



March 3, 2016

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

Dear Mr. Priest:

The Centers for Medicare & Medicaid Services (CMS) is approving Michigan's February 14, 2016 application to establish a five-year Medicaid demonstration, entitled "Flint Michigan Section 1115 Demonstration" (Project No. 11W 00302/5) in response to the public health emergency of lead exposure related to the Flint water system. Through the demonstration and associated state plan amendments, the state will expand coverage to children up to age 21 years and to pregnant women with incomes up to and including 400 percent of the federal poverty level (FPL) who were served by the Flint water system from April 2014 through a state-specified date. This demonstration is approved in accordance with section 1115(a) of the Social Security Act, and is effective as of the date of the signed approval through February 28, 2021.

With the approval of this demonstration authority and the associated state plan amendments, Medicaid-eligible children and pregnant women who were served by the Flint water system during the specified period will be eligible for all services covered under the state plan. They will be exempt from cost sharing or premiums. All such persons will have access to Targeted Case Management services and evaluation of potential sources of lead exposure in the home. The Targeted Case Management services will include assistance in gaining access to needed medical, social, educational, and other services. All state plan services, except for Targeted Case Management Services, will be delivered through the state's existing systems.

Additionally, Michigan has indicated that it will implement a state program to make available for purchase unsubsidized coverage for children up to age 21 and pregnant women with incomes above 400 percent of the FPL who were served by the Flint water system. The initiative for individuals above 400 percent of the federal poverty level does not involve federal Medicaid funds. Finally, while we are not able to accommodate the state's request for lead abatement activities through section 1115 demonstration authority, we are working with you and your staff to design and expeditiously process an alternative option through a targeted and time-limited health services initiative under title XXI of the Social Security Act. This would support certain

lead abatement activities that would complement other state and local efforts to remove lead hazards from the homes of Medicaid and CHIP eligible children and pregnant women.

In light of President Obama's emergency declaration on January 16, 2016, and consistent with 42 CFR 431.416(g)(2), we have waived the federal and state public notice processes and required time constraints to the extent necessary to provide a timely response to the public health emergency in Flint, Michigan. The state's proposal was posted concurrently for public comment at the state and federal levels beginning February 16, 2016, and the public comments received were considered as we finalized the terms and conditions of the demonstration.

CMS's approval of this demonstration is contingent upon compliance with the enclosed set of special terms and conditions (STCs) defining the nature, character, and extent of anticipated federal involvement in the project. The award is subject to our receiving your written acknowledgement of the award and acceptance of these STCs within 30 days of the date of this letter. A copy of the STCs, waivers, and expenditure authorities are enclosed. We look forward to supporting the state's implementation of the new eligibility and services as soon as possible.

Your project officer for this demonstration is Ms. Megan Lepore. She is available to answer any questions concerning your section 1115 demonstration, and her contact information is as follows:

Centers for Medicare & Medicaid Services  
Center for Medicaid and CHIP Services  
Mail Stop S2-01-16  
7500 Security Boulevard  
Baltimore, MD 21244-1850  
E-mail: [Megan.Lepore@cms.hhs.gov](mailto:Megan.Lepore@cms.hhs.gov)

Official communications regarding program matters should be sent simultaneously to Ms. Ruth Hughes, Associate Regional Administrator in our Chicago Regional Office. Ms. Hughes's contact information is as follows:

Ms. Ruth Hughes  
Associate Regional Administrator  
Centers for Medicare & Medicaid Services  
Division of Medicaid and Children Health Operations  
233 N. Michigan Avenue, Suite 600  
Chicago, IL 60601-5519

If you have questions regarding this approval, please contact Mr. Eliot Fishman, Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (410) 786-9686.

Thank you for all your work with us, as well as stakeholders in Michigan, over the past several weeks on this demonstration. Congratulations on its approval.

Sincerely,

/s/

Andrew M. Slavitt  
Acting Administrator

Enclosures

**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 (TBD)

## 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.

<b>Populations Affected by the Demonstration and Eligible for Benefits based on Service from the Flint Water System</b>	<b>Point In Time Enrollment (last day of month)</b>	<b>Title XXI Funded</b>	<b>Newly Enrolled Last Month</b>	<b>Disenrolled Last Quarter</b>
<b>All Medicaid Eligible Pregnant Women served by the Flint Water System (everybody – TCM total)</b>				
<b>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)</b>				
<b>All Medicaid Eligible Pregnant Women served by the Flint Water System affected by the demonstration because of the premium waiver (VIII group/QHP)</b>				
<b>All Medicaid Eligible Children served by the Flint Water System (everybody – TCM total)</b>				
<b>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)</b>				
<b>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)</b>				
<b>All Medicaid Eligible Children served by the Flint Water System affected by the</b>				

demonstration because of the premium waiver (VIII group)				
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**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; and 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 31 must 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 10C. 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 64.21 in 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 1 through 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 –
<b>Monthly</b>	<b>Deliverable</b>
Per paragraph 26	Monthly Enrollment Reports
<b>Quarterly</b>	<b>Deliverable</b>
Per paragraph 31	Quarterly Progress Reports
Per paragraph 31(e)	Quarterly Enrollment Reports
Per paragraph 34	Quarterly Financial Reports
<b>Annual</b>	<b>Deliverable</b>
Per paragraph 30	Annual Forum Transparency deliverable
Per paragraph 32	Draft Annual Report
<b>Renewal/Close Out</b>	<b>Deliverable</b>
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 - Reserved  
Post Approval Protocol**

**Attachment C – Reserved  
Demonstration Evaluation Plan**