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

**State Demonstrations Group**

June 25, 2025

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

Dear Director Groen:

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

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

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

## Updates to Demonstration Monitoring

Below are the updated aspects of demonstration monitoring for the Flint Michigan Section 1115 Demonstration (Project Number 11-W-00302/5).

*Reporting Cadence and Due Date*

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

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

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

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

*Structured Monitoring Report Template*

As noted in STC 25, "Monitoring Reports," monitoring reports "must follow the framework provided by CMS, which is subject to change as monitoring systems are developed / evolve and be provided in a structured manner that supports federal tracking and analysis." Pursuant to that STC, CMS is introducing a structured monitoring report template to minimize variation in content of reports across states, which will facilitate drawing conclusions over time and across demonstrations with broadly similar section 1115 waivers or expenditure authorities. The structured reporting framework will also provide CMS and the state opportunities for more comprehensive and instructive engagement on the report's content to identify potential risks and vulnerabilities and associated mitigation efforts as well as best practices, thus strengthening the overall integrity of demonstration monitoring.

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

*Demonstration Monitoring Calls*

As STC 28 "Monitoring Calls" describes, CMS may "convene periodic conference calls with the state," and the calls are intended "to discuss ongoing demonstration operation, including (but not limited to) any significant actual or anticipated developments affecting the demonstration." Going forward, CMS envisions implementing a structured format for monitoring calls to provide consistency in content and frequency of demonstration monitoring calls across demonstrations.

CMS also envisions convening quarterly monitoring calls with the state and will follow the structure and topics in the monitoring report template. We anticipate that standardizing the expectations for and content of the calls will result in more meaningful discussion and timely assessment of demonstration risks, vulnerabilities, and opportunities for intervention. The demonstration STCs will be updated in the next demonstration amendment or extension approval to reflect that monitoring calls will be held no less frequently than quarterly.

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

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

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

Sincerely,

[redacted]

Enclosure
cc: Christine Davidson, State Monitoring Lead, 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.

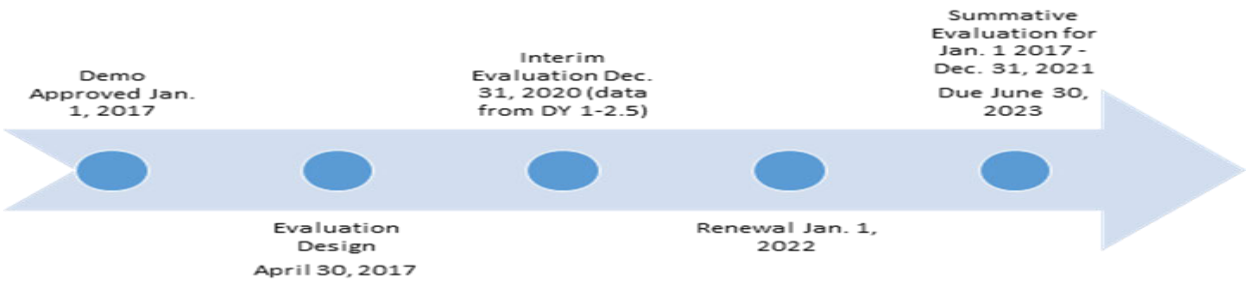
### Expectations for Evaluation Designs

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<br>-Measure 2<br>-Measure 3 | -Sample e.g. All attributed Medicaid beneficiaries<br>-Beneficiaries with diabetes diagnosis | -Medicaid fee-for-service and encounter claims records | -Interrupted time series |
| Research question 1b | -Measure 1<br>-Measure 2<br>-Measure 3<br>-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<br>-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

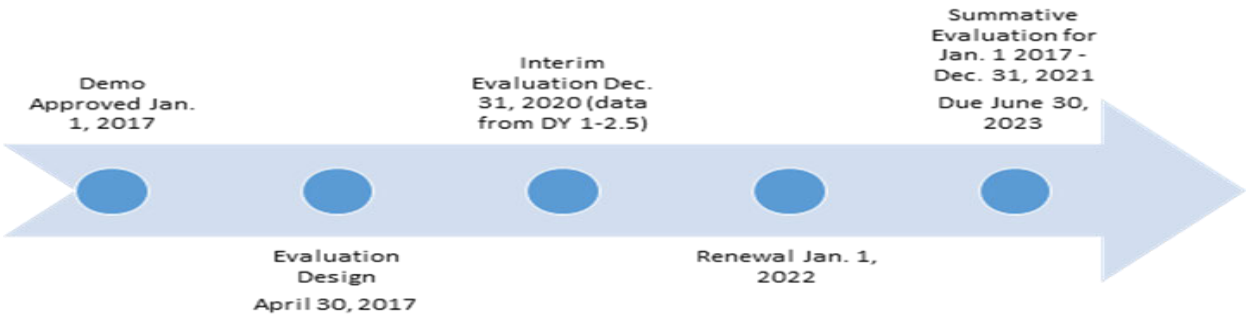
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved 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 82$^{nd}$ out of 83 counties in the state for general health outcomes and 71$^{st}$ 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*:

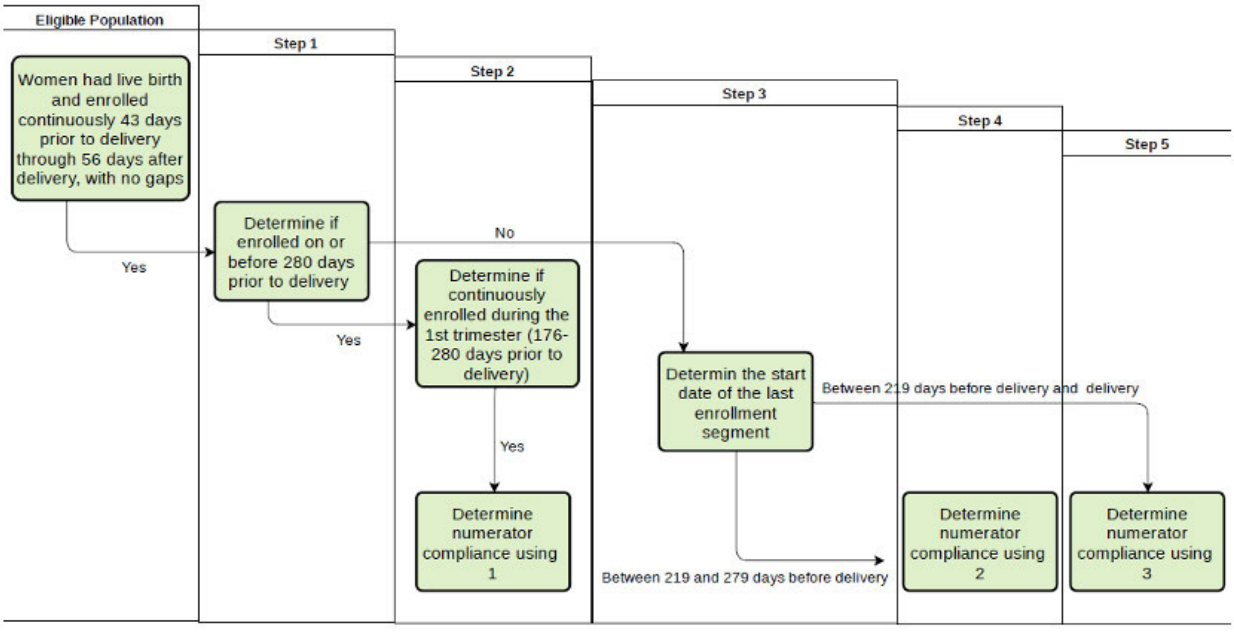
- The modified HEDIS lead screening in children measures "the percentage of children 6 years of age who had 1 or more capillary or venous lead blood test for lead poisoning by

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 5$^{th}$ 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.

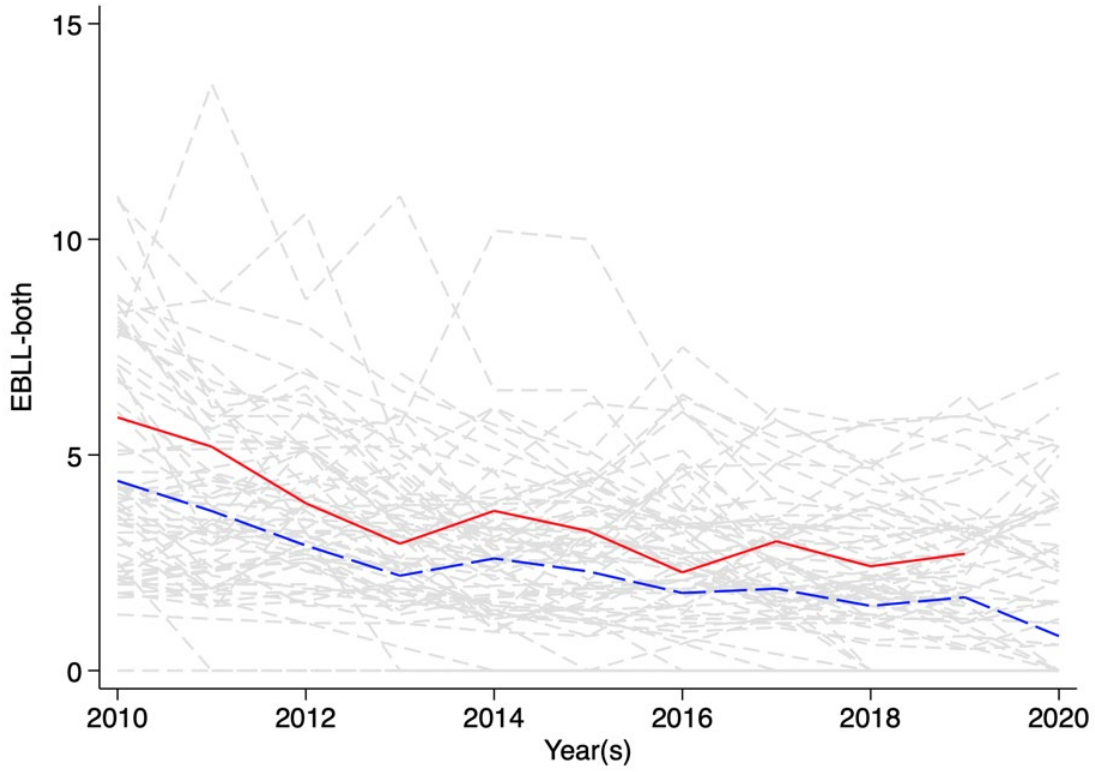
In K-means analyses, if all variables are standardized then clustering based on correlation (similarity) is equivalent to that based on squared distance (dissimilarity). Therefore, as a robustness check, we will run the K-means twice, with and without z score standardization of all features.

**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).

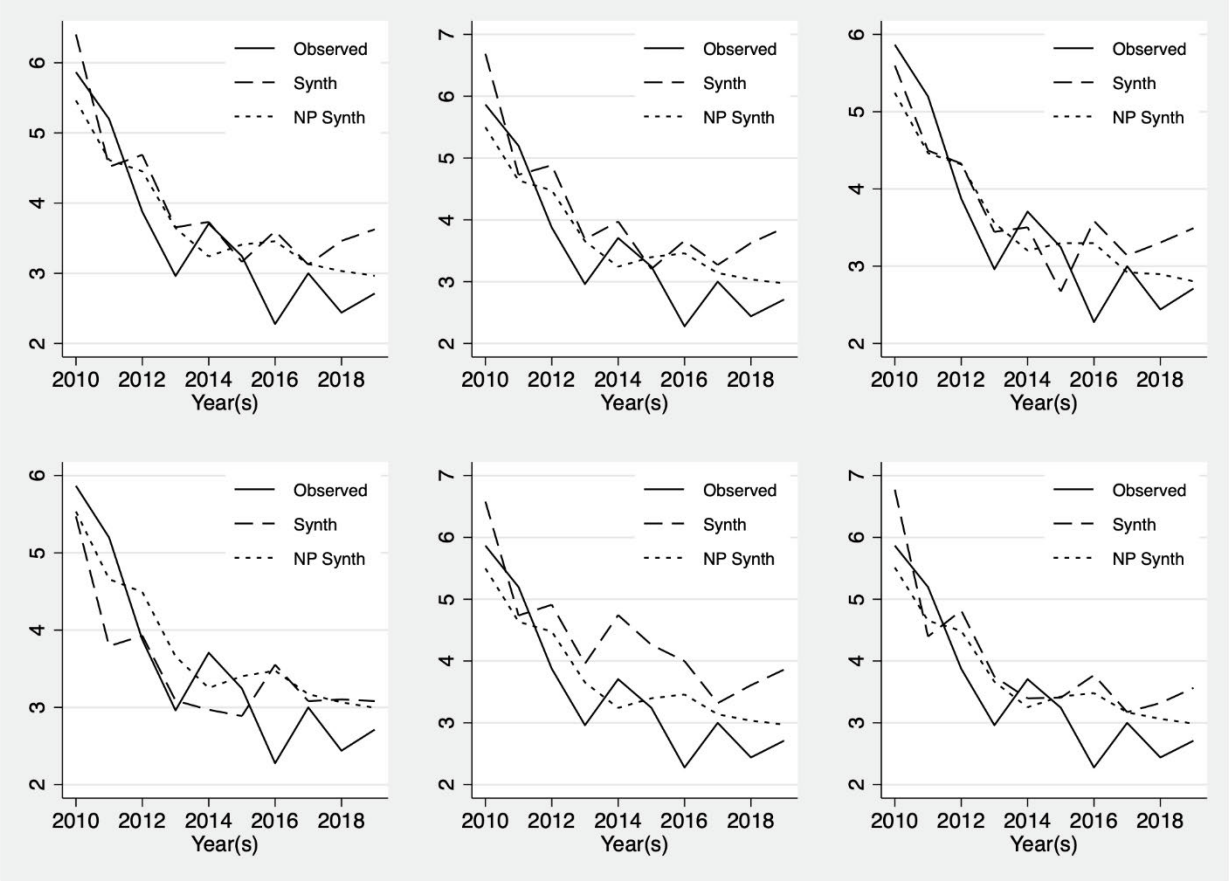
Figure C shows that the specifications in the top row and first column (unstandardized covariates and non-parametric model) tracks the Flint data the best prior to 2016; and all other specifications fall short in some aspect. The selected top counties in the best case are St. Clair, Saginaw, Jackson,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

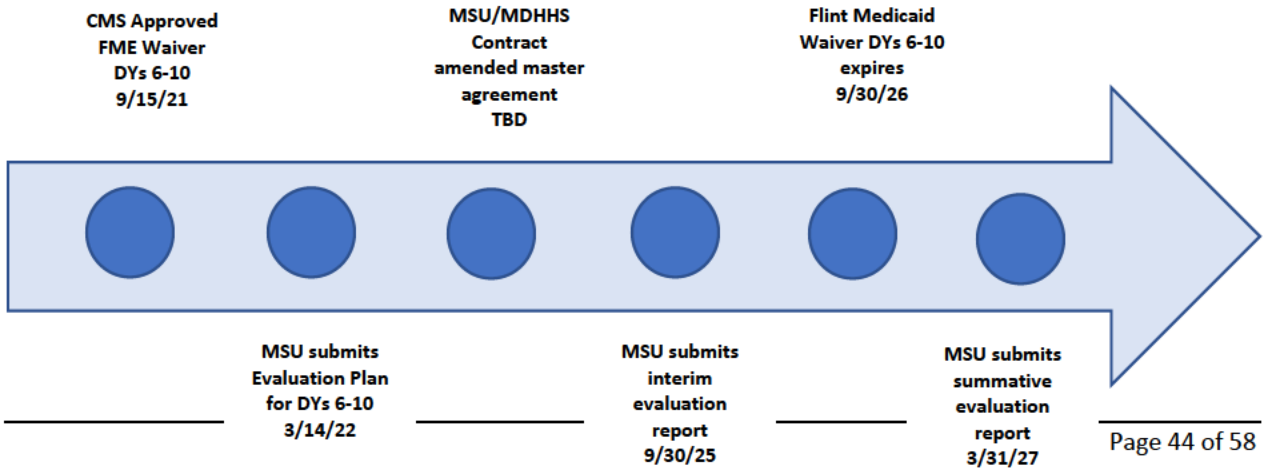
include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning 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."*<br><br>*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:<br>• # Children who received 0 well-child visits<br>• # Children who received 1 well-child visit<br>• # Children who received 2 well-child visits<br>• # Children who received 3 well-child visits<br>• # Children who received 4 well-child visits<br>• # Children who received 5 well-child visits<br>• # Children who received 6 or more well-child visits | This measure has 1 discrete numerator:<br>• At least one well-child visit with a primary care provider | This measure has 1 discrete numerator:<br>• 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:<br>• # Children who had screening for risk of development, behavioral and social delays using a standardized screening tool that was documented by their first birthday.<br>• # Children who had screening for risk of development, behavioral and social delays using a standardized screening tool that was documented by their second birthday.<br>• # Children who had screening for risk of development, behavioral and social delays using a standardized screening tool that was documented by their third birthday.<br>• # Children who had screening for risk of development, behavioral and social delays using a standardized screening tool that | This measure has 1 discrete numerator:<br>• 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:<br>• Children 3-6 years of age during the measurement period. | This measure has 1 discrete denominator:<br>• Children/ adolescents 12-21 years of age during the measurement period. | This measure has 4 discrete denominators (respectively):<br>• # Children who turn 1 by the end of the measurement period.<br>• # Children who turn 2 by the end of the measurement period.<br>• # Children who turn 3 by the end of the measurement period.<br>• # Children who turn 1 or 2 or 3 by the end of the measurement period. | This measure has 1 discrete denominator:<br>• 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."*<br><br>*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.<br><br>*Sample questions:*<br>"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.<br><br>*Sample question:*<br>"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)<br><br>"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.<br><br>*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<br><br>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<br><br>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.<br><br>*Sample questions:*<br>"In general, how would you rate your overall health?" (excellent/very good/good/fair/poor)<br><br>"In general, how would you rate your overall mental or emotional health?" (excellent/very good/good/fair/poor) | *Sample Tools:*<br>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 |