff reported that most referrals were received from Medicaid Health Plans. These were not "warm" referrals but rather spreadsheets containing contact information which may have impacted participation. GHS staff further described being contacted by several Community Mental Health organizations in different areas of the state where FME enrollees had relocated; none of these organizations ultimately provided formal TCM services.

Table 23. GHS Reported Flint Medicaid Expansion Waiver Consumer Reporting

Flint Water Waiver Aggregate Numbers				
Category	**# of Unique Consumers**			
	5/1/15–4/30/16	**5/1/16-4/30/17**	**5/1/17-4/30/18**	**5/1/18-4/30/19**
Consumers Referred *to* GHS for FME	0	1018	281	174
Consumers Screened *by* GHS for FME	0	1018	281	174
Screening Outcome		N (%)	N (%)	N (%)
Consumers Newly Enrolled in FME	0	249 (24.4)	106 (37.7)	123 (70.7)
Consumers Declining Enrollment in FME	0	10 (1.0)	4 (1.4)	1 (0.6)
Already Enrolled/Unable to Contact*	0	759	171	50
Consumers Having Annual Assessment	0	158	91	61

*Separate counts currently not available

As expected, the majority of GHS' TCM activity occurred during the first year the waiver was available. Referrals to GHS declined over time which aligns with overall enrollment patterns. This finding suggests possibly two scenarios: 1) most people who were eligible and in need of TCM services were screened at the initial offering of the waiver; 2) the screening and enrollment process at GHS has become more refined. Because of the interest in expediting TCM service delivery, some data elements that would have been informative for later evaluation were not identified for capture through specific fields. These elements are often present in progress notes and as the EMR data continues to be evaluated, data abstraction for these elements may occur.

Low participation with TCM was also documented using administrative data sources per Table 24. Specific codes were authorized for billing of TCM annual assessments (CPT T2024) and follow-up visits (CPT T1027). Although a formal comparison group was not available for the hypothesis testing as of the time of this interim report, TCM service utilization was examined in the FME enrolled population statewide. Analyses confirmed these procedure codes were not highly utilized by these beneficiaries. Variation was observed between the manual tracking put in place at GHS compared to the counts reported through claims data. Investigation into these discrepancies has not yet occurred although the relative scale of participation is consistent.

Table 24: Number and Proportion of Total FME Enrollees Using TCM Services per Administrative Health Care Data

Category	# of Unique Enrollees		
	5/1/16-4/30/17 (N, %)	5/1/17-4/30/18 (N, %)	5/1/18-4/30/19 (N, %)
Statewide FME Enrollees with either T2024 or T1027 TCM billing code	1519 (3.1)	1693 (3.5)	2032 (4.3)
Statewide FME Enrollees with T2024 (assessment)	142 (0.3)	37 (0.1)	52 (0.1)
Statewide FME Enrollees with a Reassessment T2024 TCM billing code	1087 (2.2)	1272 (2.6)	1478 (3.1)

Provider reported (GHS, MDHHS) metrics of TCM participation were found to be less than that reported through the Wave 1 beneficiary survey. Approximately 10% of survey respondents overall reported accessing these services. This may reflect an enhanced sensitivity of survey participants to the water crisis. Those interested in taking advantage of the TCM services may be more likely to take the opportunity to respond to the survey as they were more invested in the program.

Table 25: Utilization of Targeted Case Management (TCM) Reported per Beneficiary Survey

Question	Child N=2321	Adult N=221	Total N=2542
Have you ever used any Family Supports Coordination/Targeted Case Management services (for your child) since enrolling in the Flint Medicaid waiver?	N (%)	N (%)	N (%)
Yes	238 (10.3)	26 (11.8)	264 (10.4)
No	2083 (89.7)	195 (88.2)	2278 (89.6)

The evaluation team also conducted Key Informant Interviews with TCM Professionals at GHS and GFHC to obtain additional qualitative information regarding the services and client receptivity. Representatives of both organizations indicated they were able to accommodate all clients and referrals that had been received to date. Currently available staffing levels did not require stratification or triage of referrals.

Data to identify potential reasons for the low uptake of TCM services were not explicitly identified. According to the beneficiary survey, most (>80%) that participated with the program expressed some level (extremely or somewhat) of satisfaction with their experience. The full summary of the Wave 1 survey is available in Appendix 4. TCM Professionals identified some

operational aspects that had opportunities for improvement. For example, TCM providers noted that enrollees sometimes became frustrated with the time it took to put treatment plans into action. They stated that this often was attributed to factors outside of their organizations that hindered receipt of services. It is possible that individual enrollees experiencing delays communicated this to others covered through the waiver adversely affecting interest in participation.

Sub-hypotheses 2.3-2.4: Improved Access to TCM

Two additional sub-hypotheses were developed to document the impact of TCM on individual receipt of care. The logic was enrollees who participated with the TCM program received additional encouragement and assistance in recognizing the importance of the identified screenings and mitigating barriers to securing these screenings. While the waiver itself was hypothesized to increase access to care, TCM specifically was hypothesized to maximize the impact through direct assistance to enrollees in navigating the health care system.

- 2.3: *A greater proportion of TCM participants will have age-appropriate well child exams compared to TCM non-participants.*
- 2.4: *A greater proportion of TCM participants will have completed age-appropriate developmental screening compared to TCM non-participants.*

During the analytic processes, the evaluation team recognized the use of applicable procedure codes in Medicaid beneficiaries who did not appear to be enrolled in the waiver specifically. When evaluating the interim patterns associated with overall receipt of well-child exams, available data suggested that individuals receiving TCM services were more likely to have more visits compared to waiver enrollees overall. Due to ongoing cleaning and validation, data for these hypotheses are suppressed for this interim report.

Domain 3: Improved Health Outcomes

A variety of data sources contributed to the evaluation activities for Domain 3, "*Enrollees will have improved health outcomes compared to others with similar levels of lead exposure".* Not all administrative measures were available for this interim report. Six sub-hypotheses were identified. Three of these were deemed provisional at the time of approval since it was unclear whether the evaluation team would be granted access to the necessary data. As of this report date, confirmation has been received that individual level data maintained by the MDE and protected under FERPA laws would not be provided for evaluation purposes. In response, the evaluation team drafted education related questions to include into beneficiary surveys.

Sub-hypotheses 3.1-3.2: Improved Health Outcomes

- 3.1: *Enrollees will have higher completed age-appropriate immunization statuses compared to others with similar lead exposures.*
- 3.2: *Enrollees who are pregnant will deliver infants with higher birth weights compared to others with similar lead exposures.*
- Provisional 3.4*: Descriptive analysis of the proportion of children diagnosed with severe emotional disturbance and other developmental/learning disabilities including comparing rates to others with similar lead exposures.*
- Provisional 3.5: *Descriptive analysis of behavioral health conditions and supportive care among enrolled children.*
- Provisional 3.6: *Descriptive analysis of educational delays among enrolled children.*

As stated earlier a comparison group is in the process of being identified. Given a comparable population in Michigan, improved health outcomes in relation to the waiver expanded services will be examined for sub-hypotheses 3.1 and 3.2. For the purposes of this interim report, available beneficiary reported health outcomes from the Wave 1 survey are provided to address sub-hypotheses 3.3.

Sub-hypotheses 3.3: Improved Health Outcomes

- 3.3: *Enrollees report an increase in their self-reported health status over the duration of their enrollment.*

A health status ranking of *good* was the largest category for both the child and adult respondents. Approximately 80% of participants classified their health in the top three rating categories (Table 26). The child survey participants were more likely to report excellent and very good ratings compared to the adults.

Table 26: Self-Reported Overall Health Status

Question	Child N=2344	Adult N=223	Total N=2567
In general, how would you rate your (child's) overall health (both physical and behavioral/emotional) since enrolling in the Flint Medicaid Waiver?	N (%)	N (%)	N (%)
Excellent	537 (22.9)	29 (13.0)	566 (22.0)
Very Good	662 (28.2)	53 (23.8)	715 (27.8)
Good	698 (29.8)	84 (37.7)	782 (30.4)
Fair	373 (15.9)	45 (20.2)	418 (16.3)
Poor	74 (3.2)	12 (5.4)	86 (3.4)

Health status ratings were then subdivided by physical and behavioral/emotional health aspects. The experience of the individuals affected by the Flint Water Crisis has been shown to have significant impacts on emotional well-being as published by other sources. The survey estimates reinforce this observation with generally higher rankings for physical health compared to behavioral/emotional health. Tables 27 and 28 show just 2.9% reported having poor physical health compared to 12% rating behavioral/emotional health as poor.

Table 27: Self-Reported Physical Health Status

Question	Child N=2339	Adult N=223	Total N=2562
In general, how would you rate your (child's) physical health since enrolling in the Flint Medicaid Waiver?	N (%)	N (%)	N (%)
Excellent	610 (26.1)	36 (16.1)	646 (25.2)
Very Good	698 (29.8)	54 (24.2)	752 (29.3)
Good	659 (28.2)	75 (33.6)	734 (28.6)
Fair	315 (13.5)	40 (17.9)	355 (13.8)
Poor	57 (2.4)	18 (8.1)	75 (2.9)

Table 28: Self-Reported Behavioral/Emotional Health Status

Question	Child N=2336	Adult N=222	Total N=2558
In general, how would you rate your (child's) behavioral/emotional health since enrolling in the Flint Medicaid Waiver?	N (%)	N (%)	N (%)
Excellent	412 (17.6)	30 (13.5)	442 (17.3)
Very Good	456 (19.5)	41 (18.5)	297 (19.4)
Good	650 (27.8)	49 (22.1)	699 (27.3)
Fair	542 (23.2)	69 (31.1)	611 (23.9)
Poor	276 (11.8)	33 (14.9)	309 (12.1)

Sub-hypotheses 3.4-3.6: Improved Health Outcomes

- Provisional 3.4*: Descriptive analysis of the proportion of children diagnosed with severe emotional disturbance and other developmental/learning disabilities including comparing rates to others with similar lead exposures.*
- Provisional 3.5: *Descriptive analysis of behavioral health conditions and supportive care among enrolled children.*
- Provisional 3.6: *Descriptive analysis of educational delays among enrolled children.*

Several items of the Beneficiary Child Survey addressed behavioral and developmental issues. The following summary of these items addressed sub-hypotheses 3.5 and 3.6. Most of the parents reported their children were in the expected grade level in Wave 1 (Table 29). Three-quarters of respondents denied being informed their child should be tested for learning disabilities.

Table 29: Child Educational Status Reporting

Question	Yes	No	Not in School	Total
	N (%)	N (%)	N (%)	N
Is your child in the grade level expected for his or her age?	1603 (69.4)	368 (15.9)	340 (14.7)	2311
Has anyone told you that your child should be tested for learning problems?	542 (23.8)	1731(76.2)	--	2273

Respondents to the child survey were also asked to report if they had been informed by either a health care professional or daycare/school professional the child had a behavioral or emotional problem. Approximately 25% did acknowledge being so informed (Table 30).

Table 30: Child Behavioral/Emotional Problem Reporting

Question	Yes	No	Not in School	Total
	N (%)	N (%)	N (%)	N
Have you ever been told by a doctor or nurse that your child has a behavioral or emotional problem?	534 (22.4)	1751 (76.6)	--	2285
Has a daycare or school teacher or school nurse ever told you that your child has a behavioral or emotional problem?	595 (25.9)	1507 (65.7)	191 (8.3)	2293

Domain 4: Lead Hazard Investigation

The evaluation team continue to explore data reporting options for Domain 4, *"The lead hazard investigation program will reduce estimated expected ongoing or re-exposure to lead hazards in the absence of this program."* Particularly, direct access to information regarding lead hazard mitigation services are housed outside of MSA. The intent was for expansion of lead screening and investigation services for individuals affected by the water but not having a documented elevated BLL. The assumption was that early identification of environmental exposures or risks could ensure access to services intended to minimize those risks. Two sub-hypotheses were identified however the evaluation team continues to explore methods to report. As with the data limitations encountered for education data, the evaluation team drafted lead exposure related questions to include into beneficiary surveys to provide some information. The TCM Providers further identified the lack of safe water as an ongoing exposure risk.

Sub-hypotheses 4.1-4.2: Lead Hazard Investigation

- 4.1: *Enrollees without elevated blood lead levels and participating with TCM services will access lead hazard investigation services to the same degree as beneficiaries with elevated blood lead levels.*
- 4.2: *Beneficiaries found to be at risk for ongoing lead exposure will be referred for additional environmental investigation.*

According to the beneficiary survey participants, slightly more than half continue to use water supplied by the Flint water system.

Table 31: Use of Flint Water Supply

Question	Child N=2332	Adult N=224	Total N=2556
Do you (your child) use water supplied by the City of Flint, also known as tap or faucet water right now?	N (%)	N (%)	N (%)
Yes	1186 (50.9)	142 (63.4)	1328 (52.0)
No	1146 (49.1)	82 (36.6)	1228 (48.0)

Among those who use the water, almost two-thirds have continued using the water for activities where ingestion is likely (i.e. drinking/cooking/brushing teeth or washing dishes).

Table 32: Activities Using Flint Water Supply

Question	Child N=1186	Adult N=142	Total N=1328
What do you use tap water for? Check all that apply.	N (%)	N (%)	N (%)
Drinking/cooking/brushing teeth/washing dishes	800 (67.4)	99 (69.7)	899 (67.7)
Bathing/showering/washing clothes	1132 (95.4)	125 (88.0)	1257 (94.6)
Watering garden/pools/sprinklers	403 (34.0)	42 (29.6)	445 (33.5)
Other	82 (6.9)	13 (9.2)	95 (7.2)

Full remediation of water as an exposure threat will only be completed when the water service lines have been fully replaced. Although this is a community priority, work is expected to continue through 2020 before this is finished.

Although the evaluation team has not yet tested these hypotheses for this enrolled population, the collaboration with the CDC funded Flint Registry has provided community level information regarding lead exposures. The 2017 Flint Lead Free Report provided a comprehensive summary of trends emphasizing the lead prevention efforts. A copy of the report is available in Appendix 6. Notably, the percent of residential water testing with elevated lead levels has decreased from 2015 to 2017 and the number of environmental investigations has increased from 2015 to 2017. With respect to the waiver's authorization of expanding Lead Safe Home Program services to the targeted population without documented elevated BLL, the proportion of investigations for children not having the extreme levels increased from approximately 13% in 2015 to 76% in 2017.

Conclusions

This Flint Water Crisis affected a distinct community that was already, and continues to be, an economically vulnerable and exposed to environmental and social stressors.[1-2,6] The FME waiver was established in part to address resulting health effects and improve health outcomes for the next generation. Based on the available evaluation data from 2018 through 2019, the demonstration appears to have been successful in achieving the goals and objectives, albeit to different standards. Several measures in the Access to Care domain demonstrated rate increases while others remained stable. The Access to TCM and Improved Health Outcomes domains were further supported by beneficiary feedback. Analyses on the last domain Lead Hazard Investigation remain pending at the time of this interim report. Collaboration with Flint Registry colleagues provide data to suggest this is improving in the community at large from 2015 through 2017.

Despite being in operation for over three years, enrollment continues to be less than originally estimated. Original estimates identified 15,000 additional individuals who would have been eligible for the coverage due to the expanded eligibility in addition to the 30,000 that were already covered by Medicaid. The total enrolled population reached approximately 34,000 and has been decreasing over time which confirms MDHHS enrollment tracking. In this interim report, it is not possible to ascertain concrete factors that may have resulted in under-enrollment. Some of the under-enrollment may be attributed to resources that entered the Flint and Genesee County community before formal federal resources were implemented such as FME. There remain opportunities for eligible individuals to enroll in the waiver. The Flint Registry is fully operational and serves as a hub for managing referrals.

Despite encountering lower participation than originally envisioned, enrolled beneficiaries are benefiting as evidenced by administrative data, survey responses, and TCM key informant interviews. The evaluation team has documented increased utilization of services such as lead screening for children and pregnant woman. This supports good clinical practice even in non-crisis situations. Enrollees report satisfaction with the benefits. The benefits to enrollees appear to extend beyond addressing only the potential lead impacts. Those with chronic conditions report increased confidence and resources available to them for self-management.

Preliminary results also suggest an increase in developmental and behavioral screening. Not only is this a preventative measure in communities faced with environmental lead exposure but an opportunity for increased in awareness for health providers and parents in socioeconomic compromised communities. Early treatment of developmental and behavioral issues is the key to mitigating long-term consequences. Parents of affected children, whose health outcomes from lead exposure may not appear until school age and puberty, are expected to have increased need of and uptake in services in the future and begin to utilize expanded services. In

addition, the NCE began taking referrals in late 2018 and may potentially increase enrollment in FME.

The TCM benefit was used to a lesser degree than anticipated. The highest estimate of uptake came from the beneficiary survey indicating just 10% of enrollees using this. However, although the population penetration of this service was low, those that participated reported being satisfied. In addition, both beneficiaries and case managers reported that rapport is increasing, and most beneficiaries meet with case managers in their homes. This may indicate an element of trust that was not readily anticipated.

One unexpected change to survey design resulted in significant efficiency to the survey process. In response to community input, a web-based version of the beneficiary survey was implemented in addition to the planned phone and mail surveys. Several protections were put into place to ensure participants could only complete one survey and that non-waiver enrollees couldn't find the survey through internet search engines. Nearly half of all survey responses came in through the web option. This provided timelier data as well as reduced the amount of "bad data" that resulted from inattention to skip patterns that can occur on paper surveys. The web-based survey offered respondents the option to provide an email address for subsequent waves. The success of this method of Wave 2 reminders will be forthcoming in a future report.

Interpretations, Policy Implications and Interactions with Other State Initiatives

Clear and intentional coordination of Medicaid coverage with other programs and efforts to provide a full suite of services e.g. prenatal services, behavioral health services, child development services and timely, preventative screening is needed for those affected by the Water Crisis. Not only at the time of the event, but ongoing in order to sustain healthy behaviors, in general.

An example of collaboration with other initiatives occurred with the environmental lead assessment activities. As of January 1, 2017, CMS and the State of Michigan worked together on a Michigan State Plan Amendment. The collaboration resulted in a five-year Title XXI state designed Health Services Initiative (HSI) to cover expanded lead abatement services in the impacted areas of Flint for children and pregnant women. Although not directly a medical benefit, this partnership supports the health and well-being of individuals.

TCM key informants did indicate that ongoing training and education for expanded services of the FME waiver eligibility, particularly for referral making health personnel is still needed. It was also noted the referral process is often complicated. Other considerations include offering comprehensive guidance to providers and community partners about eligibility for coverage, especially in the higher income levels persons. Likewise, enrolled beneficiaries may need education about specialized services (TCM) and what these services include to address health effects possibly related to the water crisis.

Lessons Learned and Recommendations

This interim report details the first two years of the evaluation and offers information that can improve not only the present evaluation, but future Medicaid Expansion evaluations for similar environmentally related health emergencies. In this report, we found that the uptake in enrollment remains lower than expected. Reasons for this are not fully discernable at this time, but subsequent reports may reveal information that can explain this phenomenon. For instance, communication to the public, provider community, and potential beneficiaries may require ongoing multi-media dissemination. Thus, it is recommended that there be early and clear communication to the community and health providers about access methods and conditions of the expanded waiver eligibility along with ongoing training.

The newly approved service of TCM has been utilized much less than anticipated despite the reports of satisfaction from those who do engage. There may be several reasons for this observation including that those who have participated and experienced delays in being able to secure the referrals may be sharing those experiences with others. This could result in those who may have considered participating being discouraged from doing so. Another possible reason for lack of engagement was a degree of altruism. According to the TCM providers, some individuals who were resistant to participation expressed concern they would be taking services away from someone who had a more acute need. In addition, ancillary services that aided residents during the height of the crisis and beyond may have resolved some issues that would be serviced by the expansion.

The beneficiary survey conducted as part of this evaluation presented a unique opportunity to test various methods of survey participation. Conventional wisdom and previous research suggest that vulnerable populations who utilize Medicaid services do not use web-based services because of lack of knowledge or access to the internet.[7] The beneficiaries enrolled in the waiver suggested an online survey option to the evaluators. This was accommodated and, in turn, participation with the web-based survey exceeded the telephone or paper versions of the survey. Not only was this method preferred by individuals, the online options provided benefits not realized through paper or telephone. Specifically, the turn-around time to receive the data was reduced, the cost was less per survey since fewer survey staff were required and the issue of “bad data” from inattention to skip patterning was eliminated. It is important to acknowledge a small incentive was provided to all participants upon completion of the survey, regardless of modality. The team cannot be sure whether the incentive or the mode was a primary driver in a decision to participate.

The willingness of online interaction may represent opportunity for expanded outreach to a Medicaid population. Web-based access to health service information and referrals may reduce

barriers to accessing healthcare services. The use of web-based services can offer substantial cost savings for delivery of healthcare for federal and local health systems.

A full description of recommendations is limited at this time. The period of this interim report covers evaluation activities from 2018 through 2019. The evaluation is expected to continue through April 2021. As additional data sources are incorporated, utilization estimates and beneficiary ratings may change from the provisional data reported here. However, currently available data suggest that the waiver has been successful in meeting most goals and objectives.

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Appendix 1: Matrix of Evaluation Domains including Hypotheses and Measures

Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
DOMAIN 1: Access to Care			
H1.1: A greater proportion of enrollees will obtain age-appropriate well-child exams compared to others with similar lead exposures.	1. Well Child Visits in the First 15 months of Life	National Committee for Quality Assurance/NQF 1392	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
	2. Well Child visits in the Third, Fourth, Fifth and Sixth Years of Life	National Committee for Quality Assurance/NQF 1516	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
	3. Adolescent Well-Care Visits	National Committee for Quality Assurance	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
H1.2: A greater proportion of enrollees will receive age-appropriate developmental screening/assessments compared to others with similar lead exposures	1. Developmental Screening in the First Three Years of Life	Oregon Health & Science University /NQR 1448	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
	2. Socio-emotional/ Behavioral Screening for Children 4-17 years of age	n/a	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
H1.3: A greater proportion of enrollees will receive age appropriate lead testing compared to others with similar lead exposures	1. Lead Screening in Children	National Committee for Quality Assurance	Administrative claims/encounters in the MDHHS Health Services Data Warehouse

Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
H1.4: A greater proportion of enrollees with high blood lead levels will receive re-testing at the appropriate intervals compared to others with similar lead exposures	1. Follow-up of elevated blood lead level	Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)-CMS/American Academy of Pediatrics	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to lead screening and TCM monitoring data
H1.5: Enrollees who are pregnant will have more timely prenatal and postpartum care compared to others with similar lead exposures.	1. Timeliness of Prenatal Care	National Committee for Quality Assurance/NQF 1517	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to Vital Records
	2. Postpartum Care	National Committee for Quality Assurance/NQF 1517	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to Vital Records
H1.6: A greater proportion of enrollees who are pregnant will have recommended lead testing compared to others with similar lead exposures	1. Lead screening in pregnancy	American Congress of Obstetricians and Gynecologists	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to Vital Records data
H1.7: A greater proportion of enrollees will participate with home visiting services compared	1. Maternal Infant Health Program Participation	MI defined measure	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to MIHP visit and TCM monitoring data

Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
to others with similar lead levels.			
H1.8: Enrollees will attest to improved access to health care as a result of the expanded coverage.	1. Enrollee Attestation for Improved Access to Care	Agency for Healthcare Research and Quality – Consumer Assessment of Healthcare Providers and Systems (AHRQ-CAHPS) Question Modification	Beneficiary survey responses
H1.9: Enrollees will report satisfaction with their ability to access health care as a result of the expanded coverage.	1. Enrollee satisfaction with Medicaid expansion coverage	Agency for Healthcare Research and Quality – Consumer Assessment of Healthcare Providers and Systems (AHRQ-CAHPS) Question Modification	Beneficiary survey responses
DOMAIN 2: Access to Targeted Case Management			
H2.1: Referral source and participation levels with TCM will be tracked among enrollees	1. Referral Source for TCM	MI defined measure	TCM documentation visit data
	2. TCM Participation	MI defined measure	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to TCM billing/documentation
H2.2: All TCM participants will have an annual assessment conducted.	1. Annual TCM assessment	MI defined measure	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to TCM billing/documentation

Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
H2.3: A greater proportion of TCM participants will have age-appropriate well child exams compared to TCM non-participants	1. A greater proportion of TCM participants will have age-appropriate well child exams compared to TCM non-participants	National Committee for Quality Assurance /NQF 1392	TCM Program documentation linked to Administrative claims/encounter data available through the MDHHS Health Services Data Warehouse
H2.4: A greater proportion of TCM participants will have completed age-appropriate developmental screening compared to TCM non-participants	1. Impact of TCM in assuring enrollees obtain age-appropriate developmental screenings.	Oregon Health & Science University/NQF 1448 and new evaluation measure (socio-emotional/behavioral screening)	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to TCM billing/documentation visit data
DOMAIN 3: Improved Health Outcomes			
H3.1: Enrollees will have higher completed age-appropriate immunization statuses compared to others with similar lead exposures	1. Childhood Immunization Status	National Committee for Quality Assurance/NQF 0038	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
	2. Immunizations for Adolescents	National Committee for Quality Assurance/NQF 1407	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
H3.2: Enrollees who are pregnant will deliver infants with higher birth weights compared to others with similar lead exposures	1. Low Birth Weight Rate	Agency for Healthcare Research & Quality/NQF 0278	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to Vital Records

Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
H3.3: Enrollees report an increase in their self-reported health status over the duration of their enrollment.	1. Enrollee Self-Reported Health Status	AHRQ/CAHPS Question Modification	Beneficiary survey responses
	2. Enrollee Self-Reported Efficacy of Chronic Condition Management	Adult and Pediatric Condition Management Self-Efficacy (ex. Asthma Control Test)	Beneficiary survey responses
PROVISIONAL H3.4: Descriptive analysis of the proportion of children diagnosed with severe emotional disturbance and other developmental/learning disabilities including comparing rates to others with similar lead exposures.	1. Proportion of enrollees having diagnosis code(s) of interest	MI defined measure	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
PROVISIONAL H3.5: Descriptive analysis of behavioral health conditions and supportive care among enrolled children.	1. Prevalence of behavioral health conditions among enrolled children 2. Count of children enrolled in Early Childhood Programs 3. Proportion of students in Kindergarten who	MI defined measure	Beneficiary survey responses ~~MDE Data~~ Summary data available through MI Schools Dashboards

Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
	participated in Early Childhood Programs		
PROVISIONAL H3.6: Descriptive analysis of educational delays among enrolled children.	1. Prevalence of educational delays among enrolled children 2. Counts of children remaining in same grade 3. Educational Progress Standardized Testing (M-STEP, MI-Access)	MI defined measure	Beneficiary survey responses ~~MDE Data~~ Summary data available through MI Schools Dashboards
DOMAIN 4: Lead Hazard Investigation			
H4.1: Enrollees without elevated blood lead levels and participating with TCM services will access lead hazard investigation services to the same degree as beneficiaries with elevated blood lead levels.	1. Prevalence of Lead Hazard Assessment/Investigation	MI defined measure	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to Blood lead levels
H4.2: Beneficiaries found to be at risk for ongoing lead exposure will be referred for additional environmental investigation	2. Prevalence of Lead Hazard Follow-up Investigation	MI defined measure	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to Blood lead levels

Appendix 2: Approved Evaluation Plan

Flint Expansion Evaluation Final2_CM

Appendix 3: Beneficiary Survey Summary Report and Materials


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Adult_formatted_final.pdf


Reminder_SurveyMail1.pdf


Nonresponder_SurveyReminderLetter_Mail

Appendix 4: TCM Provider Key Informant Summary Report and Materials

TCM_Provider_summary_1_6_2020.pdf

TCM_ProviderSurvey_phone.pdf

Appendix 5: MSU Human Research Protection Program – Determination Letter

MSU HRPP
Determination Letter.

Appendix 6: Flint Lead Free 2017 Report, Flint Registry

Lead-Free-Report-V5.pdf

STATE OF MICHIGAN
DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

GRETCHEN WHITMER
GOVERNOR

ROBERT GORDON
DIRECTOR

December 2, 2019

NAME
TITLE
ADDRESS
CITY STATE ZIP

Dear Tribal Chair and Health Director:

RE: Section 1115 Waiver Extension Request to Assist in Addressing Health Impacts from Potential Lead Exposure in Flint, Michigan

This letter, in compliance with Section 1902(a)(73) and Section 2107(e)(1)(C) of the Social Security Act, serves as notice to all Tribal Chairs and Health Directors of the intent by the Michigan Department of Health and Human Services (MDHHS) to submit a Section 1115 waiver extension request to the Centers for Medicare & Medicaid Services (CMS) to extend the Flint Michigan Section 1115 Demonstration (Project Number 11-W-00302/5) for a period of 10 years pursuant to section 1115(a) of the Social Security Act.

Pending approval from CMS, MDHHS plans to:

- Maintain expanded Medicaid eligibility for children up to age 21 and pregnant woman who;
    - Are served by the Flint water system or were served by the Flint water system between April 2014 and the date on which the Flint water system is deemed safe by the appropriate authorities AND
    - Have household incomes up to 400 percent of the federal poverty level (FPL). Individuals up to age 21 and pregnant women with household income above 400 percent FPL can buy in to unsubsidized coverage under the program.
- Continue the established targeted case management services for children up to age 21 and pregnant women as described above.

The waiver extension will take effect on February 28, 2021, and will impact Native American pregnant women and children served by the Flint water system.

Input regarding this waiver extension is highly encouraged, and comments regarding this notice of intent may be submitted to Lorna Elliott-Egan, MDHHS Liaison to the Michigan tribes. Lorna can be reached at 517-284-4034, or via email at Elliott-EganL@michigan.gov. **Please provide all input by January 16, 2020.**

In addition, MDHHS is offering to set up group or individual consultation meetings to discuss the waiver extension, according to the tribes' preference. Consultation meetings allow tribes the opportunity to address any concerns and voice any suggestions, revisions, or objections to be relayed to the author of the proposal. If you would like additional information or wish to schedule a consultation meeting, please contact Lorna Elliott-Egan at the telephone number or email address provided above.

MDHHS appreciates the continued opportunity to work collaboratively with you to care for the residents of our state.

Sincerely,

Kate Massey, Director
Medical Services Administration

cc: Tannisse Joyce, CMS
Keri Toback, CMS
Leslie Campbell, CMS
Justyna Redlinski, CMS
Ashley Tuomi, MHPA, Executive Director, American Indian Health and Family Services of Southeastern Michigan
L. John Lufkins, Executive Director, Inter-Tribal Council of Michigan, Inc.
Keith Longie, Director, Indian Health Service - Bemidji Area Office
Lorna Elliott-Egan, MDHHS

Distribution List for L 19-44
December 2, 2019

Mr. Bryan Newland, Tribal Chairman, Bay Mills Indian Community
Ms. Audrey Breakie, Health Director, Bay Mills (Ellen Marshall Memorial Center)
Mr. Thurlow Samuel McClellan, Chairman, Grand Traverse Band Ottawa & Chippewa Indians
Mr. Soumit Pendharkar, Health Director, Grand Traverse Band Ottawa/Chippewa
Mr. Kenneth Meshigaud, Tribal Chairman, Hannahville Indian Community
Ms. G. Susie Meshigaud, Health Director, Hannahville Health Center
Mr. Warren C. Swartz, Jr., President, Keweenaw Bay Indian Community
Ms. Kathy Mayo, Interim Health Director, Keweenaw Bay Indian Community - Donald Lapointe Health/Educ Facility
Mr. James Williams, Jr., Tribal Chairman, Lac Vieux Desert Band of Lake Superior Chippewa Indians
Ms. Sadie Valliere, Health & Human Services Director, Lac Vieux Desert Band
Mr. Larry Romanelli, Ogema, Little River Band of Ottawa Indians
Mr. Daryl Wever, Health Director, Little River Band of Ottawa Indians
Ms. Regina Gasco-Bentley, Tribal Chairman, Little Traverse Bay Band of Odawa Indians
Ms. Jodi Werner, Health Director, Little Traverse Bay Band of Odawa
Mr. Bob Peters, Chairman, Match-E-Be-Nash-She-Wish Potawatomi Indians (Gun Lake Band)
Ms. Kelly Wesaw, Health Director, Match-E-Be-Nash-She-Wish Potawatomi
Mr. Jamie Stuck, Tribal Chairman, Nottawaseppi Huron Band of Potawatomi Indians
Ms. Rosalind Johnston, Health Director, Huron Potawatomi Inc.- Tribal Health Department
Mr. Matthew Wesaw, Tribal Chairman, Pokagon Band of Potawatomi Indians
Mr. Matt Clay, Health Director, Pokagon Potawatomi Health Services
Mr. Ronald Ekdahl, Tribal Chief, Saginaw Chippewa Indian Tribe
Mrs. Karmen Fox, Executive Health Director, Nimkee Memorial Wellness Center
Mr. Aaron Payment, Tribal Chairman, Sault Ste. Marie Tribe of Chippewa Indians
Mr. Leonid Chugunov, Health Director, Sault Ste. Marie Tribe of Chippewa Indians - Health Center

CC: Tannisse Joyce, Region V, CMS
Keri Toback, Region V, CMS
Leslie Campbell, Region V, CMS
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L. John Lufkins, Executive Director, Inter-Tribal Council of Michigan, Inc.
Keith Longie, Director, Indian Health Service - Bemidji Area Office
Lorna Elliott-Egan, MDHHS

Public Notice

Michigan Department of Health and Human Services
Medical Services Administration

Flint, Michigan Section 1115 Demonstration Waiver Extension Application

The Michigan Department of Health and Human Services (MDHHS) is hereby providing notice that it will be holding a public hearing and comment period seeking input on the submission of its demonstration waiver extension application to the Centers for Medicare & Medicaid Services (CMS). MDHHS is seeking a 10-year extension of the Flint Michigan Section 1115 Demonstration, also referred to as the Flint Waiver, which is set to expire on February 28, 2021.

Flint Waiver Demonstration Description and Objectives

In 2016, CMS approved Michigan's application to establish a five-year Medicaid demonstration entitled "Flint Michigan Section 1115 Demonstration" (Project Number 11-W-00302/5), in response to the public health emergency of lead exposure related to the Flint water system. The demonstration expanded coverage to low-income children up to age 21 years and pregnant women served by the Flint water system during a state-specified time period. The Flint Waiver was established in part to address resulting health effects and improve health outcomes.

Flint Waiver Demonstration Program Overview

The overarching goal of the MDHHS waiver application is to "identify and address any physical or behavioral health issues associated with actual or potential exposure to lead hazards." The demonstration expands eligibility of all Medicaid benefits for low-income children (up to age 21 including children born to eligible pregnant women) and pregnant women (through two months post-delivery) served by the Flint water region from 4/1/2014 through the date when the water is deemed safe. As of 1/13/20, the water had not yet been deemed safe although lead levels were below national thresholds. The specific eligibility modifications included:

- Increase income threshold to offer coverage to children in households with incomes from 212% federal poverty level (FPL) up to and including 400% FPL.
- Increase income threshold to offer coverage to pregnant women in households with incomes from 195% FPL up to and including 400% FPL.
- Eliminate cost sharing and Medicaid premiums for eligible children and pregnant women served by the Flint water system.

Targeted Case Management (TCM) is an added benefit to all low-income children (up to age 21 including children born to eligible pregnant women) and pregnant women (through two months post-delivery) served by the Flint water system as of 4/1/2014. The activities included in the TCM benefit are:

- Assisting enrolled eligible children and pregnant women served by the Flint water system to gain access to needed medical, social, educational, and other service(s).

Enrollment

The following table shows an unduplicated aggregate count of beneficiaries whose coverage is affected by the demonstration for each year of the current demonstration approval period. The Cumulative Enrollment row shows the total distinct number of Flint waiver enrollees over the demonstration period.

Flint Demonstration Enrollment by Demonstration Year			
Demonstration Year	**Enrollment Group**		**Total Flint Demonstration Enrollment**
	Children	**Pregnant Women**	
1	29,985	1,813	31,798
2	32,990	1,735	34,725
3	31,047	1,254	32,301
4	29,681	1,195	30,876
Cumulative Enrollment	39,375	4,046	43,421

Estimates of the expected increase or decrease in annual enrollment, as well as annual aggregate expenditures, are currently being developed.

Flint Waiver Demonstration Evaluation

A condition of this waiver authorization was the requirement for an independent evaluation, conducted by Michigan State University's Institute for Health Policy (IHP), on the evaluation goals and activities determined in collaboration with CMS. The Waiver application referred to four domains in which the expanded Medicaid offerings would support attainment of the overall waiver goal:

- Access to Care
- Access to Targeted Case Management
- Improved Health Outcomes
- Lead Hazard Investigation

The evaluation includes multiple hypotheses associated with the domains to examine the Flint Waiver's overarching goal of identifying and addressing any physical or behavioral health issues associated with actual or potential exposure to lead hazards.

Demonstration Waiver and Expenditure Authorities

MDHHS seeks the continuation of the following waivers of state plan requirements contained in §1902 of the Social Security Act, subject to the Special Terms & Conditions for the Flint Waiver §1115 Demonstration:

- *Provision of Medical Assistance §1902(a)(8); 1902(a)(10)* – To the extent necessary to permit the state to limit the provision of medical assistance (and treatment as eligible) for individuals described in the eligibility group under 1902(a)(10)(A)(ii)(XX) and the state plan, to children up to age 21 and pregnant women who were served by the Flint water system at any time from April 2014 to the state-specified date, including any child bonito a pregnant woman served by the Flint water system from April 2014 to the state-specified date. For this purpose, an individual was served by the Flint water system if, for more than one day, the individual consumed water drawn from the Flint water system and: 1) resided in a dwelling connected to this system; 2) had employment at a location served by this system; or, 3) received child care or education at a location connected to this system.
- *Comparability §1902(a)(17) or § 1902(a)(10)(B)* – To the extent necessary to enable the state to not charge premiums to individuals who resided in the area served by the Flint water system from April 2014 up to the date specified in accordance with paragraph"l8 of the special terms and conditions (STCs). Also, to the extent necessary to enable the state to provide evaluation of potential lead exposure in the home only for individual~ who meet these nonfinancial criteria.
- *Freedom of Choice §1902(a)(23*) – To the extent necessary to enable the state to restrict freedom of choice of provider for children and pregnant women with respect to targeted case management and evaluation of potential lead exposure in the home. Also, to the extent necessary to enable the state to limit beneficiary choice of providers for beneficiaries enrolled in a Managed Care Entity (MCE) and a Prepaid Inpatient Health Plan (PIHP) under the demonstration to those providers that are within the MCE and PIHP networks. No waiver of freedom of choice is authorized for family planning providers.

Additionally, MDHHS seeks the continuation of the CMS-approved expenditure authority that enables Michigan to implement the Flint Medicaid Section 1115 demonstration:

- Expenditures for evaluation of potential lead exposure in the homes of eligible children under age 21 and eligible pregnant women who resided in the area served by the Flint water system between April 2014 and the date specified in accordance with paragraph 18 of the Special Terms and Conditions, without regard to whether there has been documentation of an elevated blood lead level of an eligible household member.

Public Hearing, Review of Documents, and Comment Submission

In compliance with the public notice process as specified in 42 CFR 431.408, a public hearing has been scheduled at the date, time and location below:

February 25, 2020 at 4:00 p.m. to 6:00 p.m.
Food Bank of Eastern Michigan
2300 Lapeer Road
Flint, Michigan 48503

This public hearing will provide an overview and discussion of the demonstration waiver extension. All interested parties will be provided the opportunity to provide comments on the Flint Waiver demonstration waiver extension application.

A copy of the complete §1115 waiver application, stakeholder notice, and waiver summary is available online at https://www.michigan.gov/mdhhs/0,5885,7-339-71547-376862--,00.html. You may also request a hard copy of the complete §1115 waiver application, stakeholder notice, and waiver summary by contacting msapolicy@michigan.gov. You may also submit comments regarding the waiver to the address below or by email to msapolicy@michigan.gov.

Michigan Department of Health and Human Services
Medical Services Administration
Medicaid Policy Section
P.O. Box 30479
Lansing, MI 48909-7979

All comments on this topic should include a "Section 1115 – Flint Waiver Extension" reference somewhere in the written submission or the subject line if by e-mail. Comments will be accepted until March 24, 2020.

PUBLIC NOTICE
Michigan Department of Health and Human Services
Medical Services Administration

Section 1115 Waiver – Flint Demonstration

The Michigan Department of Health and Human Services (MDHHS) is seeking approval from the Centers for Medicare and Medicaid Services (CMS) for a 10-year extension of the Flint Michigan Section 1115 Demonstration Waiver. If approved, the state will maintain the expanded Medicaid eligibility to children up to age 21 and pregnant women served by the Flint water system with incomes up to 400 percent of the federal poverty level. The waiver will also allow the continuation of the established targeted case management services to children up to age 21 and pregnant women served by the Flint water system.

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Michigan Department of Health and Human Services
Medical Services Administration
Medicaid Policy Section
P.O. Box 30479
Lansing, MI 48909-7979

ANNOUNCEMENTS

Public Notices

CITY OF SAGINAW
PUBLIC NOTICE
PUBLIC ACCURACY TEST
Notice is hereby given that a test of the program and precinct tabulators to be used for tabulating votes for the March 10, 2020 Presidential Primary Election will be held Thursday, Feb. 27, 2020 at 4:00 p.m. in the Election Center, located on the Basement Level of City Hall, 1315 S. Washington Ave.

If you are disabled and need accommodation to provide you with an opportunity to participate or observe call the Saginaw City Clerk's Office at 989.759.1480.

Election Commission
City of Saginaw

STATE OF MICHIGAN
JUDICIAL DISTRICT
JUDICIAL CIRCUIT
COUNTY PROBATE

ORDER FOR SERVICE BY PUBLICATION/POSTING AND NOTICE OF ACTION

CASE NO. 19-04086-GCF

COURT ADDRESS:
124 W. MICHIGAN AVE.,
LANSING, MI 48933
(517) 483-4426

PLAINTIFF:
MICHIGAN DEPARTMENT OF TRANSPORTATION
425 W. OTTAWA ST.
LANSING, MI 48913
PLAINTIFF'S ATTORNEY:
JESSICA E. LEPINE (P46171)
ASSISTANT ATTORNEY GENERAL

DEFENDANT: SIMON PETER-ALEX TURNER
516 N. 26TH ST.
SAGINAW, MI 48601

To: SIMON PETER-ALEX TURNER

IT IS ORDERED:
You are being sued in this court by the Plaintiff to pay damages to MDOT's road signs and light pole. You must file your answer or take other action permitted by law in this court at the court address above on or before April 05, 2020. If you fail to do so, a default judgment may be entered against you for the relief demanded in the complaint filed in this case. A copy of this order shall be published once each week in Lansing State Journal and Saginaw News for 3 consecutive weeks, and proof of publication shall be filed in this court. A copy of this order shall be sent to Simon Peter-Alex Turner at the last-known address by registered mail, return receipt requested, before the date of the last publication, filed with this court.

STATE OF MICHIGAN
PROBATE COURT
COUNTY OF SAGINAW

NOTICE TO CREDITORS
Decedent's Estate
FILE NO. 20-140098-DE

Estate of LEONARD A. ROHDE A/K/A LEONARD AUGUST ROHDE, DECEASED. Date of Birth: October 10, 1932.

TO ALL CREDITORS:
NOTICE TO CREDITORS: The decedent, LEONARD A. ROHDE A/K/A LEONARD AUGUST ROHDE, DECEASED, died August 5, 2019.
Creditors of the decedent are notified that all claims against the estate will be forever barred unless presented to JULIE CRAFT, personal representative, or to both the probate court at 111 S. MICHIGAN, SAGINAW, MI 48602 and the personal representative within 4 months after the date of publication of this notice.
Date: February 20, 2020.

LAW OFFICE OF
CAROL M. THOMAS
JIM THOMAS P75072
5191 HAMPTON PLACE
SAGINAW, MI 48604
(989) 793-2300

JULIE CRAFT
609 CEDAR LAKE ROAD SW
DECATUR, AL 35603
(256) 654-7766

NOTICE TO CREDITORS
TO ALL CREDITORS:

The decedent, Stanley J. Szul, date of birth February 5, 1922, Settlor of the Stanley J. Szul Trust, dated February 22, 1999, who lived at 6915 Pleasant Ridge Trail, Saginaw, Michigan 48603, died January 5, 2020.
Creditors of the decedent are notified that all claims against the estate will be forever barred unless presented to Elizabeth S.zul, Trustee, at 6915 Pleasant Ridge Trail, Saginaw, Michigan 48603, or the attorney for the trustee, Jim Thomas, at 5191 Hampton Place, Saginaw, Michigan 48604, within 4 months after the date of February 20, 2020.

Medical Services Administration

Section 1115 Waiver – Flint Demonstration

The Michigan Department of Health and Human Services (MDHHS) is seeking approval from the Centers for Medicare and Medicaid Services (CMS) for a 10-year extension of the Flint Michigan Section 1115 Demonstration Waiver. If approved, the state will maintain the expanded Medicaid eligibility to children up to age 21 and pregnant women served by the Flint water system with incomes up to 400 percent of the federal poverty level. The waiver will also allow the continuation of the established targeted case management services to children up to age 21 and pregnant women served by the Flint water system.

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2300 Lapeer Road
Flint, MI 48503

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Michigan Department of Health and Human Services
Medical Services Administration
Medicaid Policy Section
P.O. Box 30479
Lansing, MI 48909-7979

MERCHANDISE

Business Office Equipment

Closing Busines Sale, Tues. 02/25/20 10a-5p 1003 Woodside Ave. Essexville Desks, file cabinets, computer monitors, cubicle dividers, and miscellaneous, for info call 989-892-7722

PETS & FARMS

Pets & Supplies

2 Brittany's (1-female) - all AKC, all good hunters/pets, great bloodlines. Starting at $500. 231-229-4278, 616-648-8190.

AKC German Short Hair Pups - excellect pedigree all shots & wormed. Not gun shy. 8 Duel champions, 4 generations. Excellent hunters or Great pets. Have Been raising 30 yrs $600.00 Shoemaker short hairs, Jonesville, MI 517-315-8505

AKC Golden Retriever Puppies. First shots and wormed. Ready to go to a good home February 20th. $700. Call or text 810-449-9013 with inquiries.

AKC LABS - Shots, wormed, dewclaws removed. Ready, born Dec. 1st 2019. $500. Call 989-661-2215 or 989-413-0064

AKC Rottweiler pups born 11/25/19 females $1500 ea 1st, 2nd & 3rd shots, dewormed, weight chart, pedigree, tails docked & dew claws removed 248-919-0056 Howell

English Springer Spaniel Puppies . English springer Spaniel Puppies 9 weeks old Valentine's Day ??. 2 females liver white and tans tan. 2 males liver white one Tri. AKC vet checked shots wormed tails and du claws removed. Started potty training come when you call them handled a lot. Great with children. Cadillac area 231-920-7079. Call or text for more information

F1B Labradoodle Puppies, Ready feb 29th, with $300 paypal deposit required, $1250 asking price LaGrange Indiana possible delivery available 260-336-0205 like us on fb @stateline doodles

GERMAN SHEPHERD AKC PUPS, LG, Sable/black/tan, training started/crate, $350 obo. 989-635-7856 or 989-450-7119

Morkypoo's & Multipoo's, Puppies- Adorable, non sheding, tiny & toy size . vaccinated, health guar., family owned. Also 1 Fluffy Dorky puppy. call 616-443-6004

PEMBROKE WELSH CORGIES- Cute & playful, 1st shots & wormed, $600. 517-726-0706.

Pure Bred Boxer Puppies. Very playful, very friendly, 1st shots & wormed. $550. 269-223-9194

Pure Bred English Shepherd Puppies. Very playful, nice colors . 1st shots & wormed. $250. 269-223-9194

Purebred Yellow Labs . Purebred 6 week yellow labs. Males and Females available. Sweet temperaments. First shots given and regular dewormings. Located in Paw Paw. $600. Contact John 269-501-2167.

Siberian Husky Pups for Sale. 1st shots & dewormed. Very Very nice. $400. 517-726-0706

TRANSPORTATION

Classic Antique

1968 Chevrolet Camaro SS. asking $14800, clean title, very clean, new tires, garage kep. Contact: chelcurt48@gmail.com or 6163266820

SUVs

2017 BMW X5. no accidents, 28k miles, 3.0L V6 300hp, clean title, $22800. Call or Text 7342346122

EMPLOYMENT

General Help Wanted

Newspaper Delivery Contractors
Advance Local, Michigan

Earn up to $1,250/mo. plus tips with NO collections, delivering newspapers as an INDEPENDENT Newspaper Delivery Contractor.

We need motivated self-starters to deliver our publications* as independent contractors. Advance Local, Michigan is looking for reliable people to deliver our publications multiple days weekly.

Multiple routes are available with a mix of porch and tubed delivery stops.

* Advance Local, Michigan publications include the Ann Arbor News, The Bay City Times, The Flint Journal, The Grand Rapids Press, Jackson Citizen Patriot, Kalamazoo Gazette, The Muskegon Chronicle, The Saginaw News, and others.

Schedule / Shift: Multiple routes are available with a mix of porch and tubed delivery stops.

Requirements:
• Must be at least 18 years of age or older
• Must be able to lift 40-lbs. bundles
• Applicant's name MUST appear on the proof of insurance

Email or Call today:
MI.Carrier.GKMJ@advancelocal.com or 616-224-4779

Please leave your name, address, phone number, best number to reach you and what city or area you would like to deliver. We will forward this information to our District Manager and they will be in contact with you ASAP. Please mention any previous delivery experience.

Newspaper Delivery Contractors
Advance Local, Michigan

Earn up to $1,250/mo. plus tips with NO collections, delivering newspapers as an INDEPENDENT Newspaper Delivery Contractor.

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Email or Call today:
MI.Carrier.GKMJ@advancelocal.com or 616-224-4779

Please leave your name, address, phone number, best number to reach you and what city or area you would like to deliver. We will forward this information to our District Manager and they will be in contact with you ASAP. Please mention any previous delivery experience.

Health Care

Clinical Research Directors, Flint, Mi: Direct the clinical research projects, staff & activities for all the current and upcoming projects. Ensure adherence to standard operating procedures, good clinical practice and FDA regulation. Send res to: Onyx Clinical Research, 2241 S Linden Ave, Suite D, Flint, MI, 48532.

REAL ESTATE

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

ROBERT GORDON
DIRECTOR

April 21, 2020

TO: Interested Party

RE: Consultation Summary
Flint Michigan Section 1115 Demonstration

Thank you for your comment(s) to the Medical Services Administration relative to Project Number 11-W-00302/5. Your comment(s) has been considered in the preparation of the final publication, a copy of which is attached for your information.

Responses to specific comments are addressed below.

Comment: Comments from individuals, health care professionals, and a health care organization indicated support for the continuation of the Flint Waiver.

Response: The Michigan Department of Health and Human Services (MDHHS) thanks you for your comments in support of renewing the waiver.

Comment: Several attendees to the public forum commented on operational and systems issues with the waiver, including enrollment, communication, and the state's processing system.

Response: While these comments are not related to the waiver renewal, they will be shared as MDHHS looks to improve broader systems and operations.

Comment: Several attendees to the public forum expressed an interest in expanding the waiver to cover children over the age of 21 and include an increase in rates for targeted case management services.

Response: MDHHS will look to address the health needs of individuals over 21 through existing or future waiver programs, as well as examine provider rates.

I trust your concerns have been addressed. If you wish to comment further, send your comments to MSAPolicy@michigan.gov:

Sincerely,

Kate Massey, Director
Medical Services Administration

Michigan Department of Health and Human Services
Program Policy Division
PO Box 30479
Lansing MI 48909

February 20, 2019

<Provider Name>
<Provider Address 1>
<Provider Address 2>
<City> <State> zipcode5-zipcode4

Dear Interested Party:

RE: Flint Michigan Section 1115 Waiver Extension

The Michigan Department of Health and Human Services (MDHHS) is seeking approval from the Centers for Medicare & Medicaid Services (CMS) for a 10-year extension of the Flint Michigan Section 1115 Demonstration Waiver. If approved, the state will maintain the expanded Medicaid eligibility to children up to age 21 and pregnant women served by the Flint water system with incomes up to 400 percent of the federal poverty level. The waiver will also allow the continuation of the established targeted case management services to children up to age 21 and pregnant women served by the Flint water system. The proposed effective date is February 28, 2021.

A copy of the complete Section 1115 waiver, stakeholder notice, and waiver summary is available online at https://www.michigan.gov/mdhhs/0,5885,7-339-71547-376862--,00.html. You may request a hard copy of the complete Section 1115 waiver, stakeholder notice, and waiver summary by contacting msapolicy@michigan.gov. You may also submit questions or comments regarding the waiver to the address below or by email to msapolicy@michigan.gov. All comments on this topic should include a "Section 1115 – Flint Waiver Extension" reference somewhere in the written submission or the subject line if by email. All comments are due by March 26, 2020.

Michigan Department of Health and Human Services
Medical Services Administration
Program Policy Division
P.O. Box 30479
Lansing, MI 48909-7979

A public hearing has been scheduled at the date, time and location below.

- February 25, 2020 at 4:00 p.m. to 6:00 p.m.
  Food Bank of Eastern Michigan
  2300 Lapeer Road
  Flint, MI 48503

We thank you in advance for your participation.

Sincerely,

Kate Massey, Director
Medical Services Administration

STATE OF MICHIGAN
DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

GRETCHEN WHITMER
GOVERNOR

ROBERT GORDON
DIRECTOR

FOR IMMEDIATE RELEASE:
Feb. 25, 2020

CONTACT: Bob Wheaton
517-241-2112
wheatonb@michigan.gov

MDHHS seeks public comment on renewal of Medicaid expansion program to assist those in Flint affected by water crisis

LANSING, Mich. – The Michigan Department of Health and Human Services (MDHHS) is requesting public comment on its plan to renew expanded Medicaid coverage to assist people who have been affected by the Flint water crisis.

In 2016, the federal Centers for Medicare & Medicaid Services (CMS) approved Michigan's application for a five-year Medicaid demonstration project in response to the public health emergency due to lead exposure related to the Flint water system. The demonstration expanded coverage to low-income children up to age 21 and pregnant women served by the Flint water system during a state-specified time period and who would not otherwise have been eligible for Medicaid.

"The people of Flint need and deserve state assistance in the continuing recovery from the water crisis," said Kate Massey, senior deputy director of MDHHS Medical Services Administration. "We are committed to continuing to provide help. As of January 2020, 43,421 young people and pregnant women have received expanded Medicaid coverage so that their health needs related to lead exposure can be addressed."

The project expires Feb. 28, 2021, and must be renewed by CMS to continue. MDHHS is seeking approval for a 10-year extension. If approved, the state will maintain the expanded Medicaid coverage to children and pregnant women served by the Flint water system with incomes up to 400 percent of the federal poverty level.

The project is called the Flint Michigan Section 1115 Demonstration. A copy of the complete application, stakeholder notice, and waiver summary is available on the Section 1115 Waiver webpage. You can request hard copies of the materials by contacting msapolicy@michigan.gov. You may also submit comments by email to msapolicy@michigan.gov or by writing the address below:

Michigan Department of Health and Human Services, Medical Services Administration Medicaid Policy Section, P.O. Box 30479, Lansing, MI 48909-7979.Comments should include "Section 1115 – Flint Waiver Extension" in the email subject line. Comments will be accepted until March 26, 2020.

# # #

Michigan Department of Health and Human Services
Medical Services Administration

Medical Care Advisory Council
AGENDA

DATE: Wednesday, August 14, 2019
TIME: 1:00 pm to 4:30 pm
WHERE: Michigan Public Health Institute (MPHI)
2436 Woodlake Circle
Okemos, MI
517-324-8300 **Conference Line: 1-877-336-1829 Access Code: 2166657**

1. Welcome, Introductions, Announcements ..... Jackie Prokop
    a. MCAC Chair Update – Alison Hirschel and Bill Mayer to co-chair
2. Budget Update ..... Erin Emerson
3. Healthy Michigan Plan (HMP) ..... Council and MSA Staff
    a. Legislative Changes – Senate Bill 362 and 363
    b. Webinars – General overview
        1. Will do subtopics in subsequent months
    c. September Beneficiary letters and mailing
        1. Group subject to workforce engagement
            i. Exemption form
            ii. Special Processing Unit
        2. Group who have an exemption
        3. 48-month cumulative enrollment changes
    d. Council review of beneficiary letters
    e. HMP operations and process questions
        i. What are the best practices your organization employs for HMP beneficiary engagement?
        ii. What are your plans for rolling out the HMP changes?
        iii. What tools or information do you need from the department?
4. Flint Waiver renewal ..... Erin Emerson
5. General Updates ..... Council and MSA Staff
    a. Peace of Mind Registry
6. Future Agenda items ..... Bill Mayer
7. Policy Updates ..... Jackie Prokop
    a. Targeted Case Management program for parolees
8. 4:30 – Adjourn

Next Meeting: Thursday, November 14, 2019

MICHIGAN DEPARTMENT OF HEALTH & HUMAN SERVICES

Flint Medicaid Expansion Waiver Extension

February 25, 2020

Overview

- Current waiver is set to expire on February 28, 2021
- DHHS is seeking public comment on the Flint Medicaid Expansion extension
- Michigan is seeking a 10-year extension of the current waiver
- No changes to the current waiver are proposed in this extension request

Waiver Background

- Background
  - In January 2016, President Obama declared an emergency in the State of Michigan and ordered federal aid to supplement state and local efforts
  - In February 2016, MDHHS requested to expand Medicaid eligibility for children and pregnant women impacted by the water crisis
- The Flint Medicaid Expansion Demonstration Waiver
  - CMS approved the Demonstration in response to the public health emergency of lead exposure related to the Flint water system
  - Expanded eligibility for the full array of Medicaid benefits to low-income children and pregnant women not otherwise eligible for Medicaid

Waiver Goals

- Expand Eligibility
  - Eligibility was expanded to cover children and pregnant women served by the Flint water system with incomes up to and including 400 percent of the federal poverty level
- Add a Family Supports Coordination benefit (formally known as Targeted Case Management)
  - Assists enrolled children and pregnant women in accessing needed medical, social, educational, and other service(s)

Eligibility Categories

- Children (up to age 21 & including children born to eligible pregnant women)
  - Increase income threshold to offer coverage to children in households with incomes from 212% federal poverty level (FPL) up to & including 400% FPL
- Pregnant Women (through two months post-delivery)
  - Increase income threshold to offer coverage to pregnant women in households with incomes from 195% FPL up to & including 400% FPL

2019 FPL Guidelines (Annual)

Persons in Family/Home	Federal Guideline (100% FPL)	Children (212% FPL)	Pregnant Women (195% FPL)	Flint Waiver (400% FPL)
1	$ 12,490	$ 26,479	$ 24,356	$ 49,960
2	$ 16,910	$ 35,849	$ 32,975	$ 67,640
3	$ 21,330	$ 45,220	$ 41,594	$ 85,320
4	$ 25,750	$ 54,590	$ 50,213	$ 103,000
5	$ 30,170	$ 63,960	$ 58,832	$ 120,680
6	$ 34,590	$ 73,331	$ 67,451	$ 138,360
7	$ 39,010	$ 82,701	$ 76,070	$ 156,040
8	$ 43,430	$ 92,072	$ 84,689	$ 173,720

2019 FPL Guidelines (Monthly)

Persons in Family/Home	Federal Guideline (100% FPL)	Children (212% FPL)	Pregnant Women (195% FPL)	Flint Waiver (400% FPL)
1	$ 1,041	$ 2,207	$ 2,030	$ 4,163
2	$ 1,409	$ 2,987	$ 2,748	$ 5,637
3	$ 1,778	$ 3,768	$ 3,466	$ 7,110
4	$ 2,146	$ 4,549	$ 4,184	$ 8,583
5	$ 2,514	$ 5,330	$ 4,903	$ 10,057
6	$ 2,883	$ 6,111	$ 5,621	$ 11,530
7	$ 3,251	$ 6,892	$ 6,339	$ 13,003
8	$ 3,619	$ 7,673	$ 7,057	$ 14,477

Benefits & Cost Sharing

- Benefits
  - Access to the full array of Medicaid benefits for eligible individuals
  - Additional family supports coordination services (formally targeted case management)
- Cost Sharing
  - Eliminate cost sharing and Medicaid premiums for eligible children and pregnant women served by the Flint water system

Implementation & Delivery

- Implementation
  - Waiver is set to expire on 2/28/2021
  - Extension proposes to continue current services through 2031
- Delivery Systems
  - Medicaid services are primarily delivered through the state's contracted Medicaid Health Plans
  - Genesee County is covered by Blue Cross Complete, McLaren, Meridian, HAP Empowered, Molina, and UnitedHealthcare
  - Family Supports Coordination is available through Genesee Health Systems

Enrollment & Cost Projections

	DY2020 (Projected)	DY 2021 (Projected)	DY 2022 (Projected)	DY 2023 (Projected)	DY 2024 (Projected)
Total Member Months	**305,452**	**298,502**	**293,280**	**289,788**	**288,020**
TCM-Only Benes	294,054	286,180	280,034	275,618	272,926
Full Coverage Benes	11,398	12,322	13,246	14,170	15,094
Total Utilization	**$4,185,264**	**$4,496,131**	**$4,820,518**	**$5,160,882**	**$5,521,010**
TCM-Only Benes	$2,164,074	$2,267,412	$2,376,775	$2,494,407	$2,623,871
Full Coverage Benes	$2,021,190	$2,228,720	$2,443,743	$2,666,475	$2,897,139

Waiver & Public Comment

- Waiver Application
  - The complete waiver extension application can be found online at https://www.michigan.gov/mdhhs/0,5885,7-339-71547-376862--,00.html
- Public Comment
  - Submit comments by email or hard copy (next slide)
  - Comments will be accepted until March 26, 2020

Contact Information

Comment by emailing msapolicy@michigan.gov or mail:

Michigan Department of Health and Human Services
Medical Services Administration
Medicaid Policy Section
P.O. Box 30479
Lansing, MI 48909-7979

All comments on this topic should include a “Section 1115 – Flint Waiver Extension” reference somewhere in the written submission or the subject line if by e-mail.

Family Supports Coordination

GENESEE HEALTH SYSTEM

What is Family Supports Coordination?

- Provides support to gain access to needed medical, social, educational, behavioral health and other services
- Assesses needs, Links and Coordinates to supports and services, and Monitors status and ongoing needs

Family Supports Coordination: Benefit Details

- Provided by licensed, credentialed professionals, such as Social Workers and Nurses
- Primarily community and home based
- 1 Assessment and 5 follow-up case management visits annually per eligible individual

Contact Information

Elizabeth Burtch

Genesee Health System

810-496-5664

Flint Waiver Enrollment and Cost Projections (by demonstration year)

	DY 2016*	DY 2017	DY 2018	DY 2019	DY2020 (Projected)	DY 2021 (Projected)	DY 2022 (Projected)	DY 2023 (Projected)	DY 2024 (Projected)	DY2025 (Projected)	DY 2026 (Projected)	DY 2027 (Projected)	DY 2028 (Projected)	DY 2029 (Projected)
Total Member Months	**220,725**	**341,171**	**325,798**	**312,804**	**305,452**	**298,502**	**293,280**	**289,788**	**288,020**	**281,935**	**277,577**	**273,219**	**268,862**	**264,504**
TCM-Only Benes	215,908	332,516	315,998	302,506	294,054	286,180	280,034	275,618	272,926	265,917	260,635	255,353	250,072	244,790
Full Coverage Benes	4,817	8,655	9,800	10,298	11,398	12,322	13,246	14,170	15,094	16,018	16,942	17,866	18,790	19,714
Total Utilization		**$ 3,221,038**	**$ 3,730,902**	**$ 3,863,461**	**$ 4,185,264**	**$ 4,496,131**	**$ 4,820,518**	**$ 5,160,882**	**$ 5,521,010**	**$ 5,837,634**	**$ 6,171,258**	**$ 6,504,883**	**$ 6,838,507**	**$ 7,172,132**
TCM-Only Benes	$ 650,859	$ 1,646,424	$ 1,952,738	$ 2,078,898	$ 2,164,074	$ 2,267,412	$ 2,376,775	$ 2,494,407	$ 2,623,871	$ 2,729,284	$ 2,843,943	$ 2,958,602	$ 3,073,261	$ 3,187,920
Full Coverage Benes	$ 870,028	$ 1,574,615	$ 1,778,164	$ 1,784,563	$ 2,021,190	$ 2,228,720	$ 2,443,743	$ 2,666,475	$ 2,897,139	$ 3,108,350	$ 3,327,315	$ 3,546,281	$ 3,765,246	$ 3,984,212

**Program enrollment began in May 2016*