DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-01-16
Baltimore, Maryland 21244-1850

State Demonstrations Group

August 8, 2017

Chris Priest
Director
Michigan Medical Services Administration
Capitol Commons
400 South Pine
Lansing, MI 48909

Dear Mr. Priest:

I am pleased to inform you that the Centers for Medicare & Medicaid Services (CMS) has approved Michigan's proposed evaluation design for the section 1115 demonstration entitled "Flint Michigan Section 1115 Demonstration," (Project Number 11-W-00302/5). The CMS has added the approved evaluation design to the approved special terms and conditions (STCs) as Attachment C. A copy of the STCs that includes the new attachment is enclosed with this letter.

If you have any questions, please do not hesitate to contact your project officer, Ms. Jennifer Kostesich. Ms. Kostesich can be reached at Jennifer.Kostesich@cms.hhs.gov.
We look forward to continuing to work with your staff on the administration of this demonstration.

Sincerely,

/s/

Andrea J. Casart
Director
Division of Medicaid Expansion Demonstrations

Enclosure
cc: Ruth Hughes, Associate Regional Administrator, CMS Chicago Regional Office

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

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

AWARDEE: **Michigan Department of Health and Human Services**

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures incurred by Michigan identified below, which are not otherwise included as expenditures under section 1903 of the Act, shall, for the period of this demonstration, beginning the date of the signed approval letter through February 28, 2021, be regarded as expenditures under the state's Title XIX plan.

The expenditure authority listed below promotes the objectives of title XIX by: increasing overall coverage of low-income individuals in the state, improving health outcomes for Medicaid and other low-income populations in the state, and increasing access to, stabilizing, and strengthening the availability of provider and provider networks to serve Medicaid and low-income individuals in the state.

The following expenditure authority enables Michigan to implement the Flint Medicaid section 1115 demonstration:

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

CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER LIST

NUMBER: **11W 00302/5**

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 or identified as not applicable in accompanying expenditure authorities, shall apply to the demonstration project beginning the date of the signed approval letter through February 28, 2021. In addition, these waivers may only be implemented consistent with the approved Special Terms and Conditions (STCs).

Under the authority of section 1115(a)(1) of the Social Security Act (the Act), the following waivers of state plan requirements contained in section 1902 of the Act are granted subject to the STCs for the Flint Michigan section 1115 demonstration.

1. Provision of Medical Assistance **Sections 1902(a)(8); 1902(a)(10)**

To the extent necessary to permit the state to limit the provision of medical assistance (and treatment as eligible) for individuals described in the eligibility group under 1902(a)(10)(A)(ii)(XX) and the state plan, to children up to age 21 and pregnant women who were served by the Flint water system at any time from April 2014 to the state-specified date, including any child 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.

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

To the extent necessary to enable the state to not charge premiums to individuals who resided in the area served by the Flint water system from April 2014 up to the date specified in accordance with paragraph 18 of the STCs. Also, to the extent necessary to enable the state to provide evaluation of potential lead exposure in the home only for individuals who meet these non-financial criteria.

3. 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 and evaluation of potential lead exposure in the home. Also, to the extent necessary to enable the state to limit beneficiary choice of providers for beneficiaries enrolled in a Managed Care Entity (MCE) and a Prepaid Inpatient Health Plan (PIHP) under the demonstration to those providers that are within the MCE and PIHP networks. No waiver of freedom of choice is authorized for family planning providers.

CENTERS FOR MEDICARE AND MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: 11W 00302/5

TITLE: Flint Michigan Section 1115 Demonstration

AWARDEE: Michigan Department of Health and Human Services

I. PREFACE

The following are the special terms and conditions (STCs) for Michigan's "Flint Michigan" section 1115(a) Medicaid demonstration (hereinafter referred to as "demonstration") to enable Michigan (hereinafter "state") to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted waivers of requirements under Section 1902(a) of the Social Security Act (Act), and expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS during the life of the demonstration. The STCs are effective as of the date of award of the demonstration. This demonstration is approved through February 28, 2021.

The STCs have been arranged into the following subject areas:

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

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

Attachment A: Quarterly Progress Report Content and Format (TBD)
Attachment B: Post Approval Protocol
Attachment C: Demonstration Evaluation Plan

II. PROGRAM DESCRIPTION AND OBJECTIVES

On January 16, 2016, President Obama declared an emergency in the State of Michigan and ordered federal aid to supplement state and local response efforts due to the emergency conditions in the areas of Flint, Michigan affected by contaminated water. In a letter and application dated February 14, 2016, Michigan requested to expand eligibility for children and pregnant women in Flint, Michigan and to offer expanded benefits for those affected by the water crisis. Through this demonstration and the associated state plan amendments the state will expand eligibility to low-income children and pregnant women who were served by the Flint water system during a specified period of time and who would not otherwise be eligible for Medicaid. This population consists of children in households with incomes from 212 percent of the federal poverty level (FPL) up to and including 400 percent of the FPL and pregnant women in households with incomes from 195 percent up to and including 400 percent of the FPL. This population will receive care primarily through Medicaid managed care plans and receive all state plan benefits including, for children, EPSDT. The state will add a new Targeted Care Management benefit through the state plan to all children and pregnant women served by the Flint water system during the defined period who have been determined eligible for Medicaid; the demonstration provides authority to limit the provision of these specialized services to certain providers. This demonstration provides authority for the state to offer screening and evaluation of potential lead exposure in the home for all eligible children and pregnant women who were served by the Flint water system during the specified period. The demonstration also provides authority to permit the state to eliminate Medicaid premiums for eligible individuals served by the Flint water system during the specified period. The demonstration will be authorized through February 28, 2021.

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, Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.

2. **Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program, expressed in law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to this demonstration.

3. **Changes in Medicaid Law, Regulation, and Policy.** The state must, within the timeframes specified in law, regulation, or policy statement, come into compliance with any changes in Federal law, regulation, or policy affecting the Medicaid program 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 paragraph 7. CMS will notify the state 30 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 of Changes in Federal Law, Regulation, and Policy on the Demonstration.**

    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 and allotment neutrality worksheet for the demonstration as necessary to comply with such change. The modified budget neutrality agreement and modified allotment neutrality will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph.

    b. If mandated changes in the federal law require state legislation, the changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law.

    c. Should there be future changes in federal law related to the FFP associated with the demonstration, the state may seek to end the demonstration (as per STC 9) or seek an amendment (as per STC 7).

5. **State Plan Amendments.** The state will not be required to submit Title XIX state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid 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 state plan governs.

6. **Changes Subject to the Amendment Process.** Changes related to demonstration features, such as eligibility, enrollment, benefits, enrollee rights, delivery systems, cost sharing, evaluation design, 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 or begin operational changes to these elements without prior approval by CMS of the amendment to the demonstration. In certain instances, amendments to the Medicaid state plan may or may not require amendment to the demonstration as well. Amendments to the demonstration are not retroactive and FFP will not be available for changes to the demonstration that have not been approved through the amendment process set forth in paragraph 7.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 days 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 upon non-compliance with these STCs, including but not limited to failure by the state to submit required elements of a viable amendment request as found in these STCs, required reports and other deliverables required in the approved STCs in a timely fashion according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:

    a. Demonstration of Public Notice 42 CFR 431.408 and tribal consultation: The state must provide documentation of the state's compliance with public notice process as specified in 42 CFR 431.408 and documentation that the tribal consultation requirements outlined in paragraph 15 have been met. Such documentation shall include a summary of public comments and identification of proposal adjustments made to the amendment request due to the public input;

    b. Demonstration Amendment Summary and Objectives: The state must provide a detailed description of the amendment, including what the state intends to demonstrate via this amendment as well as the impact on beneficiaries, with sufficient supporting documentation, the objective of the change and desired outcomes including a conforming Title XIX and/or Title XXI SPA, if necessary;

    c. Waiver and Expenditure Authorities: The state must provide a list waivers and expenditure authorities that are being requested or terminated, along with the reason, need and the citation along with the programmatic description of the waivers and expenditure authorities that are being requested for the amendment;

    d. A budget neutrality data analysis worksheet: The state must provide a worksheet which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement, including the underlying spreadsheet calculation formulas. Such analysis shall 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, or feature) the impact of the amendment;

    e. Allotment Neutrality Worksheet. The state must provide an up-to-date CHIP (title XXI funding) allotment neutrality worksheet that identifies the impact of the proposed amendment on the state's available title XXI allotment.

f. Updates to existing demonstration reporting, quality and evaluation plans: A description of how the evaluation design and quarterly and annual 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 demonstration extensions under sections 1115(e) or 1115(f) are advised to observe the timelines contained in those statutes. Otherwise, no later than 12 months prior to the expiration date of the demonstration, the governor or chief executive officer of the state must submit to CMS either a demonstration extension request or a transition and phase-out plan consistent with the requirements of paragraph 9.

a. Compliance with Transparency Requirements at 42 CFR 431.412. As part of the demonstration extension requests the state must provide documentation of compliance with the transparency requirements 42 CFR 431.412 and the public notice and Tribal consultation requirements outlined in paragraph 15.

b. Upon application from the state, CMS reserves the right to temporarily extend the demonstration including making any amendments deemed necessary to effectuate the demonstration extension including but not limited to bringing the demonstration into compliance with changes to federal law, regulation and policy.

9. Demonstration Transition and 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 its notification letter and a draft transition and phase-out plan to CMS no less than six (6) months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with its approved tribal consultation SPA. Once the 30-day public comment period has ended, the state must provide a summary of each public comment received, the state's response to the comment and how the state incorporated the received comment into the revised phase-out plan.

b. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of the phase-out activities. Implementation of phase-out activities must be no sooner than 14 days after CMS approval of the phase-out plan.

c. 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 eligibility prior to the termination of the program for the affected beneficiaries including any individuals on demonstration waiting lists, and ensure ongoing coverage for those beneficiaries determined eligible for ongoing coverage, as well as any community outreach activities including community resources that are available.

d. Phase-out Procedures: The state must comply with all notice requirements found in 42 CFR 431.206, 431.210, and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration beneficiaries as outlined in 42 CFR 431.220 and 431.221. If a demonstration participant beneficiary 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 eligibility under a different eligibility category.

e. Exemption from Public Notice Procedures 42.CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements in the event it determines that the objectives of Title XIX and XXI would be served or under circumstances described in 42 CFR 431.416(g).

f. Federal Financial Participation (FFP): If the project is terminated or any relevant waivers suspended by the state, FFP shall be limited to normal closeout costs associated with terminating the demonstration including services and administrative costs of disenrolling beneficiaries.

10. Expiring Demonstration Authority and Transition. For demonstration authority that expires prior to the overall demonstration's expiration date, the state must submit a demonstration authority expiration plan to CMS no later than 6 months prior to the applicable demonstration authority's expiration date, consistent with the following requirements:

a. Expiration Requirements: The state must include, at a minimum, in its demonstration expiration 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 eligibility for the affected beneficiaries, and ensure ongoing coverage for eligible individuals, as well as any community outreach activities.

b. Expiration Procedures: The state must comply with all notice requirements found in 42 CFR 431.206, 431.210 and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration beneficiaries as outlined in 42 CFR 431.220 and 431.221. If a demonstration participant beneficiary 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 eligibility under a different eligibility category.

c. Federal Public Notice: CMS will conduct a 30-day federal public comment period consistent with the process outlined in 42 CFR 431.416 in order to solicit public input on the state's demonstration expiration plan. CMS will consider comments received during the 30-day period during its review and approval of the state's demonstration expiration plan. The state must obtain CMS approval of the demonstration expiration plan prior to the implementation of the expiration activities. Implementation of expiration activities must be no sooner than 14 days after CMS approval of the plan.

d. Federal Financial Participation (FFP): FFP shall be limited to normal closeout costs associated with the expiration of the demonstration including services and administrative costs of disenrolling beneficiaries.

11. **CMS Right to Amend, Terminate or Suspend.** CMS may amend, suspend or terminate the demonstration in whole or in part at any time before the date of expiration, whenever it determines, following a hearing that the state has materially failed to comply with the terms of the project. CMS will promptly notify the state in writing of the determination and the reasons for the suspension or termination, together with the effective date.

12. **Finding of Non-Compliance.** The state does not relinquish its rights to challenge CMS' finding that the state materially failed to comply.

13. **Withdrawal of Waiver Authority.** CMS reserves the right to withdraw waivers or expenditure authorities at any time it determines that continuing the waivers or expenditure authorities would no longer be in the public interest or promote the objectives of Title XIX or 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 or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services and administrative costs of disenrolling beneficiaries.

14. **Adequacy of Infrastructure.** The state must 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.

15. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the State Notice Procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994). The state must also comply with the Tribal consultation requirements in section 1902(a)(73) of the Act as amended by section 5006(e) of the American Recovery and Reinvestment Act (ARRA) of 2009, the implementing regulations for the Review and Approval Process for section 1115 demonstrations at 42 CFR. 431.408, and the Tribal consultation requirements contained in the state's approved state plan, when any program changes to the demonstration, including (but not limited to) those referenced in paragraph 7, are proposed by the state.

    a. In states with federally recognized Indian Tribes, consultation must be conducted in accordance with the consultation process outlined in the July 17, 2001 letter or the consultation process in the state's approved Medicaid state plan if that process is specifically applicable to consulting with tribal governments on waivers (42 C.F.R. 431.408(b)(2)).

    b. In states with federally recognized Indian Tribes, Indian Health Services programs, and/or Urban Indian Organizations, the state is required to submit evidence to CMS regarding the solicitation of advice from these entities prior to submission of any demonstration proposal, amendment and/or renewal of this demonstration (42 CFR. 431.408(b)(3)).

    c. 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.

16. **Federal Financial Participation (FFP).** No federal matching for expenditures (administrative or services) for this demonstration will be available until the approval date identified in the demonstration approval letter, or a later date if so identified elsewhere in these STCs or in the lists of waiver or expenditure authorities.

17. **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 FOR THE DEMONSTRATION

18. **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. The state may amend the demonstration to further refine the eligibility criteria, and such amendment will be expedited by CMS under current rules and regulations. 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 18(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.

19. **Post Approval Protocol.** Within 30 days of approval of these STCs, the state must submit to CMS for approval a protocol clearly explaining how eligible individuals will be identified, both initially and for the duration of demonstration eligibility. The state may request changes to the protocol, which must be approved by CMS, and which will be effective prospectively. This protocol will be included in the STCs as Attachment B. Changes may be subject to an amendment to the STCs in accordance with paragraph 7, depending upon the nature of the proposed change.

V. BENEFITS

20. **Flint Michigan Benefit Package.** Flint beneficiaries will receive all Medicaid state plan benefits including, for children, EPSDT benefits. Such Medicaid benefits will include a new Targeted Case Management benefit that will be set forth in the state plan. In addition, this demonstration provides a benefit for evaluation of potential sources of lead exposure in the home for Flint beneficiaries who:
    a. Are eligible as described in STC 18, and
    b. Do not have elevated blood levels. (This same diagnostic benefit is provided through the state plan for children with elevated blood lead levels.)

VI. COST SHARING

21. **Cost-sharing.** There will be no cost-sharing charged to Flint beneficiaries regardless of eligibility group.

22. **Premiums.** There will be no premiums charged to Flint beneficiaries regardless of eligibility group.

VII. DELIVERY SYSTEM

23. Flint Michigan Demonstration. Flint beneficiaries will receive services through the same managed care and fee-for-service arrangements as currently authorized in the state.

24. 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 18. 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. 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.

VIII. GENERAL REPORTING REQUIREMENTS

25. General Financial Requirements. The state must comply with all general financial requirements under Title XIX, including reporting requirements related to monitoring budget neutrality, set forth in Section IX of these STCs.

26. Monthly Enrollment Report. Within 20 days following the first day of each month, the state must report demonstration enrollment figures for the month just completed to the CMS Project Officer and Regional Office contact via e-mail, using the table below. The data requested under this subparagraph are similar to the data requested for the Quarterly Progress Report in Attachment A under Enrollment Count, except that they are compiled on a monthly basis.

Populations Affected by the Demonstration and Eligible for Benefits based on Service from the Flint Water System	**Point In Time Enrollment** (last day of month)	**Title XXI Funded**	**Newly Enrolled Last Month**	**Disenrolled Last Quarter**
All Medicaid Eligible Pregnant Women served by the Flint Water System (everybody – TCM total)				
All Medicaid Eligible Pregnant Women served by the Flint Water System affected by the demonstration because of the Freedom of choice waiver (XX group total – FOC waiver)				
All Medicaid Eligible Pregnant Women served by the Flint Water System affected by the demonstration because of the premium waiver (VIII group/QHP)				
All Medicaid Eligible Children served by the Flint Water System (everybody – TCM total)				
All Medicaid Eligible Children served by the Flint Water System affected by the demonstration because of the screening (all groups – screening without regard to exposure level)				
All Medicaid Eligible Children served by the Flint Water System affected by the demonstration because of the Freedom of choice waiver (XX group total – FOC waiver)				
All Medicaid Eligible Children served by the Flint Water System affected by the				

demonstration because of the premium waiver (VIII group)				

27. **Reporting Requirements Related to Budget Neutrality.** The state must comply with all reporting requirements for monitoring budget neutrality set forth in Section X of these STCs, including the submission of corrected budget neutrality data upon request.

28. **Maintenance of Coverage and Enrollment Standards for Children.** The state shall, throughout the course of the demonstration renewal, include a review of enrollment data to provide evidence that children are not denied enrollment and continue to show that it has continued procedures to enroll and retain eligible children for CHIP.

    a. The state's established monitoring process ensures that expenditures for the demonstration will not exceed available title XXI funding (i.e., the title XXI allotment or reallocated funds) and the appropriate state match.

29. **Monitoring Calls.** CMS will convene periodic conference calls with the state. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration. Areas to be addressed include, but are not limited to: transition and implementation activities, MCO operations and performance, enrollment, cost sharing, quality of care, access, the benefit package, audits, lawsuits, financial reporting and budget neutrality issues, progress on evaluations, legislative developments, and any demonstration amendments the state is considering submitting. CMS will provide updates on any amendments or concept papers under review, as well as federal policies and issues that may affect any aspect of the demonstration. The state and CMS will jointly develop the agenda for the calls.

30. **Post Award Forum.** Within six months of the demonstration's implementation, and annually thereafter, the state will afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 30 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 can use either its Medical Care Advisory Committee, or another meeting that is open to the public and where an interested party can learn about the progress of the demonstration to meet the requirements of these STCs. The state must include a summary of the comments and issues raised by the public at the forum and include the summary in the progress report, as specified in paragraph 31, associated with the quarter in which the forum was held. The state must also include the summary in its annual report as required in paragraph 32.

31. **Quarterly Progress Reports.** The state must submit quarterly progress reports in accordance with the guidelines in Attachment A no later than 60 days following the end of each quarter. The report template will be agreed upon by CMS and the state within 30 days of approval of this demonstration. The intent of these reports is to present the state's analysis and the status of the various operational areas. These quarterly progress and annual reports will include performance information on a set of process and outcome

metrics to be developed in consultation with CMS that will assist the state, CMS and other parties in understanding trends in enrollment, services and supports being accessed by enrollees, and health and other beneficiary outcomes including comparisons to affected populations that are not enrolled and to unaffected populations in the state. The state will provide this performance information for the duration of time that enrollees are covered. In addition, quarterly and annual reports must include the following, but are not limited to:

a. An updated budget neutrality monitoring spreadsheet;

b. Events occurring during the quarter or anticipated to occur in the near future that affect health care delivery, including, but not limited to: benefits, enrollment and disenrollment, complaints and grievances, quality of care, and access that is relevant to the demonstration, pertinent legislative or litigation activity, and other operational issues;

c. Updates on the post award forums required under paragraph 30.

d. Action plans for addressing any policy, administrative, or budget issues identified;

e. Monthly enrollment reports for demonstration beneficiaries, that include the member months and end of quarter, point-in-time enrollment for each demonstration population;

f. Information on beneficiary complaints, grievances and appeals filed during the quarter by type including; access to urgent, routine, and specialty services, and a description of the resolution and outcomes. Evaluation activities and interim findings. 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. The discussion shall also include interim findings, when available; status of contracts with independent evaluator(s), if applicable; sand status of study participant beneficiary recruitment, if applicable.

g. Identify any quality assurance/monitoring activity in current quarter.

32. Demonstration Annual Report. The annual report must, at a minimum, include the requirements outlined below. The state will submit the draft Annual Report no later than 90 days after the end of each demonstration year. Within 30 days of receipt of comments from CMS, a final Annual Report must be submitted for the demonstration year (DY) to CMS.

a. All items included in the Quarterly Progress Report pursuant to paragraph 31must be summarized to reflect the operation/activities throughout the DY;

b. Total annual expenditures for the demonstration population for each DY, with administrative costs reported separately

c. Yearly enrollment reports for demonstration enrollees for each DY (enrollees include all individuals enrolled in the demonstration) that include the member months, as required to evaluate compliance with the budget neutral agreement;

33. Final Report. Within 120 days following the end of the demonstration, the state must submit a draft final report to CMS for comments. The state must take into consideration CMS' comments for incorporation into the final report. The final report is due to CMS no later than 90 days after receipt of CMS' comments.

IX. GENERAL FINANCIAL REQUIREMENTS

This project is approved for Title XIX and XXI expenditures applicable to services rendered during the demonstration period. This Section describes the general financial requirements for these expenditures.

34. Quarterly Financial Reports. The state must provide quarterly Title XIX expenditure reports using Forms CMS-64 and CMS 64.21, to separately report total Title XIX expenditures for services provided through this demonstration under section 1115 authority. This project is approved for expenditures applicable to services rendered during the demonstration period. CMS shall provide Title XIX FFP for allowable demonstration expenditures, only as long as they do not exceed the pre-defined limits on the costs incurred, as specified in Section X of the STCs.

35. Reporting Expenditures under the Demonstration. The following describes the reporting of expenditures subject to the budget neutrality agreement:

a. **Tracking Expenditures.** In order to track expenditures under this demonstration, the state will report demonstration expenditures through the Medicaid and State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES); following routine CMS-64 reporting instructions outlined in Section 2500 and Section 2115 of the State Medicaid Manual. All demonstration expenditures subject to budget neutrality limits must be reported each quarter on separate Forms CMS-64.9 WAIVER and/or 64.9P WAIVER and/or CMS 64.21, identified by the demonstration project number assigned by CMS (including the project number extension, which indicates the DY in which services were rendered or for which capitation payments were made). For monitoring purposes, cost settlements must be recorded on the appropriate prior period adjustment schedules (Forms CMS-64.9 Waiver) for the Summary Line 10B, in lieu of Lines 9 or l0C. For any other cost settlements (i.e., those not attributable to this demonstration), the adjustments should be reported on lines 9 or 10C, as instructed in the State Medicaid Manual. Once the appropriate waiver form is selected for reporting expenditures, the state will continue to be required to

identify the program code and coverage (children or adults). The term, "expenditures subject to the budget neutrality limit," is defined below in paragraph 36.

b. **Cost Settlements.** For monitoring purposes, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (Form CMS-64.9P Waiver) for the Summary Sheet Line 10B, in lieu of Lines 9 or 10C. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual.

c. **Premium and Cost Sharing Contributions.** Premiums and other applicable cost sharing contributions that are collected by the state from enrollees under the demonstration must be reported to CMS each quarter on Form CMS-64 Summary Sheet line 9.D, columns A and B. In order to assure that these collections are properly credited to the demonstration, premium and cost-sharing collections (both total computable and federal share) should also be reported separately by DY on the Form CMS-64 Narrative. In the calculation of expenditures subject to the budget neutrality expenditure limit, premium collections applicable to demonstration populations will be offset against expenditures. These Section 1115 premium collections will be included as a manual adjustment (decrease) to the demonstration's actual expenditures on a quarterly basis.

d. **Pharmacy Rebates.** The state may propose a methodology for assigning a portion of pharmacy rebates to the demonstration populations, in a way that reasonably reflects the actual rebate-eligible pharmacy utilization of those populations, and which reasonably identifies pharmacy rebate amounts with DYs. Use of the methodology is subject to the approval in advance by the CMS Regional Office, and changes to the methodology must also be approved in advance by the Regional Office. The portion of pharmacy rebates assigned to the demonstration using the approved methodology will be reported on the appropriate Forms CMS-64.9 Waiver for the demonstration and not on any other CMS 64.9 form to avoid double –counting. Each rebate amount must be distributed as state and Federal revenue consistent with the Federal matching rates under which the claim was paid.

e. **Use of Waiver Forms for Medicaid.** For each DY, separate Forms CMS-64.9 Waiver and/or 64.9P Waiver shall be submitted reporting expenditures for individuals enrolled in the demonstration, subject to the budget neutrality limits (Section X of these STCs). The state must complete separate waiver forms for the following Medicaid eligibility groups/waiver names:

    i. MEG 1 – "Flint lead diagnostics" (all health care diagnostic expenditures for Flint eligible children and pregnant women, starting February XX, 2016)

f. **Demonstration Years.** Demonstration Years (DYs) will be defined as follows:

Demonstration Year 1 (DY 1)	March 1, 2016 – February 28, 2017
Demonstration Year 2 (DY 2)	March 1, 2017 – February 28, 2018
Demonstration Year 3 (DY 3)	March 1, 2018 – February 28, 2019
Demonstration Year 4 (DY 4)	March 1, 2019 – February 29, 2020
Demonstration Year 5 (DY 5)	March 1, 2020 – February 28, 2021

36. Expenditures Subject to the Budget Neutrality Limits. For purposes of this Section, the term "expenditures subject to the budget neutrality limit" must include:

a. All demonstration medical assistance expenditures for lead investigation with dates of services within the demonstration's approval period; and

b. All expenditures that are subject to the budget neutrality agreement are considered demonstration expenditures and must be reported on Forms CMS-64.9 Waiver and /or 64.9P Waiver.

37. Administrative Costs. Administrative costs will not be included in the budget neutrality limit, but the state must separately track and report additional administrative costs that are directly attributable to the demonstration, using Forms CMS-64.10 Waiver and/or 64.10P Waiver, with waiver name "ADM".

38. Claiming Period. All claims for expenditures subject to the budget neutrality limit (including any cost settlements) must be made within 2 years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including any cost settlements) must be made within 2 years after the conclusion or termination of the demonstration. During the latter 2-year period, the state must continue to identify separately net expenditures related to dates of service during the operation of the section 1115 demonstration on the Form CMS-64 and/or CMS 64.21in order to properly account for these expenditures in determining budget neutrality.

39. Reporting Member Months. The following describes the reporting of member months for demonstration populations:

a. For the purpose of calculating the budget neutrality expenditure cap and for other purposes, the state must provide to CMS, as part of the Quarterly Progress Report required under paragraph 31, the actual number of eligible member months for the demonstration populations defined in paragraph 18. The state must submit a

statement accompanying the Quarterly Progress Report, which certifies the accuracy of this information. Member months must be reported for Flint Michigan starting March 1, 2016.

b. To permit full recognition of "in-process" eligibility, reported counts of member months may be subject to revisions after the end of each quarter. Member month counts may be revised retrospectively as needed.

c. The term "eligible member months" refers to the number of months in which persons are eligible to receive services. For example, a person who is eligible for 3 months contributes 3 eligible member months to the total. Two individuals who are eligible for 2 months each contribute 2 eligible member months to the total, for a total of 4 eligible member months.

40. Standard Medicaid Funding Process. The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure cap and separately report these expenditures by quarter for each federal fiscal year (FFY) on the Form CMS-37 for both the Medical Assistance Payments (MAP) and State and Local Administration Costs (ADM). CMS will make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter just ended. The CMS will reconcile expenditures reported on the Form CMS-64 quarterly with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

41. Standard CHIP Funding Process. The standard CHIP funding process will continue to be used during the demonstration. Michigan will continue to estimate matchable CHIP expenditures on the quarterly Form CMS-21B. On a separate CMS-64.21, the state provides updated estimates of expenditures for the demonstration population. CMS will continue to make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state must submit the Form CMS-64.21 quarterly CHIP expenditure report. CMS will reconcile expenditures reported on the Form CMS-64.21 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

42. Extent of FFP 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 as outlined below, subject to the limits described in Section X:

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 state plan.

c. Medical Assistance expenditures made under section 1115 demonstration authority, including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability or CMS payment adjustments.

43. Sources of Non-Federal Share. The state must certify that the matching non-federal share of funds for the demonstration is state/local monies. The state further certifies that such funds shall not be used as the 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. CMS may 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. Any amendments that impact the financial status of the program shall require the state to provide information to CMS regarding all sources of the non-federal share of funding.

c. The state assures that all health care-related taxes comport with section 1903(w) of the Act and all other applicable federal statutory and regulatory provisions, as well as the approved Medicaid state plan.

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

ii. Units of government, including governmentally operated health care providers, may certify that state or local tax dollars have been expended as the non-federal share of funds under the demonstration.

iii. To the extent the state utilizes certified public expenditures (CPEs) as the funding mechanism for Title XIX (or under section 1115 authority) payments, 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.

iv. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for payments under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such tax revenue (state or local) used to satisfy

demonstration expenditures. The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.

e. The state may use intergovernmental transfers to the extent that such funds are derived from state or local tax revenues 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.

f. Under all circumstances, health care providers must retain 100 percent of the reimbursement amounts claimed by the state as demonstration expenditures. Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state and/or local government to return and/or redirect 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, and 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.

X. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

44. Limit on Title XIX Funding. The state shall be subject to a limit on the amount of federal Title XIX funding that the state may receive on selected Medicaid expenditures during the period of approval of the demonstration. The limit is determined by using the per capita cost method described in paragraph 48. The budget neutrality expenditure limits are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. The data supplied by the state to CMS to set the annual caps is subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit. CMS' assessment of the state's compliance with these annual limits will be done using the Schedule C report from the CMS-64.

45. Title XXI Limits. Michigan continues to be subject to a limit on the amount of federal title XXI funding that it may receive on demonstration expenditures during the demonstration period. Federal title XXI funding available for demonstration expenditures is limited to the state's available allotment, including currently available reallocated funds. Should the state expend its available title XXI federal funds for the claiming period, no further enhanced federal matching funds will be available for costs of the approved title XXI separate child health program or demonstration until the next allotment becomes available.

46. Title XXI Administrative Costs. Total expenditures for outreach and other reasonable costs to administer the title XXI state plan and the demonstration that are applied against the state's title XXI allotment may not exceed 10 percent of total title XXI expenditures.

47. Risk. The state will be at risk for the per capita cost (as determined by the method described below) for demonstration populations as defined in paragraph 18, but not at risk for the number of enrollees in the demonstration population. By providing FFP without regard to enrollment in the demonstration populations, CMS will not place the state at risk for changing economic conditions that impact enrollment levels. However, by placing the state at risk for the per capita costs of current eligibles, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration.

48. Calculation of the Budget Neutrality Limit for Flint Michigan Demonstration. For the purpose of calculating the overall budget neutrality limit for the demonstration, separate annual budget limits will be calculated for each DY on a total computable basis, as described in STC 48(d)below. The annual limits will then be added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality limit by the Composite Federal Share, which is defined in STC 49 below. The demonstration expenditures subject to the budget neutrality limit are those reported under the waiver name "Flint Lead Diagnostics."

a. The MEG listed in the table below is included in the calculation of the budget neutrality limit for the Flint demonstration.
b. The state shall finalize a budget neutrality agreement with CMS by March 15, 2016.
c. The budget neutrality cap is calculated by taking the PMPM cost projection for the above group in each DY, times the number of eligible member months for that group and DY, and adding the products together across DYs. The federal share of the budget neutrality cap is obtained by multiplying total computable budget neutrality cap by the federal share.
d. The state will not be allowed to obtain budget neutrality "savings" from this population.

MEG	DY 1 – PMPM	DY 2 – PMPM	DY 3 – PMPM	DY 4 – PMPM	DY 5 – PMPM
Flint Lead Diagnostics	$10.49	$10.49	$10.49	$10.49	$10.49

49. Composite Federal Share Ratio. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period, as reported through the MBES/CBES and summarized on Schedule C (with consideration of additional allowable demonstration offsets such as, but not limited to, premium collections) by total computable demonstration expenditures for the same period as reported on the same forms. Should the demonstration be terminated

prior to the end of the extension approval period (see paragraphs 9 and 11), the Composite Federal Share will be determined based on actual expenditures for the period in which the demonstration was active. For the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed upon method.

50. Future Adjustments to the Budget Neutrality Expenditure Limit. CMS reserves the right to adjust the budget neutrality expenditure limit to be consistent with enforcement of impermissible provider payments, health care related taxes, new federal statutes, or policy interpretations implemented through letters, memoranda, or regulations with respect to the provision of services covered under the demonstration.

51. Enforcement of Budget Neutrality. CMS shall enforce budget neutrality over the life of the demonstration rather than on an annual basis. However, if the state's expenditures exceed the calculated cumulative budget neutrality expenditure cap by the percentage identified below for any of the demonstration years, the state must submit a corrective action plan to CMS for approval. The state will subsequently implement the approved corrective action plan.

Year	Cumulative target definition	Percentage
DY 1	Cumulative budget neutrality limit for DY 1 plus:	2.0 percent
DY 2	Cumulative budget neutrality limit for DY 1 and DY 2 plus:	1.5 percent
DY 3	Cumulative budget neutrality limit for DY 1through DY 3 plus:	1.0 percent
DY 4	Cumulative budget neutrality limit for DY 1 through DY 4 plus:	0.5 percent
DY 5	Cumulative budget neutrality limit for DY 1 through DY 5 plus:	0 percent

52. Exceeding Budget Neutrality. If at the end of the demonstration period the cumulative budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the budget neutrality agreement, an evaluation of this provision will be based on the time elapsed through the termination date.

53. Impermissible DSH, Taxes or Donations. The CMS reserves the right to adjust the budget neutrality expenditure limit in order to be consistent with enforcement of impermissible provider payments, health care related taxes, new Federal statutes, or with policy interpretations implemented through letters, memoranda, or regulations. CMS reserves the right to make adjustments to the budget neutrality expenditure limit if CMS determines that any health care-related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is in violation of the provider

donation and health care related tax provisions of Section 1903(w) of the Act. Adjustments to the budget neutrality agreement will reflect the phase-out of impermissible provider payments by law or regulation, where applicable.

XI. EVALUATION OF THE DEMONSTRATION

54. Submission of Draft Evaluation Design Update. The state must submit to CMS for approval, within 120 days of the approval date of the Flint Michigan demonstration draft evaluation design. At a minimum, the draft design must include a discussion of the goals, objectives and specific testable hypotheses, including those that focus specifically on target populations for the demonstration, and more generally on beneficiaries, providers, plans, market areas and public expenditures. The analysis plan must cover all elements in paragraph 56. The design should be described in sufficient detail to determine that it is scientifically rigorous. The data strategy must be thoroughly documented.

The design should describe how the evaluation and reporting will develop and be maintained to assure its scientific rigor and completion. In summary, the demonstration evaluation will meet all standards of leading academic institutions and academic journal peer review, as appropriate for each aspect of the evaluation, including standards for the evaluation design, conduct, interpretation, and reporting of findings. Among the characteristics of rigor that will be met are the use of best available data; controls for and reporting of the limitations of data and their effects on results; and the generalizability of results.

The design must describe the state's process to contract with an independent evaluator, ensuring no conflict of interest.

The design, including the budget and adequacy of approach, to assure the evaluation meets the requirements of paragraph 56, is subject to CMS approval. The budget and approach must be adequate to support the scale and rigor reflected in the paragraph above. The rigor also described above also applies as appropriate throughout Section XI.

55. Cooperation with Federal Evaluators. Should HHS undertake an evaluation of any component of the demonstration, the state shall cooperate fully with CMS or the evaluator selected by HHS in addition, the state shall submit the required data to HHS or its contractor.

56. Evaluation Design.

a. Domains of Focus – The state must propose as least one research question that it will investigate within each of the domains listed below.

The state proposes several hypotheses that will be tested to evaluate the success of the Flint Michigan demonstration. These hypotheses include the following:

i. Enrollees will access services to identify and address physical or behavioral health issues associated with lead exposure at a rate higher than others with similar levels of lead exposure.

ii. Enrollees who access Targeted Case Management services will access needed medical, social, educational, and other services at a rate higher than others with similar levels of lead exposure.

iii. Enrollees will have improved health outcomes compared to others with similar levels of lead exposure.

iv. The lead hazard investigation program will reduce estimated expected ongoing or re-exposure to lead hazards in the absence of this program.

b. Measures - The draft evaluation design must discuss the outcome measures that shall be used in evaluating the impact of the demonstration during the period of approval, including:

i. A description of each outcome measure selected, including clearly defined numerators and denominators, and National Quality Forum (NQF) numbers (as applicable);

ii. The measure steward;

iii. The baseline value for each measure;

iv. The sampling methodology for assessing these outcomes; and

c. Sources of Measures - CMS recommends that the state use measures from nationally-recognized sources and those from national measures sets (including CMS's Core Set Core Set of Health Care Quality Measures for Medicaid-Eligible Adults).

d. The evaluation design must also discuss the data sources used, including the use of Medicaid encounter data, enrollment data, electronic health record (EHR) data, and consumer and provider surveys. The draft evaluation design must include a detailed analysis plan that describes how the effects of the demonstration shall be isolated from other initiatives occurring in the state. The evaluation designs proposed for each question may include analysis at the beneficiary, provider, and aggregate program level, as appropriate, and include population stratifications to the extent feasible, for further depth and to glean potential non-equivalent effects on different sub-groups.

e. The evaluation will explore and explain through developed evidence the effectiveness of the demonstration for each hypothesis, including total costs in accordance with the evaluation design as approved by CMS.

f. Included in the evaluation will be examinations using a robust set of measures of provider access and clinical quality measures compared to a comparable population.

g. The state will compare total costs under the state plan to costs that were incurred under the Flint Michigan demonstration. This will include an evaluation of provider rates, healthcare utilization and associated costs, and administrative expenses over time.

h. The state will compare changes in access and quality to associated changes in costs. To the extent possible, component contributions to changes in access and quality and their associated levels of investment in Michigan will be determined and compared to improvement efforts undertaken in other delivery systems.

57. Final Evaluation Design and Implementation. CMS shall provide comments on the draft design update and the draft evaluation strategy within 60 days of receipt, and the state shall submit a final design within 60 days of receipt of CMS' comments. The state must implement the evaluation design and submit its progress in each of the Quarterly Progress Reports and Annual Reports. Upon approval, the final evaluation design will be included in these STCs as Attachment C.

58. Interim Evaluation Report. The state must submit an interim evaluation report to CMS as part of any future request to extend the demonstration, or by June 30, 2020 if no extension request has been submitted by that date. The interim evaluation report will discuss evaluation progress and present findings to date.

59. Final Evaluation Report. The state must submit to CMS a draft of the Evaluation Final Report within 60 days of the end of the demonstration. The state must submit the Final Evaluation Report within 60 days after receipt of CMS' comments. The final report must include the following:

a. An executive summary;

b. A description of the demonstration, including programmatic goals, interventions implemented, and resulting impact of these interventions;

c. A summary of the evaluation design employed, including hypotheses, study design, measures, data sources, and analyses;

d. A description of the population included in the evaluation (by age, gender, race/ethnicity, etc.);

e. Final evaluation findings, including a discussion of the findings (interpretation and policy context); and

f. Successes, challenges, and lessons learned.

XII. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

The state is held to all reporting requirements outlined in the STCs; this schedule of deliverables should serve only as a tool for informational purposes only.

Per award letter - Within 30 days of the date of award	Confirmation Letter to CMS Accepting Demonstration STCs
Per paragraph 48(b)	Finalize Budget Neutrality Agreement
Per paragraph 19	Submit Post Approval Protocol
Per paragraph 31	Finalize Quarterly Progress Report Template
Per paragraph 54	Submit Draft Evaluation Design
Per paragraph 8	Submit Demonstration Extension Application
Per paragraph 58	Submit Interim Evaluation Report
Per paragraph 30 - Within 6 months of amendment implementation	Post-award Forum Transparency deliverable –
Monthly	**Deliverable**
Per paragraph 26	Monthly Enrollment Reports
Quarterly	**Deliverable**
Per paragraph 31	Quarterly Progress Reports
Per paragraph 31(e)	Quarterly Enrollment Reports
Per paragraph 34	Quarterly Financial Reports
Annual	**Deliverable**
Per paragraph 30	Annual Forum Transparency deliverable
Per paragraph 32	Draft Annual Report
Renewal/Close Out	**Deliverable**
Per paragraph 33	Final Report
Per paragraph 59	Draft Final Evaluation
Per paragraph 59	Final Evaluation

Attachment A – Reserved
Quarterly Progress Report Content and Format

Attachment B
Post Approval Protocol

Consistent with the Special Terms and Conditions, the following protocol describes how the Michigan Department of Health and Human Services (MDHHS) will identify individuals who may be eligible for the State's Flint Michigan Section 1115 Demonstration (11 W 00302/5) and provide for maintenance of that eligibility. Medicaid eligibility will be provided for select Michigan residents as described below, subject to the authority of this Section 1115 Demonstration.

I. Eligibility Criteria

A. Eligible Individuals

Eligibility applies to any pregnant woman or child up to age 21 with household income up to and including 400% of the Federal Poverty Level (FPL) who has been served by the Flint water system during the time period specified in the Special Terms and Conditions of the Flint Michigan Demonstration (STC #18(a)). 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. These criteria would also include individuals who were incarcerated or in a health care facility at a location served by the Flint water system.

Beneficiaries who are determined eligible as a result of this demonstration, and individuals who are eligible under existing Medicaid eligibility rules and were served by the Flint water system will be uniquely identified in the State's eligibility system of record and the Medicaid Management Information System (MMIS). Identified individuals will receive the enhanced benefits and reduced cost-sharing as described in the demonstration.

The specified time period noted above will be defined by the State and begins in April 2014. The end date for this specified time period will be established in accordance with the Special Terms and Conditions of the Flint Michigan Demonstration.

B. Income and Asset Standards

Individuals with MAGI-based income up to and including 400% of the FPL will be eligible. No asset test will be applied.

C. Annual Renewals

MDHHS will use an electronic administrative renewal process to redetermine eligibility under this demonstration. Renewals will occur once in each twelve month eligibility period, and income and residency will be verified at that time. The State will first attempt to renew eligibility using an ex parte process, based on data available to the agency. Those who cannot be found eligible through the ex parte process based on the information available to the agency will be sent a prepopulated renewal form requesting the additional information needed to complete an eligibility determination. Beneficiaries will need to complete the form and return it to the agency. In addition, any individual who has already been determined eligible for a Medicaid category as of the effective date of this protocol and is also eligible for the demonstration will maintain their current eligibility according to the rules described above. However, these individuals may be reevaluated using the modified income and exposure to Flint water system standards if they lose their eligibility at any time before the end of the specified time period noted above.

D. Duration of Eligibility

Those determined eligible based on the above criteria will retain their Medicaid eligibility according to the following schedule:

- Pregnant Women: The duration of the pregnancy and during the two calendar months post-delivery. This will be consistent with the current Medicaid eligibility framework. MDHHS will complete a redetermination (as described above) for the women enrolled under this demonstration prior to the end of their post-partum period to determine their eligibility for ongoing coverage.

- Children: Children will be eligible until the age of 21. MDHHS will complete an annual redetermination for each child enrolled under this demonstration, using first the ex parte renewal process and then prepopulated forms if necessary.

- Individuals determined eligible for emergency services only (ESO) will be limited to the current ESO benefits under this demonstration and will not receive the enhanced demonstration benefits. MDHHS will complete an

annual passive redetermination for each individual enrolled under this demonstration.

II. Identifying Potentially Eligible Individuals

A. Outreach

The State has identified the addresses served by the Flint water system and plans to conduct outreach to potentially eligible individuals residing at these addresses. This will include written notification by MDHHS as well as coordination with community organizations who can educate impacted individuals (including those who may be eligible based on employment or receipt of education-or child care related services) on the availability of Medicaid coverage. Potentially eligible individuals will be encouraged to apply for health care coverage through a variety of methods, and the State anticipates that community organizations as well as the current Medicaid infrastructure will be a significant help in this regard. Initially, the State plans to deploy additional staff to the Genesee County office to assist with application processing. The additional staff will continue to be available for the Genesee County office as needed. The organizations that serve as qualified entities for presumptive eligibility and outstationed workers (at provider sites) have been trained and will support this effort. Eligibility staff located in schools will also provide application assistance.

Active Medicaid beneficiaries who have been affected by Flint water will be identified in the state's system for the duration of their Medicaid eligibility. Beneficiaries and applicants with addresses served by the Flint water system whose cases have been closed or denied in March, April or May of 2016 for being over the income limit or having comprehensive health insurance (for MIChild beneficiaries) will receive a notice directing them to reapply for coverage. In addition, beneficiaries who have addresses served by the Flint water system who may be eligible under the demonstration but are currently in a spenddown category will be reprocessed.

B. Application Process

When an individual applies for Medicaid coverage, he or she will be required to identify the address in which they resided, worked, received child care, or received education services during the aforementioned timeframe, and attest to the dates during which they resided, worked, received child care, or received education services at that particular address and that he or she consumed water drawn from the Flint water system. Based on self-attestation of address, initial Medicaid eligibility will be granted. MDHHS will review the reported address post eligibility to assure that it is an address served by the Flint water system and that the dates identified for residing, working, receiving child care or receiving

educational service are within the specified time period covered under the demonstration.

Additionally, a sample of cases will be reviewed to verify the applicant's self-attestation. Efforts will be made to verify that the individual resided, worked, received child care, or education at the provided address during the applicable time period. This verification may be accomplished through data reviews and/or other manual processes (e.g., contacting the school or child care to verify the beneficiary's attestation). In the event the beneficiary's attestation cannot be verified through data reviews and/or the manual processes, the case will be sent to the MDHHS case worker to follow-up with the beneficiary.

If the reported address does not match one of the addresses on the list, the self-attestation is determined to be inaccurate, or the reported dates are found to not be within the specified time period, case closure proceedings will be initiated in compliance with current Medicaid policy and federal regulations. MDHHS will follow existing processes used to end eligibility, including reviewing eligibility on all other bases for Medicaid and providing advance notice of termination and fair hearing rights. However, if an individual meets other Medicaid eligibility requirements, they will be approved for Medicaid eligibility, but will not receive the expanded benefits and reduced cost-sharing under this demonstration. Advance notice and fair hearing rights also will be provided for such individuals who are moved from coverage under the demonstration to coverage under a non-demonstration eligibility category which does not include the expanded benefits or reduced cost-sharing available under the demonstration.

C. Post-Eligibility Identification

Once an individual has been determined eligible, he or she will be identified in the State's eligibility system of record and MMIS as a member of the Flint Michigan Demonstration. This designation will apply to the beneficiary throughout the duration of their eligibility and will allow them to access the expanded services and reduced cost-sharing described in the Special Terms and Conditions, Medicaid State Plan and this eligibility protocol. The State will also identify these individuals to ensure compliance with financial and other demonstration related reporting requirements.

III. Premiums and Cost Sharing

Michigan does not impose premiums or cost sharing on individuals eligible for Medicaid or the Healthy Michigan Plan for pregnant women or individuals who are under age 21. As a result, these individuals will have no premiums or cost-sharing for Medicaid-covered services under this demonstration. Families with children under age 19 covered by MIChild (the State's title XXI-funded Medicaid expansion program for families with incomes between 160-212% of the FPL) are charged a

monthly premium. However, individuals eligible for MIChild and this demonstration will be exempt from all premiums and cost-sharing for the duration of their eligibility under the demonstration. Additionally, individuals who are enrolled in the Marketplace Option beginning in 2018 and eligible for this demonstration will be exempt from all premiums and cost-sharing for the duration of their eligibility under this demonstration.

Finally, if an individual is eligible for the demonstration and Michigan's Freedom to Work program, they would also be exempt from premiums and cost-sharing if their income is at or below 400% of the FPL. If their income is greater than 400% of the FPL, they will be subject to the appropriate premiums and cost-sharing under current Medicaid policy.

Attachment C
Demonstration Evaluation Plan

Introduction

Flint, Michigan has experienced decades of social and economic challenges as its population has shrunk from nearly 200,000 to under 100,000 people. According to recent U.S. Census data, 41% of the population is in poverty and 14% of the population under age 65 lack health insurance. (1) This contrasts with a statewide poverty estimate of 16.2% and just 10% of the statewide population under 65 years of age lacking health care coverage.(1) Additionally, the dropout rate in Flint Community Schools exceeds 21%. Over 80% of the students are classified as economically disadvantaged and nearly all students (96%) participate in free and reduced lunch programs. (2,3) According to 2011-2012 attendee and absence data published by Flint Community Schools, the proportion of children with absences during the school year exceeded 10% in elementary school, increased dramatically to over 30% for middle school years and decreased to 13% for high school.(2) Compounding these challenges, the city's water source was changed in April 2014, which subsequently caused lead to leach from pipes, increasing the incidence of elevated lead levels in tap water and in children's blood. In January 2016, President Obama declared an emergency in Flint, leveraging federal aid to support state and local response efforts. (4) The declaration expired 8/14/16 although some federal resources remained. These efforts were pursued because lead is a known neurotoxin, and lead poisoning may result in growth, developmental, and educational difficulties. (5) Young children (under 6 years) and children experiencing *in utero* exposure are most at risk. (5) Access to health care and support services is necessary to ensure appropriate screening and monitoring to identify and manage individuals with elevated blood lead levels. The Michigan Department of Health and Human Services (MDHHS) estimates that approximately 27,000 individuals are currently covered by Medicaid in the Flint area. The State of Michigan applied for a Medicaid Section 1115 waiver in February 2016 to expand eligibility and benefits in recognition of the cohort of individuals potentially exposed to the contaminated water yet lacking insurance coverage and the ability to seek care to address this exposure. (6,7)

Goals/Objectives

The U.S. Center for Medicare & Medicaid Services (CMS) granted the Medicaid waiver application to support access to care and targeted case management for at-risk persons affected by the contaminated water. As described in the Special Terms and Conditions (STC) of the waiver, *"This population consists of children in households with incomes from 212 percent of the federal poverty level (FPL) up to and including 400 percent of the FPL and pregnant women in households with incomes from 195 percent up to and including 400 percent of the FPL."* The waiver further eliminates all cost-sharing and premiums for this population and allows "… *the state to offer screening and evaluation of potential lead exposure in the home for all eligible children and pregnant women who were served by the Flint water system during the specified period*…". The population resulting from the expanded eligibility is projected to be approximately 14,000 and MDHHS anticipates 50% (~7,000) of these individuals will take advantage of this coverage. These projections include pregnant women. The demonstration has been approved through 2/28/2021.

The approved demonstration is intended to support an overarching goal *to identify and address any physical or behavioral health issues associated with actual or potential exposure to lead hazards.* The specific objectives intended to support attainment of the goal are to:

1. Expand eligibility of all Medicaid benefits for low-income children (up to age 21 and including children born to eligible pregnant women) and pregnant women (through two months post-delivery) served by the Flint water system from 4/1/2014 through (*Date TBD*) and not otherwise eligible for Medicaid.
    a. Increase income threshold to offer coverage to children in households with incomes from 212% federal poverty level (FPL) up to and including 400% FPL.
    b. Increase income threshold to offer coverage to pregnant women in households with incomes from 195% FPL up to and including 400% FPL.
    c. Eliminate cost-sharing and Medicaid premiums for eligible children and pregnant women served by the Flint water system.
    d. Permit eligible children and pregnant women above the 400% FPL and served by the Flint water system to buy into Medicaid benefits by paying premiums.
2. Add a Targeted Case Management (TCM) benefit to all low-income children (up to age 21 and including children born to eligible pregnant women) and pregnant women (through two months post-delivery) served by the Flint water system from 4/1/2014 through (*Date TBD*).
    a. Assist enrolled eligible children and pregnant women served by the Flint water system to gain access to needed medical, social, educational, and other service(s).

Evaluation Activities

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 nearly two decades. The mission of MSU-IHP is to improve the health status of Michigan residents through health services research, policy analysis, education and outreach, and support of quality improvement activities. 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. The evaluation team is made up of:

- Hong Su An, PhD; Institute for Health Policy, College of Human Medicine, MSU
- Debra Darling, BSN, RN, CCP; Institute for Health Policy, College of Human Medicine, MSU
- Julie DuPuis, MPA, Institute for Health Policy, College of Human Medicine, MSU
- Mona Hanna-Attisha, MD, MPH, FAAP; Department of Pediatrics, College of Human Medicine, MSU/Hurley Medical Center
- Joan Ilardo, PhD, LMSW; Office of Research, College of Human Medicine, MSU
- Christine Karl, RN, BA; 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; Division of Public Health, College of Human Medicine, MSU
- Lin Stork, MA Office of Survey Research, MSU
- Leslee Wilkins, Institute for Health Policy, College of Human Medicine, MSU

Scientific Rigor
MSU-IHP has assembled an evaluation team consisting of faculty and staff from additional MSU departments and units where subject matter expertise is needed to support the scientific rigor of evaluation efforts. Selection for the evaluation team also included review of potential conflicts of interest. The evaluation team will identify and seek to use the best available data with the appropriate statistical methodologies to answer the proposed research questions. Reports and analytic summaries will acknowledge potential limitations of selected data and methods with discussion of impacts on generalizability of findings.

Anticipated data sources to address the research questions include Medicaid eligibility and enrollment data as well as health service claims/encounter data adjudicated through Medicaid. These data elements will support evaluation of utilization and costs of care and are available to MSU-IHP through the MDHHS Data Warehouse. We will use the Census Tract level and Block Group level characteristics to derive indicators for socioeconomic status and/or find potential matching comparison persons. Additionally, beneficiary surveys are planned to provide a data source for exposure, satisfaction and outcomes that cannot be measured through health care administrative data. Other targeted data include data maintained through the MI Care Improvement Registry which retains lead testing records. The TCM process will generate clinical assessment and referral data and we will attempt to incorporate this information as it becomes available. Lastly, we seek to collaborate with others including local service providers and/or researchers to incorporate elements of socio-emotional and developmental scoring and delivery of educational supports collected and maintained outside MDHHS. Ultimately, the completeness of reporting will depend on the extent to which necessary data elements are available to the evaluation team.

Limitations associated with this evaluation will be the difficulty identifying one suitable comparison group and the availability of certain data elements. For those individuals already covered through Medicaid in the targeted region, our plans to leverage Medicaid and lead screening data include identifying multiple comparison groups that will vary based on sub-population and applicable measure(s) (i.e., children vs. pregnant women and developmental screening). As an example, children under age 19, without the expansion are eligible for MIChild if their household income is at or below 200% of FPL. We can use the Regression Discontinuity Design (RDD) to form a quasi-experiment to recover the causal effect of the expansion (8). Moreover, we will report multiple rates per measure. One rate will restrict to existing Medicaid eligibility limitations to facilitate comparisons to published estimates while a second rate will be calculated for those who are eligible through the expanded FPL limits. We may spatially link beneficiaries in Flint and vicinity to

corresponding Census Tract and Block Groups and compare regional-level outcomes such as changes in well child or development screening visits.

Of specific concern, the *expansion* population exceeding the existing FPL limits represents a cohort of individuals for whom utilization baseline data is not readily available. We will look to published commercial utilization estimates and engage collaboratively with health plans in the state to request their assistance with providing similar commercial estimates on the targeted Flint area. Thus, with reasonable controls for income and geographic organization of health care services, we can compare rates of pre/post-natal care and pediatric services among children and adolescents. This expansion cohort further presents challenges due to missing data after enrollment. 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 use non-participants as the second comparison group. We will use the propensity score matching methods to make the two groups (participants vs. non-participants) as similar as possible based on the self-reported data and the outcomes will include self-reported healthcare access, utilization, and overall health status.

The evaluation will analyze the impacts of the demonstration while controlling for other activities occurring in the affected area as documented. The ability to directly attribute observed changes in access, utilization and outcomes to the implementation of the waiver services will be complex. The federal declaration has provided access to significant federal resources that are operating in the affected area. Additionally, there are many supports and services being offered by local/state governmental, private, and public non-profit organizations in the region. As mentioned, the availability of other forms of health care coverage will impact the ability to determine the effectiveness of the waiver due to incomplete Medicaid claims/encounter data. The TCM services may overlap with other services provided by current Medicaid health plans, other support agencies, and/or health care providers. We propose conducting a community inventory to account for the prevalent activities and will seek opportunities to identify appropriate comparison groups and regions. For those measures based on administrative data, we will describe the pre-exposure experience of beneficiaries in the affected region for later comparisons and may further reference state or national benchmarks. Our pre-exposure timeframe will reflect April 1, 2013 – March 31, 2014. For new enrollees coming into the program as a result of the expansion eligibility, we will use their initial year experience with utilization as a baseline and monitor their experience over the ensuing years of their participation. The exposure period will begin April 1, 2014 and continue through (*Date TBD*).

We originally proposed convening an Advisory Panel for the evaluation that would include community leaders and representatives of the Healthy Flint Research Coordinating Center that is being established in the region. The Research Coordinating Center includes Michigan State University, University of Michigan-Ann Arbor, University of Michigan-Flint, and Community Based Organization Partners with the goal being to coordinate projects that may have already started or are being developed related to economic, environmental, behavioral and physical health of residents. Since our initial proposal, a team in Flint has received funding to plan and establish a

registry that will track not only activities occurring in the area but also individual health, education and social markers. Dr. Mona Hanna-Attisha is the principal investigator (PI) on that effort and we will be engaging with this initiative and their accompanying Advisory Committee and subcommittees where appropriate. (11) In turn, she has been added to this evaluation team. We have shifted our approach from 'creating our own' to joining with others. Our goal in doing so is to realize the benefits of collaborative efforts and avoid subjecting community members and leaders to 'committee fatigue'. We anticipate we will be able to identify pertinent data points and maximize reporting quality and quantity by collaborating.

There is no shortage of research questions that can be generated in response to this event. For the purposes of this evaluation however, we will confine our efforts to evaluation questions relevant to evaluating authorized waiver activities. We will cooperate with the registry planning efforts to identify and suggest reporting elements that could be used to inform the evaluation. Community leaders would assist the evaluation team in documenting the breadth of activities and be able to direct members of the evaluation team to key contacts.

The following describes a high level overview of the target population, including overarching considerations for timelines, potential comparison groups, and cost analyses. Domain specific detailed evaluation plans and hypotheses generated in response to review of the state's documented objectives with consideration and identification of necessary data elements begin on page 12.

Target Population for Waiver
The eligibility criteria for receiving Medicaid coverage has been established by MDHHS policy to include:

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

The Eligibility Protocol further clarifies these criteria would also include individuals who were incarcerated or who resided in a health care facility at a location served by the Flint water.

Per MDHHS Policy, pregnant women covered under the waiver will remain eligible throughout their pregnancy and for a period of two months post-partum. Children will remain eligible until age 21 as long as other eligibility requirements are met.

Individuals above the 400% FPL but otherwise meeting the eligibility criteria may enroll in Medicaid by paying the appropriate premiums and participating with cost-sharing as described per current Medicaid policy.

MDHHS will use specific program codes to identify existing beneficiaries and newly enrolled beneficiaries who meet criteria for this waiver. These codes will facilitate tracking of individuals who could have been exposed to the contaminated water. Enrollment data contained in the warehouse may also contain reference to FPL so that beneficiaries can be categorized appropriately as expansion eligibility or not. These program and poverty level codes will be used when selecting target populations and potential comparison groups.

Overall Evaluation Timeline
This evaluation plan will cover activities from 7/1/2017 through 4/30/2021. The demonstration project is scheduled to conclude 2/28/2021. Table 1 shows the proposed schedule of activities.

Table 1: Proposed Timeline for Evaluation Activities

Time Period	Activities
Partial Year 1: 7/1/2017 – 9/30/2017	• Identify key contacts for targeted data sources • Participate with Registry Advisory Committee • Draft beneficiary survey • Implement Wave 1 beneficiary survey (~15 months post-enrollment target: September/October 2017) • Draft TCM Provider Survey/Key Informant Interview • Implement Wave 1 TCM Provider Survey/Key Informant Interviews (~15 months post TCM implementation: September/October 2017) • Draft community inventory tool • Program administratively derived measures and report for pre-exposure year (4/1/13 – 3/31/14), year 1 (4/1/14 – 3/31/15) and year 2 (4/1/15 – 3/31/16) • Assemble and test different methods to generate comparison groups • Identify and test data sources for TCM (needs assessments, plans of care, screenings, referrals, etc.) • Identify and test data sources and methods for linkage with Department of Education information • Identify research co-occurring studies and evaluation for possible incorporation into evaluation • Generate quarterly updates • Generate interim annual report
Year 2: 10/1/2017 – 9/30/2018	• Continuing Wave 1 beneficiary survey (~15 months post-enrollment target: September 2017) • Wave 1 Beneficiary Survey analysis and report findings • Implement Wave 2 Beneficiary Survey (~24 months post-enrollment: June/July 2018) • Continue Wave 1 TCM Provider Survey/Key Informant Interviews (~15 months post TCM implementation: September/October 2017)

Time Period	Activities
	• Wave 1 TCM Provider Survey/Key Informant Interviews analysis and report findings • Implement Wave 2 TCM Provider Survey/Key Informant Interviews (~24 months post TCM implementation: June/July 2018) • Ongoing community inventory surveillance • Ongoing monitoring of community based co-occurring studies and evaluation for possible incorporation into evaluation • Run TCM measures and conduct data analysis for timeframe 5/1/16 – 4/30/17 (year 1 delivery) • Run annual administrative measures and conduct analysis and trending for timeframe 4/1/16 – 3/31/17 • Monitor increase in enrollment and services for cost evaluation for timeframe(s) • Generate quarterly updates • Generate interim annual report
Year 3: 10/1/2018 – 9/30/2019	• Research and report potential commercial comparison group estimates for expanded financial limit cohort • Wave 2 Beneficiary Survey analysis and report findings • Summarize Wave 2 TCM Provider Survey/Key Informant Interviews and report findings • Ongoing community inventory surveillance • Ongoing monitoring of community based co-occurring studies and evaluation for possible incorporation into evaluation • Run TCM measures and conduct data analysis for timeframe 5/1/17 – 4/30/18 • Run annual administrative measures and conduct data analysis/trending for timeframe 4/1/17 – 3/31/18 • Monitor change in enrollment and services for cost evaluation • Generate quarterly updates • Generate interim annual report
Year 4: 10/1/2019 – 9/30/2020	• Implement Wave 3 Beneficiary Survey (~48 months post-enrollment: June/July 2020) • Implement Wave 3 TCM Provider Survey/Key Informant Interviews (~48 months post TCM implementation: June/July 2020) • Ongoing community inventory surveillance • Ongoing monitoring of community based co-occurring studies and evaluation for possible incorporation into evaluation • Run TCM measures and conduct data analysis for timeframe 5/1/18 – 4/30/19 • Run annual administrative measures and conduct data analysis/trending for timeframe 4/1/18 – 3/31/19 • Monitor increase in enrollment and services for cost evaluation • Generate quarterly updates • Generate interim annual report
Year 5 – Wrap Up: 10/1/2020 – 4/30/2021	• Wave 3 Beneficiary Survey analysis and report findings • Summarize Wave 3 TCM Provider Survey/Key Informant Interviews and report findings • Ongoing community inventory surveillance

Time Period	Activities
	• Ongoing monitoring of community based co-occurring studies and evaluation for possible incorporation into evaluation • Run TCM measures and conduct data analysis for timeframe 5/1/19 – 4/30/20 • Run annual administrative measures and conduct data analysis/trending for timeframe 4/1/19 – 3/31/20 • Monitor increase in enrollment and services for cost evaluation • Generate quarterly updates • Generate final evaluation report (4/30/2021)

General Data Sources
The evaluation will require multiple data sources to test the hypotheses. Some of the data elements are currently available to members of the evaluation team and measures relying on these data could be implemented immediately. Other sources include state departments other than MDHHS and further investigation will be required to determine the full scope and nature of available data. Additionally, access to these data may be limited by state or federal statutes and the evaluation team will be bound by such regulations. Lastly, there are certain data points that will support the evaluation but will require new data collection processes. The full scope of activities and timeframes will depend on data availability to the evaluation team.

MDHHS Medicaid Data: (Currently Available, Evaluation Team has access)
We anticipate analyzing Medicaid administrative data sources (e.g., enrollment, claims/encounter) available through the MDHHS Data Warehouse at least semi-annually. Some access/quality of care measures to be evaluated (e.g., immunization status) will be conducted on an annual basis as recommended by the measure stewards. Claims/encounter data will require a lag period to allow for claim processing. No less than 180 days will be used for this claim run-out period.

MDHHS Program Data: (Currently Available, Evaluation Team *does not yet have* access)
Since Medicaid covered services represent only a portion of the services for which beneficiaries will be eligible, we will further seek to collaborate with other units in MDHHS (e.g., Lead Screening Program, Maternal Infant Health Program, etc). Efforts will be made to link external datasets with the enrollment data so that we can look for variation by group (ex. existing enrollees vs new enrollees).

MDE Early Education Service Data: (Full scope unknown, Evaluation Team *does not yet have* access)
Early education services such as Early Head Start will be important to support children who have been exposed to the contaminated water. A portion of the referrals to these services could be captured through claims data but data would be lacking on those that self-refer. Screening outcomes and resultant service delivery would also be incomplete if the team was to rely solely on Medicaid claims/encounter data. Education data will be increasingly important over the years of the evaluation and primary/secondary school data elements will need to be identified. We have scheduled preliminary meetings with MDE representatives to begin to discuss mechanisms by which data may be shared. We will further collaborate with the registry planning to begin to identify

pertinent elements that should be incorporated into this registry and support efforts to address legal barriers to these data.

Per MDE, school data may be split into "Early Childhood" and "K-12 grade" populations. For the "Early Childhood" population, summary data regarding:

1) counts of children enrolled/participating in Early Childhood Programs (e.g. Early On Michigan, Great Start for Kids, MI HeadStart), and
2) proportion of students in Kindergarten who participated in Early Childhood programs,

are currently available by county and school district. This data will be useful to provide general community trends prior to the water switch and then annually thereafter. These two measures will be obtained through the MDE website with ability to report by gender, disadvantaged status, race/ethnicity, and homelessness.

Kindergarten – 12th Grade education has similar summary reporting available for a variety of metrics by county, school district and school. Specifically, we will trend measures of academic performance and behavioral elements:

1) student counts
2) pupil:teacher ratios
3) counts of children retained in same grade
4) drop-out rate
5) graduation rate
6) attendance
7) educational progress standardized tests (grades 3-9, 11)

It is important to note the educational progress standardized testing in Michigan changed with the 2014-2015 school year from the Michigan Educational Assessment Program (MEAP) to the Michigan Student Test of Educational Progress (M-STEP). We will require consultation from MDE staff to assist in the interpretation of data as this coincides with the water switch. MI-Access is an alternate test available for students with cognitive impairments when the others are felt to be inappropriate. We will identify discrete elements of the standardized testing in collaboration with MDE colleagues and would appreciate the opportunity to pull in CMS colleagues for further discussion.

The evaluation team plans to trend these metrics at the levels aggregated by the MDE data. Our main interest however remains in linking standardized test scoring and program participation at the individual beneficiary level. We are interested in linking education metrics to health service utilization in order to detect associations between these items using chi-square or t-tests as indicated. We would appreciate the opportunity to work with CMS to work through federal legislation that limits disclosure of student information. The individuals responsible for designing

the Flint Registry also have identified this as a potential barrier and will be seeking guidance from a variety of sources on this. We anticipate that consolidating our efforts will benefit both teams.

U.S. Census Data: (Currently Available, Evaluation Team has access)
We will use available census data (in partnership with MSU medical geographer Dr. Richard Sadler) as well as federal agencies operating in Flint to assist us in identifying characteristics of the Flint region to better categorize waiver participants versus non-participants. Census Tract or Block Group level data will support the evaluation efforts to better describe the affected area, pinpoint key population sub-groups, and provide data needed to construct comparison groups.

Beneficiary Survey Data: (Collection Planned)
We further propose to conduct brief interviews with beneficiaries. The beneficiary survey is necessary to document levels of exposure to the contaminated water, satisfaction with accessing health care and TCM services and self-reported health status. Elements not readily available through administrative health care data sets will be incorporated into the survey including family characteristics, knowledge of benefits (e.g., TCM, transportation) and additional educational and behavioral characteristics of enrollees. The survey document will be shared with MDHHS and CMS representatives for review and input prior to implementation. Additionally, the survey may be expanded to include elements identified by the registry planning that could be used to support future evaluations. The survey will permit more accurate reporting of the level of exposure for sub-group analyses. Additionally, surveys will also permit us to track services received through formal or informal community action so that we can appropriately consider these influences during the evaluation. In order to carry out these surveys, IHP will partner with MSU's Office for Survey Research (OSR), part of MSU's Institute for Public Policy and Social Research. OSR has provided instrument development, data collection and analysis to university, state, county and municipal government and businesses since 1989.

The survey will be conducted via multiple methods. Initially, telephone contact will be employed with a print survey used for telephone non-response or at beneficiary request. This print survey will also direct respondents how to complete the survey via web or to call a toll free number if they prefer. Print surveys will also permit inclusion of water-affected individuals attending the Michigan School for the Deaf which is based in Flint. The survey will be conducted in English and we will work with community representatives to determine the need for Spanish or other translation services. Although the proportion of households reporting a language other than English as the primary language in the home is small overall, we anticipate the prevalence to be higher among the cohort of individuals eligible for expanded Medicaid. These individuals would also be associated with greater access to care issues due to potential language barriers. All enrollees will be included in the sampling frame and weighting used as necessary to ensure a representative sample. Parents or guardians will be targeted to complete the survey on behalf of beneficiaries less than 18 years of age.

We plan to conduct surveys at several intervals. The first survey wave will occur approximately 12 months of enrollment. A follow-up survey will be conducted approximately 24 months after enrollment and we will attempt to contact the same individuals for this second wave in order to

track changes over time in their knowledge about the expansion program and services, utilization and health status. A final wave is being considered at 48 months post-enrollment and the goal would be to follow-up with the same respondents. We anticipate using non-monetary incentives (i.e. newsletters) to promote longitudinal participation with the surveys. The required sample size is estimated using following formula:

$$N = \frac{Z_{\alpha/2}^2 * P * (1 - P)}{E^2}$$

Where P is the proportion of event of interest for the survey, E is the margin of error (precision) deemed acceptable, α is level of significance, and $Z_{\alpha/2}$ is the $\frac{\alpha}{2}$-th normal quantile. We applied a 5% of margin of error with a 95% confidence level. The number of new enrollees secondary to the waiver is approximately 2500; when combined with the existing Flint Medicaid covered population (approximately 25,000) there are nearly 27,500 individuals who would be eligible to participate with the survey. Using the formula above, to estimate the proportion of event of interest with 5% margin of error would require 384 completed surveys. We have rounded up for simplicity to 400 completed surveys as our target.

Since we are interested in doing 3 waves so we must plan accordingly to ensure that we are left with at least 400 at the end. Thus, we will significantly oversample for wave 1 to ensure we can sustain our end goal acknowledging loss to follow up. We assume our loss to follow-up will be 33% at wave 2 and 50% at wave 3. Assuming an original response rate of 30%, we will target 4000 individuals in wave 1.

Our community comparison samples (individuals who are not enrolled in Medicaid) will be selected at each wave. We will not attempt to retain community members longitudinally. The community responses will provide a comparison for the results obtained from our target beneficiaries for outcome(s) such as self-reported health status and access to care. We will test for independence between these estimates using chi-square or t-tests as appropriate. We will also explore obtaining Michigan BRFSS data at the zip code level to provide estimates of general health status and access to care measures for the region prior to the survey period. We plan to ask CMS to assist negotiating with CDC to facilitate obtaining these data.

We may use an address based sample informed by the Flint Water department service area and drawn from a city parcel database. This will allow us to select individuals in the targeted geographic region. This address based sample further encourages the participation of households that no longer have landline telephones. We are further exploring the feasibility of adding relevant questions to the *MI State of the State Survey* to provide statewide level comparisons.

TCM Provider Survey/Key Informant Interview: (Collection Planned)
The evaluation team proposes a TCM Provider Survey/Key Informant Interview in order to obtain additional qualitative and quantitative data elements that would not be available through MDHHS administrative claims/encounter sources. Topic areas to be included in the interviews include satisfaction with assessment tools, ease of reporting activities, enrollee engagement, prevalent areas

of involvement, referral and interest as well as other metrics as the TCM policy is finalized. IHP quality improvement (QI) staff with experience in conducting interviews will conduct these in-person when possible or via telephone.

Genesee Health System is the Designated Provider Organization for TCM and all services are to be carried out through the use of case managers. Case managers must have current Michigan licensure as a registered nurse or social worker. We plan to survey or interview 100% of these case managers working at each time point. The first wave will occur within 12 months of TCM implementation. A follow-up survey will be conducted approximately 24 months after implementation. A final wave is being considered at 48 months post-implementation.

Community Assessment Data: (Collection Planned)
We will conduct a community assessment to identify additional supports and services being offered to residents other than those provided through Medicaid coverage. Key informant interviews are planned with leading governmental, private, and public non-profit organizations operating in the region to carry out this assessment.

Human Subjects Review
Elements of this evaluation might require human subjects review. Investigators will submit a formal request for determination to the MSU Human Research Protection Program (HRPP) and the MDHHS Institutional Review Board (IRB) offices and provide evidence of the review and determination. Should a formal human subjects review be warranted, applications will be submitted and approved by MSU and MDHHS review boards as necessary prior to any proposed work.

Potential Comparison Populations
The hypotheses put forward by the State of Michigan and refined into sub-hypotheses by the evaluation team reference conducting comparisons to *"…others with similar levels of lead exposure*." The unfortunate fact is that we will be unable to accurately describe the extent of the exposure of the affected individuals. Moreover, the process followed for lead screening before and during the exposure period does not permit us to know true blood lead levels at the individual level and how they fluctuated over time. The population most at risk would normally not be tested per American Academy of Pediatrics (AAP) recommendations (i.e. screening starts at 1 year of age). This means that the infants being exposed through formula and their maximum levels will remain unknown. The only true measure of lead exposure would be available through bone or dental samples. Dr. Hanna-Attisha reports that they are planning to collect dental samples as part of the surveillance registry which will be the most accurate measure. We may be able to leverage these data in the final years of the evaluation.

We will use existing data on Medicaid beneficiaries in the same geographic region for a timeframe immediately preceding the water supply switch and compare to those eligible for the demonstration but already covered (~21,000), enabling the community to act as its own control. We will generate two cohorts within the Flint area – the first cohort will align beneficiaries with the water service maps while the second cohort will encompass Genesee County. We are exploring the electronic availability of assessment data for the approximately 330 beneficiaries covered through the Serious

Emotional Disturbance Waiver (SEDW) as a potential comparison cohort and will further consider whether this would be a suitable control population. We will further investigate relevant characteristics through existing geographically-related data sources such as the U.S. Census, the American Community Survey, and/or community health profiles such as the Speak To Your Health Community Survey. Based on the recognized difficulty measuring actual exposure and uptake levels of lead, we will emphasize socio-economic characteristics of communities which may help promote consistency in other known methods of lead exposure.

We look forward to collaborating with federal agencies (i.e. CDC, CMS, etc.) to obtain data from communities in other states that have experienced water based lead exposures (i.e. Washington DC). Reuters recently reported over 3,000 communities nationwide with greater prevalence of elevated blood lead levels. (10) While we cannot drill down to individuals, community reporting may serve as reasonable comparison communities.

The expansion population further represents a cohort of individuals who are at higher socio-economic status than existing Medicaid beneficiaries. Therefore, it is possible members of the cohort may have access to health care coverage through other avenues. For these individuals, we may encounter either a lack of data due to absence of coverage or incomplete data due to another insurer having primary responsibility for health care claims. We will explore the feasibility of collaborating with commercial payers in the region along with provider organizations to obtain data elements to support the evaluation. The team anticipates conducting stratified analyses based on presence/absence of other insurance in an effort to determine true lack of services versus services paid for by other insurance.

Table 2 summarizes the various comparison groups that we could target as part of the evaluation.

Table 2: Comparison Group Characteristics

Group #	Group Description	Pros	Cons
1	Medicaid beneficiaries residing in the target Flint area based on water exposure map in the year prior to the water switch (4/1/2013 – 3/31/2014)	• Representative of the involved community • Administrative health data available through MDHHS Data Warehouse • Individuals remaining in region could act as own controls • Lead screening values available through MDHHS Childhood Lead Prevention Program and MCIR for all screened children (regardless of insurer)	• Does not incorporate beneficiaries qualifying with higher SES levels • Population change over time • Observed changes in
2	Commercially insured individuals in Michigan	• Address experience of higher SES (133-400% FPL) • Lead screening values available through MDHHS Childhood Lead Prevention Program and MCIR	• Administrative health data not available to evaluators

Group #	Group Description	Pros	Cons
		for all screened children (regardless of insurer)	• Not all commercially covered children tested for lead
3	Communities known to have elevated lead exposures nationally	• Could represent reasonably similar cohort • Consider county health rankings reporting to provide comparison information	• Individual level data not available • Community action reporting anticipated to be incomplete and poorly documented
4	Beneficiaries covered through the Michigan SEDW	• Could have assessment data (behaviorial, educational, developmental, etc) available through administrative means	• Population by definition already known to have significant diagnoses and might not have sufficient data points to create appropriately matched samples (individuals eligible for waiver at risk for psychiatric inpatient admission and require 24 hour care)

Cost Comparisons

According to the Waiver STCs, analysis of total costs is a required element of the evaluation. The costs associated with the Flint waiver will be reported as a proportion of total state costs. Additionally, the total state costs over recent years (including prior to the water supply switch) will be trended. Components of total costs such as administrative expenses, provider rates, and healthcare utilization will be evaluated individually, comparing historical spending (with appropriate inflationary adjustments) for existing Medicaid beneficiaries. Concurrent spending comparisons with geographic areas thought to represent areas at high risk for lead exposure along with similar socio-economic characteristics and demographics may also contribute to the overall cost analyses. We will further describe the additional costs associated with the expanded population (those who would otherwise not have met criteria for Medicaid coverage) and the expanded TCM benefit.

Post-hoc power and statistical considerations

As we will extract administrative data for most of the comparisons between the waiver enrollees and corresponding comparison groups in Table 2, we will have approximately 2,500 new enrollees and can select group 1 comparison from a large reservoir of existing beneficiaries based on water exposure map. These comparisons can be matched on important confounding characteristics. Thus the minimum detectable effect size (MDEZ) for matched samples at 80% power for continuous outcomes is .06 and the range of MDEZ for proportions is from 1% to 3% when the null prevalence is from .05 to .5. Any clinically meaningful effect size would be bigger than the MDEZs that we can detect. Thus we have enough power to generate meaningful comparisons.

Attachment C
Demonstration Evaluation Plan

Domain 1: Access to services

The approved demonstration will provide Medicaid coverage and access to health care services to a cohort of individuals who were exposed to the contaminated water and potentially at risk for physical and behavioral issues but possibly lacking ability to seek services.

Hypotheses

1. "*Enrollees will access services to identify and address physical or behavioral health issues associated with lead exposure at a rate higher than others with similar levels of lead exposure*."
    - Hypothesis 1.1: A greater proportion of enrollees will obtain age-appropriate well-child exams compared to others with similar lead exposures.
    - Hypothesis 1.2: A greater proportion of enrollees will receive age-appropriate developmental screening/assessments compared to others with similar lead exposures.
    - Hypothesis 1.3: A greater proportion of enrollees will receive age appropriate lead testing compared to others with similar lead exposures.
    - Hypothesis 1.4: A greater proportion of enrollees with high blood lead levels will receive re-testing at the appropriate intervals compared to others with similar lead exposures.
    - Hypothesis 1.5: Enrollees who are pregnant will have more timely prenatal and postpartum care compared to others with similar lead exposures.
    - Hypothesis 1.6: A greater proportion of enrollees who are pregnant will have recommended lead testing compared to others with similar lead exposures.
    - Hypothesis 1.7: A greater proportion of enrollees will participate with Maternal Infant Home Program services compared to others with similar lead levels.
    - Hypothesis 1.8: The majority of enrollees will attest to improved access to health care as a result of the expanded coverage.
    - Hypothesis 1.9: The majority of enrollees will report improved satisfaction with their ability to access health care as a result of the expanded coverage.

Performance Measures

The State of Michigan proposed an over-arching hypothesis focused on measuring access to care as part of the waiver application. The evaluation team drilled down to identify additional hypotheses that could be tested using endorsed measures published through the National Quality Forum (NQF). Moreover, the selection of nationally recognized measures provides opportunities for comparison of results both within the targeted region (pre-post exposure estimates) as well as potentially comparing results to somewhat similar (based on socio-economic similarities) groups. Selected comparisons may be restricted to individuals who meet the exposure categories and previously identified Medicaid income thresholds to ensure similarities. For pre-post comparison we will use paired *t*-test or McNemar chi-square test. For comparisons between groups we will use *F*-test or Mantel-Haenszel test stratified by matching factors. As we begin to assemble the data to address the

hypotheses, we may require modifying eligible timeframes to ensure congruence with exposure periods. While we may shift start or end dates, we will adhere to requirements for total observation months and continuous enrollment. For example, the measures requiring a 12 month observation could shift from January – December timeframes to April – March timeframes. Thus, references to measurement "year" in NQF documentation will be replaced with measurement "period".

The sub-hypotheses identified for Domain 1 were selected for their relevance to screening, the identification and management of individuals who would be identified as high-risk for lead exposure, and represent the target population for the waiver application.

H1.1: A greater proportion of enrollees will obtain age-appropriate well-child exams compared to others with similar lead exposures.

Characteristic	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
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.
NQF Number	1392	1516	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)
Numerator	This measure has 7 discrete numerators: • # Children who received 0 well-child visits • # Children who received 1 well-child visit • # Children who received 2 well-child visits • # Children who received 3 well-child visits • # Children who received 4 well-child visits • # Children who received 5 well-child visits	This measure has 1 discrete numerator: • At least one well-child visit with a primary care provider	This measure has 1 discrete numerator: • At least one comprehensive well-care visit with a PCP or an OB/GYN practitioner during the measurement year.

Characteristic	Detail Description	Detail Description	Detail Description
	• # Children who received 6 or more well-child visits		
Denominator	Children 15 months old during the measurement period.	This measure has 1 discrete denominator: • Children 3-6 years of age during the measurement period.	This measure has 1 discrete denominator: • Children/adolescents 12-21 years of age during the measurement period.
Baseline Value(s)	Baseline values will be obtained from multiple sources: • Existing statewide Medicaid weighted average reports • Region specific estimates will be calculated for a measurement period prior to the water switch.	Baseline values will be obtained from multiple sources: • Existing statewide Medicaid weighted average reports • Region specific estimates will be calculated for a measurement period prior to the water switch.	Baseline values will be obtained from multiple sources: • Existing statewide Medicaid weighted average reports • Region specific estimates will be calculated for a measurement period prior to the water switch.
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
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

H1.2: A greater proportion of enrollees will receive age-appropriate developmental screening/assessments compared to others with similar lead exposures.

Characteristic	Detail Description	Detail Description
Measure Title	Developmental Screening in the First Three Years of Life	Socio-emotional/Behavioral Screening for Children 4-17 years of age
Measure Description	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.
NQF Number	1448	n/a
Measure Steward	Oregon Health & Science University	n/a
Numerator	This measure has 4 discrete numerators: • # Children who had screening for risk of development, behavioral and social delays using a standardized screening tool that was documented by their first birthday.	This measure has 1 discrete numerator: • At least one socio-emotional/behavioral screen with a PCP or an OB/GYN practitioner during the measurement year.

Characteristic	Detail Description	Detail Description
	• # Children who had screening for risk of development, behavioral and social delays using a standardized screening tool that was documented by their second birthday. • # Children who had screening for risk of development, behavioral and social delays using a standardized screening tool that was documented by their third birthday. • # Children who had screening for risk of development, behavioral and social delays using a standardized screening tool that was documented by their first, second, or third birthday. (*Combination estimate)*	
Denominator	This measure has 4 discrete denominators (respectively): • # Children who turn 1 by the end of the measurement period. • # Children who turn 2 by the end of the measurement period. • # Children who turn 3 by the end of the measurement period. • # Children who turn 1 or 2 or 3 by the end of the measurement period.	This measure has 1 discrete denominator: • Children/adolescents 4-17 years of age during the measurement period.
Baseline Value(s)	Baseline values will be obtained from multiple sources: • Existing statewide Medicaid weighted average reports • Region specific estimates will be calculated for a measurement period prior to the water switch.	Baseline values will be obtained from multiple sources: • Region specific estimates will be calculated for a measurement period prior to the water switch.
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data	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

H1.3: A greater proportion of enrollees will receive age appropriate lead testing compared to others with similar lead exposures.

Characteristic	Detail Description
Measure Title	Lead Screening in Children
Measure Description	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.
NQF Number	n/a
Measure Steward	National Committee for Quality Assurance
Numerator	# of children with at least one lead capillary or venous blood test on or before the child's second birthday.
Denominator	# of children who turn 2 years old during the measurement period.

Characteristic	Detail Description
Baseline Value(s)	Baseline values will be obtained from multiple sources: • Existing statewide Medicaid weighted average reports • Region specific estimates will be calculated for a measurement period prior to the water switch.
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data matched with MCIR and Childhood Lead Prevention Program
Anticipated Data Source	Administrative claims/encounters, MCIR, and Childhood Lead Screening Data in the MDHHS data warehouse

H1.4: A greater proportion of enrollees with high blood lead levels will receive re-testing at the appropriate intervals compared to others with similar lead exposures.

Characteristic	Detail Description
Measure Title	Follow-up of elevated blood lead level
Measure Description	The percentage of children with elevated blood lead levels having retests according to recommended timeframes established by MDHHS Lead Policy.
NQF Number	n/a
Measure Steward	Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)-CMS/American Academy of Pediatrics
Numerator	# of children with elevated blood lead levels having re-testing with specified timeframes.
Denominator	# of children with elevated blood lead levels during the measurement period.
Baseline Value(s)	Baseline values will be obtained from multiple sources: • Region specific estimates will be calculated for a measurement period prior to and after the water switch.
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data
Anticipated Data Source	Administrative claims/encounters in the MDHHS data warehouse linked to state lead screening and TCM monitoring data

H1.5: Enrollees who are pregnant will have more timely prenatal and postpartum care compared to others with similar lead exposures.

Characteristic	Detail Description	Detail Description
Measure Title	Timeliness of Prenatal Care	Postpartum Care
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.
NQF Number	1517	1517
Measure Steward	National Committee for Quality Assurance	National Committee for Quality Assurance
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.
Denominator	Medicaid deliveries of live births between February 4 of the year prior to the	Medicaid live birth deliveries between February 4 of the year prior to the

Characteristic	Detail Description	Detail Description
	measurement period and February 3 of the measurement period.	measurement period and February 3 of the measurement period.
Baseline Value(s)	Baseline values will be obtained from multiple sources: • Existing statewide Medicaid weighted average reports • Region specific estimates will be calculated for a measurement period prior to and after the water switch.	Baseline values will be obtained from multiple sources: • Existing statewide Medicaid weighted average reports • Region specific estimates will be calculated for a measurement period prior to and after the water switch.
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data	No sampling – plan to use 100% available claims/encounter data
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

H1.6: A greater proportion of enrollees who are pregnant will have recommended lead testing compared to others with similar lead exposures.

Characteristic	Detail Description
Measure Title	Lead screening in pregnancy
Measure Description	The percentage of pregnant women screened for elevated blood lead levels during pregnancy.
NQF Number	n/a
Measure Steward	American Congress of Obstetricians and Gynecologists
Numerator	Percentage of deliveries that received 1 or more capillary or venous lead blood test during pregnancy.
Denominator	Medicaid live birth deliveries between February 4 of the year prior to the measurement period and February 3 of the measurement period.
Baseline Value(s)	Baseline values will be obtained from multiple sources: • Region specific estimates will be calculated for a measurement period prior to and after the water switch.
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data
Anticipated Data Source	Administrative claims/encounters in the MDHHS data warehouse linked to Vital Records data

H1.7: A greater proportion of enrollees will participate with Maternal Infant Health Program (MIHP) services compared to others with similar lead levels.

Characteristic	Detail Description
Measure Title	MIHP Participation
Measure Description	The percentage of deliveries participating with the Maternal Infant Health Program.
NQF Number	n/a
Measure Steward	n/a
Numerator	Percentage of deliveries receiving 1 or more visit with MIHP during pregnancy or after birth.
Denominator	Medicaid deliveries of live births between February 4 of the year prior to the measurement period and February 3 of the measurement period.

Characteristic	Detail Description
Baseline Value(s)	Baseline values will be obtained from multiple sources: • Region specific estimates will be calculated for a measurement period prior to and after the water switch. • Comparison to historical participation estimates
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data
Anticipated Data Source	Administrative claims/encounters in the MDHHS data warehouse linked to MIHP visit and TCM Monitoring data

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

Characteristic	Detail Description
Measure Title	Enrollee Attestation for Improved Access to Care
Measure Description	Surveyed enrollees will agree or strongly agree with a statement acknowledging the Medicaid program as one method for improving access to health care.
NQF Number	n/a
Measure Steward	Agency for Healthcare Research and Quality – Consumer Assessment of Healthcare Providers and Systems (AHRQ-CAHPS) Question Modification
Numerator	Number of respondents who report they "agree " or "strongly agree" with a statement about Medicaid improving health care access. *Sample questions:* "In the last 6 months, how often was it easy to get the care, tests, or treatment you needed?" (never/sometimes/usually/always) "Overall, enrolling in the Medicaid expansion made it easier to get the health care that I needed" (strongly agree to strongly disagree)
Denominator	Number of survey participants.
Baseline Value(s)	--
Sampling Methodology	Random/weighted sampling
Anticipated Data Source	Beneficiary survey

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

Characteristic	Detail Description
Measure Title	Enrollee satisfaction with Medicaid expansion coverage
Measure Description	Surveyed enrollees ranking of their health care coverage using 0-10 scale (0=worst health care possible, 10=best health care possible)
NQF Number	--
Measure Steward	AHRQ CAHPS Question Modification
Numerator	Mean of health care scores provided by survey beneficiaries. *Sample question:*

Characteristic	Detail Description
	"Using any number from 0 to 10, where 0 is the worst health care possible and 10 is the best health care possible, what number would you use to rate all your health care"
Denominator	Number of survey participants.
Baseline Value(s)	--
Sampling Methodology	Random/weighted sampling
Anticipated Data Source	Beneficiary survey

Domain 2: Access to TCM

The approved demonstration would provide an expanded benefit, specifically TCM, to facilitate needed medical, social, educational and other services to a cohort of individuals who were exposed to the contaminated water and are potentially at risk for physical or behavioral health consequences. Required elements of TCM have been described in MDHHS policy and include assessments, planning, linkage, advocacy, coordination, referral, monitoring and follow-up activities.

The sub-hypotheses identified for Domain 2 were selected for their relevance to aspects of the TCM responsibilities and goals. Specifically, the measures focus on the TCM objectives to facilitate needed screening as well as identify and manage individuals believed to be high-risk for lead exposure.

We would explore the feasibility of adding an additional hypothesis to this domain focusing on utilization of educational supports for children however these data are limited by federal regulation. The work to create the newly funded registry could help address the legal and data seeking hurdles we will face. The evaluation team will continue to pursue opportunities by which these data can be accessed or made available to contribute to the evaluation. For continuous outcome measures we will use *t*-test and for discrete outcomes we will use chi-square test if the sample size is large. In the event that few individuals access TCM services we will use nonparametric rank test for continuous outcomes and exact test for discrete outcomes to carry out the analyses.

Hypotheses

2. *"Enrollees who access TCM services will access needed medical, social, educational, and other services at a rate higher than others with similar levels of lead exposure."*
    - Hypothesis 2.1: Referral source and participation levels with TCM will be tracked among enrollees.
    - Hypothesis 2.2: All TCM participants will have an annual assessment conducted.
    - Hypothesis 2.3: A greater proportion of TCM participants will have age-appropriate well child exams compared to TCM non-participants.
    - Hypothesis 2.4: A greater proportion of TCM participants will have completed age-appropriate developmental screening compared to TCM non-participants.

Hypothesis 2.1: Referral source and participation levels with TCM will be tracked among enrollees.

Characteristic	Detail Description	Detail Description
Measure Title	Referral Source	TCM Participation
Measure Description	The percentage of enrollees in the region who participate with the TCM expanded benefit by referral source (primary care physician vs. Medicaid health plan vs. self-referral)	The percentage of enrollees in the region who participate with the TCM expanded benefit.
NQF Number	n/a	n/a
Measure Steward	n/a	n/a
Numerator	Percentage of enrollees having at least 1 visit with TCM referred by: • their primary care physician • their Medicaid Health Plan • Self-referral • Others	Percentage of enrollees having at least 1 visit with TCM
Denominator	Total number of enrollees participating with TCM	Total number of enrollees eligible to receive TCM
Baseline Value(s)	n/a	n/a
Sampling Methodology	No sampling – plan to use 100% TCM documentation	No sampling – plan to use 100% available claims/encounter data
Anticipated Data Source	TCM documentation visit data	Administrative claims/encounters in the MDHHS data warehouse linked to TCM billing/documentation visit data

Hypothesis 2.2: All TCM participants will have an annual assessment conducted.

Characteristic	Detail Description
Measure Title	Annual TCM Assessment
Measure Description	The percentage of TCM participants who had 1 reassessment within one year of original assessment.
NQF Number	n/a
Measure Steward	n/a
Numerator	Number of enrollees having a completed reassessment within 365 days of initial assessment.
Denominator	Total number of enrollees who had contact with TCM.
Baseline Value(s)	n/a
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data
Anticipated Data Source	Administrative claims/encounters in the MDHHS data warehouse linked to TCM billing/documentation visit data

Hypothesis 2.3: A greater proportion of TCM participants will have age-appropriate well child exams compared to TCM non-participants.

Characteristic	Detail Description
Measure Title	Impact of TCM in assuring enrollees obtain age-appropriate well-child exams.

Measure Description	Reference to Hypothesis 1.1 – will further analyze NQF #1392 measure by TCM participation status.
NQF Number	1392
Measure Steward	National Committee for Quality Assurance
Numerator	TCM participants meeting Hypothesis 1.1 numerator elements
Denominator	Total number of enrollees eligible to receive TCM.
Baseline Value(s)	--
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data
Anticipated Data Source	Administrative claims/encounters in the MDHHS data warehouse linked to TCM billing/documentation to identify participation status

Hypothesis 2.4: A greater proportion of TCM participants will have completed age-appropriate developmental screening compared to TCM non-participants.

Characteristic	Detail Description
Measure Title	Impact of TCM in assuring enrollees obtain age-appropriate developmental screenings.
Measure Description	Reference to Hypothesis 1.2 – will further analyze measures by TCM participation status (both #1448 and the new evaluation measure: socio-emotional/behavioral screening)
NQF Number	1448
Measure Steward	Oregon Health & Science University
Numerator	TCM participants meeting Hypothesis 1.2 numerator elements
Denominator	Total number of enrollees eligible to receive TCM.
Baseline Value(s)	--
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data
Anticipated Data Source	Administrative claims/encounters in the MDHHS data warehouse linked to TCM billing/documentation to identify participation status

Domain 3: Improved Health Outcomes

The approved demonstration would provide opportunities for access to health care and additional supports leading to improved overall health status and health outcomes for eligible individuals who were exposed to the lead contaminated water and who are potentially at risk for physical and behavioral health consequences.

The sub-hypotheses identified for Domain 3 were selected for their relevance to health outcomes that might be susceptible to lead exposure among individuals who would be identified as high-risk for lead exposure and represent the target population for the waiver 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 more accurately may be described as process measures, the association of each with optimized health status is well documented.

Using the potential comparison groups identified in the prior section, we will carry out the testing of the hypotheses using the paired *t*-test, McNemar chi-square test. When certain risk factors are not

balanced despite the effort of matching we will use regression adjustment to control these factors via linear or generalized linear mixed effects models.

Hypotheses

3. "*Enrollees will have improved health outcomes compared to others with similar levels of lead exposure*."
    - Hypothesis 3.1: Enrollees will have higher completed age-appropriate immunization statuses compared to others with similar lead exposures.
    - Hypothesis 3.2: Enrollees who are pregnant will deliver infants with higher birth weights compared to others with similar lead exposures.
    - Hypothesis 3.3: Enrollees report an increase in their self-reported health status over the duration of their enrollment.

The following hypotheses are suggested as outcomes that may be investigated should the necessary data be made available to the evaluation team. We will incorporate some questions regarding behavioral and educational development for parent/guardian self-report into our planned surveys. We will further work with the registry development team to explore opportunities to work collaboratively and potentially share data with Michigan Department of Education staff at the beneficiary level.

- *Provisional Hypothesis 3.4: We will conduct a descriptive analysis of the proportion of children diagnosed with severe emotional disturbance and other developmental/learning disabilities including comparing rates to others with similar lead exposures.*
- *Provisional H3.5: Descriptive analysis of behavioral health conditions among enrolled children (i.e. rate/proportion of children suspended or expelled).*
- *Provisional H3.6: Descriptive analysis of educational delays among enrolled children (i.e. rate/proportion of children receiving special education services – IEPs, early preschool performance, reading and math scores at end of grades 3, 4, and 5)*

Hypothesis 3.1: Enrollees will have higher completed age-appropriate immunization statuses compared to others with similar lead exposures.

Characteristic	Detail Description	Detail Description
Measure Title	Childhood Immunization Status	Immunizations for Adolescents
Measure Description	Percentage of children 2 years of age who had 4 diphtheria, tetanus and acellular pertussis (DtaP); three 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.
NQF Number	0038	1407

Characteristic	Detail Description	Detail Description
Measure Steward	National Committee for Quality Assurance	National Committee for Quality Assurance
Numerator	# children who received the recommended vaccines by their second birthday. Separate rates calculated for each vaccine as well as 9 separate combination rates.	# adolescents 13 years of age who had one dose of meningococcal vaccine and one tetanus, diphtheria toxoids and acellular pertussis vaccine (Tdap) or one tetanus, diphtheria toxoids vaccine (Td) by their 13th birthday.
Denominator	# children who turn 2 years of age during the measurement period.	# adolescents who turn 13 years of age during the measurement period.
Baseline Value(s)	Baseline values will be obtained from multiple sources: • Existing statewide Medicaid weighted average reports • Region specific estimates will be calculated for a measurement period prior to and after the water switch.	Baseline values will be obtained from multiple sources: • Existing statewide Medicaid weighted average reports • Region specific estimates will be calculated for a measurement period prior to and after the water switch.
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data	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

Hypothesis 3.2: Enrollees who are pregnant will deliver infants with higher birth weights compared to others with similar lead exposures.

Characteristic	Detail Description
Measure Title	Low Birth Weight Rate
Measure Description	Low birth weight (<2500 gram) infants per 1,000 newborns (excluding transfers)
NQF Number	0278
Measure Steward	Agency for Healthcare Research & Quality
Numerator	# of newborns, among cases meeting inclusion/exclusion rules for the denominator, with any-listed ICD-9-CM (ICD-10) diagnosis codes for birth weight less than 2,500 grams.
Denominator	# of newborns in region
Baseline Value(s)	Baseline values will be obtained from multiple sources: • Existing statewide Medicaid weighted average reports • Region specific estimates will be calculated for a measurement period prior to and after the water switch.
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data
Anticipated Data Source	Administrative claims/encounters in the MDHHS data warehouse linked to Vital Records

Hypothesis 3.3: Enrollees report an increase in their self-reported physical and behavioral/emotional health status and their ability to manage chronic conditions over the duration of their enrollment.

Characteristic	Detail Description	Detail Description
Measure Title	Enrollee Self-Reported Health Status	Enrollee Self-Reported Efficacy of Chronic Condition Management

Characteristic	Detail Description	Detail Description
Measure Description	Surveyed enrollees self-evaluation for overall health status.	Surveyed enrollees self-evaluation for managing chronic conditions
NQF Number	--	--
Measure Steward	AHRQ CAHPS/BRFSS Question Modification	--
Numerator	Number of respondents participating with at least 2 survey waves who have an increase in the level of self-reported health status. *Sample questions:* "In general, how would you rate your overall health?" (excellent/very good/good/fair/poor) "In general, how would you rate your overall mental or emotional health?" (excellent/very good/good/fair/poor)	Number of respondents participating with at least 2 survey waves who report efficacy in managing chronic conditions. *Sample Tools:* Adult/Pediatric Asthma Control Test
Denominator	Number of survey participants.	Number of survey participants.
Baseline Value(s)	--	--
Sampling Methodology	Random/weighted sampling	Random/weighted sampling
Anticipated Data Source	Beneficiary survey responses	Beneficiary survey responses

Provisional Hypothesis 3.4: We will conduct a descriptive analysis of the proportion of children diagnosed with severe emotional disturbance and other developmental/learning disabilities including comparing rates to others with similar lead exposures.

Characteristic	Detail Description
Measure Title	Enrollee Diagnosed with Severe Emotional Disturbance, Developmental and/or Learning Disabilities
Measure Description	Proportion of enrollees having diagnosis code(s) of interest
NQF Number	--
Measure Steward	--
Numerator	Number of enrollees diagnosed with condition(s) of interest
Denominator	Number of enrollees
Baseline Value(s)	--
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data
Anticipated Data Source	Administrative claims/encounters in the MDHHS data warehouse

Provisional Hypothesis 3.5: Descriptive analysis of behavioral health conditions and supportive care among enrolled children (i.e. rate/proportion of children suspended or expelled).

Characteristic	Detail Description	Detail Description	Detail Description
Measure Title	Prevalence of behavioral health conditions among enrolled children	Count of children enrolled in Early Childhood Programs	Proportion of students in Kindergarten who participated in Early Childhood Programs

Characteristic	Detail Description	Detail Description	Detail Description
Measure Description	Surveyed enrollees identify behavioral health conditions that exposed children are experiencing according to parent/guardian report.	MDE reporting based on county and school district level.	MDE reporting based on county and school district level.
NQF Number	--	--	--
Measure Steward	--	--	--
Numerator	Number of children identified as having behavioral health condition diagnosed by a health care provider and reported by parent/guardian. *Sample questions:* "Has a health care provider ever diagnosed your child with a behavioral health condition?" "Has a daycare or school employee ever told you your child has a behavioral health condition?"		
Denominator	Number of survey participants.		
Baseline Value(s)	--	Historical reporting back to 2013.	Historical reporting back to 2013.
Sampling Methodology	Random/weighted sampling	n/a	n/a
Anticipated Data Source	Beneficiary survey	MDE Reporting	MDE Reporting

Provisional Hypothesis 3.6: Descriptive analysis of educational delays among enrolled children (i.e. rate/proportion of children receiving special education services – IEPs, early preschool performance, reading and math scores at end of grades 3, 4, and 5).

Characteristic	Detail Description	Detail Description	Detail Description
Measure Title	Prevalence of educational delays among enrolled children	Counts of children remaining in same grade	Educational Progress Standardized Testing (M-STEP, MI-Access)
Measure Description	Surveyed enrollees identify educational delays that exposed children have received from education providers.	MDE reporting based on county and school district level.	MDE reporting based on county and school district level.
NQF Number	--	--	--
Measure Steward	--	--	--
Numerator	Number of children identified as having educational delays		Specific elements TBD in collaboration with MDE

Characteristic	Detail Description	Detail Description	Detail Description
	identified by an educational provider. *Sample questions:* "Has a daycare or school employee ever told you your child does not learn as other children who are the same age?"		
Denominator	Number of survey participants.		
Baseline Value(s)	--	Historical reporting back to 2013.	Historical reporting back to 2013.
Sampling Methodology	Random/weighted sampling	n/a	n/a
Anticipated Data Source	Beneficiary survey	MDE Reporting	MDE Reporting

Domain 4: Lead Hazard Investigation

The waiver supports a lead hazard investigation program intended to reduce the estimated expected ongoing or re-exposure to lead hazards. This benefit covers an evaluation of potential sources of lead for eligible members even in the absence of elevated blood levels. Abatement services are not directly funded through this mechanism.

The hypothesis identified for Domain 4 will rely on monitoring the frequency with which eligible beneficiaries receive lead hazard assessment/investigation services (screening through the TCM process and formal environmental investigation). We will request information on abatement activities conducted by authorized organizations and include this as available.

Hypothesis

4. *"The lead hazard investigation program will reduce estimated expected ongoing or re-exposure to lead hazards in the absence of this program."*
    - 4.1: Beneficiaries without elevated blood lead levels and participating with TCM services will access lead hazard assessment/investigation services to the same degree as beneficiaries with elevated blood lead levels.
    - 4.2: Beneficiaries found to be at risk for ongoing lead exposure will be referred for additional environmental investigation.

Hypothesis 4.1: Beneficiaries without elevated blood lead levels and participating with TCM services will access lead hazard assessment/investigation services to the same degree as beneficiaries with elevated blood lead levels.

Characteristic	Detail Description
Measure Title	Prevalence of Lead Hazard Assessment/Investigation
Measure Description	Proportion of beneficiaries covered by the waiver having a lead hazard investigation conducted. This will be further subdivided by elevated blood lead level (>=5 mcg) and proportions compared for non-elevated vs. elevated cohorts.
NQF Number	--
Measure Steward	--
Numerator	# of beneficiaries covered by the waiver participating with TCM (submission of T2024)
Denominator	# beneficiaries covered by the waiver
Baseline Value(s)	Baseline values may be available through billing for environmental investigations – this would provide a reference for the cohort of individuals having elevated lead levels.
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data
Anticipated Data Source	Administrative claims/encounters in the MDHHS data warehouse linked to Blood lead level data

Hypothesis 4.2: Beneficiaries found to be at risk for ongoing lead exposure will be referred for additional environmental investigation.

Characteristic	Detail Description
Measure Title	Prevalence of Lead Hazard Follow-up Investigation
Measure Description	Proportion of beneficiaries covered by the waiver found to be at high-risk/fail a lead assessment and referred for follow-up environmental assessment. This will be further subdivided by elevated blood lead level (>=5 mcg) and proportions compared for non-elevated vs. elevated cohorts.
NQF Number	--
Measure Steward	--
Numerator	# of beneficiaries covered by the waiver with elevated blood lead level receiving environmental investigation (submission of T1028EP, T1029, T1029TS)
Denominator	# beneficiaries covered by the waiver
Baseline Value(s)	Baseline values may be available through billing for environmental investigations – this would provide a reference for the cohort of individuals having elevated lead levels.
Sampling Methodology	No sampling – plan to use 100% available claims/encounter data
Anticipated Data Source	Administrative claims/encounters in the MDHHS data warehouse linked to Blood lead level data

Attachment C
Demonstration Evaluation Plan

Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
DOMAIN 1: Access to Care			
H1.1: A greater proportion of enrollees will obtain age-appropriate well-child exams compared to others with similar lead exposures.	1. Well Child Visits in the First 15 months of Life	National Committee for Quality Assurance/NQF 1392	Administrative claims/encounters in the MDHHS data warehouse
	2. Well Child visits in the Third, Fourth, Fifth and Sixth Years of Life	National Committee for Quality Assurance/NQF 1516	Administrative claims/encounters in the MDHHS data warehouse
	3. Adolescent Well-Care Visits	National Committee for Quality Assurance	Administrative claims/encounters in the MDHHS data warehouse
H1.2: A greater proportion of enrollees will receive age-appropriate developmental screening/assessments compared to others with similar lead exposures	1. Developmental Screening in the First Three Years of Life	Oregon Health & Science University /NQR 1448	Administrative claims/encounters in the MDHHS data warehouse
	2. Socio-emotional/ Behavioral Screening for Children 4-17 years of age	n/a	Administrative claims/encounters in the MDHHS data warehouse
H1.3: A greater proportion of enrollees will receive age appropriate lead testing compared to others with similar lead exposures	1. Lead Screening in Children	National Committee for Quality Assurance	Administrative claims/encounters in the MDHHS data warehouse
H1.4: A greater proportion of enrollees with high blood lead levels will receive re-testing at the appropriate intervals compared to others with similar lead exposures	1. Follow-up of elevated blood lead level	Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)-CMS/American Academy of Pediatrics	Administrative claims/encounters in the MDHHS data warehouse linked to lead screening and TCM monitoring data
H1.5: Enrollees who are pregnant will have more timely prenatal and postpartum care compared to others with similar lead exposures.	1. Timeliness of Prenatal Care	National Committee for Quality Assurance/NQF 1517	Administrative claims/encounters in the MDHHS data warehouse linked to Vital Records
	2. Postpartum Care	National Committee for Quality Assurance/NQF 1517	Administrative claims/encounters in the MDHHS data warehouse linked to Vital Records

Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
H1.6: A greater proportion of enrollees who are pregnant will have recommended lead testing compared to others with similar lead exposures	1. Lead screening in pregnancy	American Congress of Obstetricians and Gynecologists	Administrative claims/encounters in the MDHHS data warehouse linked to Vital Records data
H1.7: A greater proportion of enrollees will participate with home visiting services compared to others with similar lead levels.	1. Maternal Infant Health Program Participation	MI defined measure	Administrative claims/encounters in the MDHHS data warehouse linked to MIHP visit and TCM monitoring data
H1.8: Enrollees will attest to improved access to health care as a result of the expanded coverage.	1. Enrollee Attestation for Improved Access to Care	Agency for Healthcare Research and Quality – Consumer Assessment of Healthcare Providers and Systems (AHRQ-CAHPS) Question Modification	Beneficiary survey responses
H1.9: Enrollees will report satisfaction with their ability to access health care as a result of the expanded coverage.	1. Enrollee satisfaction with Medicaid expansion coverage	Agency for Healthcare Research and Quality – Consumer Assessment of Healthcare Providers and Systems (AHRQ-CAHPS) Question Modification	Beneficiary survey responses
DOMAIN 2: Access to Targeted Case Management			
H2.1: Referral source and participation levels with TCM will be tracked among enrollees	1. Referral Source for TCM	MI defined measure	TCM documentation visit data
	2. TCM Participation	MI defined measure	Administrative claims/encounters in the MDHHS data warehouse linked to TCM billing/documentation
H2.2: All TCM participants will have an annual assessment conducted.	1. Annual TCM assessment	MI defined measure	Administrative claims/encounters in the MDHHS data warehouse linked to TCM billing/documentation

Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
H2.3: A greater proportion of TCM participants will have age-appropriate well child exams compared to TCM non-participants	1. A greater proportion of TCM participants will have age-appropriate well child exams compared to TCM non-participants	National Committee for Quality Assurance /NQF 1392	TCM Program documentation linked to Administrative claims/encounter data available through the MDHHS data warehouse.
H2.4: A greater proportion of TCM participants will have completed age-appropriate developmental screening compared to TCM non-participants	1. Impact of TCM in assuring enrollees obtain age-appropriate developmental screenings.	Oregon Health & Science University/NQF 1448 and new evaluation measure (socio-emotional/behavioral screening)	Administrative claims/encounters in the MDHHS data warehouse linked to TCM billing/documentation visit data
DOMAIN 3: Improved Health Outcomes			
H3.1: Enrollees will have higher completed age-appropriate immunization statuses compared to others with similar lead exposures	1. Childhood Immunization Status	National Committee for Quality Assurance/NQF 0038	Administrative claims/encounters in the MDHHS data warehouse
	2. Immunizations for Adolescents	National Committee for Quality Assurance/NQF 1407	Administrative claims/encounters in the MDHHS data warehouse
H3.2: Enrollees who are pregnant will deliver infants with higher birth weights compared to others with similar lead exposures	1. Low Birth Weight Rate	Agency for Healthcare Research & Quality/NQF 0278	Administrative claims/encounters in the MDHHS data warehouse linked to Vital Records
H3.3: Enrollees report an increase in their self-reported health status over the duration of their enrollment.	1. Enrollee Self-Reported Health Status	AHRQ/CAHPS Question Modification	Beneficiary survey responses
	2. Enrollee Self-Reported Efficacy of Chronic Condition Management	Adult and Pediatric Condition Management Self-Efficacy (ex. Asthma Control Test)	Beneficiary survey responses
PROVISIONAL H3.4: Descriptive analysis of the proportion of children diagnosed with severe emotional	1. Proportion of enrollees having diagnosis code(s) of interest	MI defined measure	Administrative claims/encounters in the MDHHS data warehouse

Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
disturbance and other developmental/learning disabilities including comparing rates to others with similar lead exposures.			
PROVISIONAL H3.5: Descriptive analysis of behavioral health conditions and supportive care among enrolled children.	1. Prevalence of behavioral health conditions among enrolled children 2. Count of children enrolled in Early Childhood Programs 3. Proportion of students in Kindergarten who participated in Early Childhood Programs	MI defined measure	Beneficiary survey responses MDE Data
PROVISIONAL H3.6: Descriptive analysis of educational delays among enrolled children.	1. Prevalence of educational delays among enrolled children 2. Counts of children remaining in same grade 3. Educational Progress Standardized Testing (M-STEP, MI-Access)	MI defined measure	Beneficiary survey responses MDE Data
DOMAIN 4: Lead Hazard Investigation			
H4.1: Enrollees without elevated blood lead levels and participating with TCM services will access lead hazard investigation services to the same degree as beneficiaries with elevated blood lead levels.	1. Prevalence of Lead Hazard Assessment/Investigation	MI defined measure	Administrative claims/encounters in the MDHHS data warehouse linked to Blood lead levels
H4.2: Beneficiaries found to be at risk for ongoing lead exposure will be referred for additional environmental investigation	2. Prevalence of Lead Hazard Follow-up Investigation	MI defined measure	Administrative claims/encounters in the MDHHS data warehouse linked to Blood lead levels

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