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


June 24, 2021

Elizabeth Matney
Medicaid Director
Iowa Medicaid Enterprise
1305 E Walnut Street
Des Moines, IA 50319

Dear Ms. Matney:

The Centers for Medicare & Medicaid Services (CMS) is approving Iowa's section 1115 demonstration amendment (Project Number 11-W-00289/7), in accordance with section 1115(a) of the Social Security Act. Approval of this amendment will enable the state to test the effects of providing dental benefits via prepaid ambulatory health plans (PAHPs) to children. This amendment aims to better coordinate dental care for children, helping to promote oral health in an accessible and cost-effective manner. This approval is effective as of the date of this letter through December 31, 2024, upon which date, unless extended or otherwise amended, all authorities granted to operate this demonstration will expire.

CMS's approval of this section 1115(a) demonstration amendment is subject to the limitations specified in the attached waiver authorities, special terms and conditions (STCs), and any supplemental attachments defining the nature, character, and extent of federal involvement in this project. The state may deviate from Medicaid state plan requirements only to the extent those requirements have been specifically listed as waived or not applicable under the demonstration.

Consistent with CMS requirements for systematic monitoring and robust evaluation of section 1115 demonstrations, the state will be required to incorporate the amendment component into the demonstration's monitoring and evaluation deliverables.

*Consideration of Public Comments*

The state provided public notice for this amendment in accordance with the processes described in the September 27, 1994 Federal Register notice (59 FR 49249) as generally acceptable methods of state public notice for demonstration amendments.

The state held a 30-day public comment period from January 7, 2021 through February 10, 2021. The public notice and the waiver amendment, regarding the proposal were posted at

https://dhs.iowa.gov/public-notices/dwp-kids, non-electronic copies were made available for review at Iowa Department of Human Services (DHS) Field Offices. Additional notice was also provided to stakeholders via the Iowa Medicaid e-News on January 15, 2021. A summary notice was published in several newspapers of widest circulation in each city with a population of 100,000 or more. The notice provided the option for any individual to submit written feedback to the State by email or by United States Postal Service (USPS) mail. Comments were accepted via email and a physical address was provided for written comments to be submitted by mail. The state also held two public hearings to offer an opportunity for the public to provide written or verbal comments on the amendment on January 20, 2021 and on January 21, 2021.

The federal public comment period opened on March 26, 2021 and closed on April 26, 2021. CMS received four comments regarding the application during the federal comment period. Three of the comments were not related and one did not support the amendment. The opposing comment asserted that the application failed to meet the standard requirements for an 1115 amendment and should be considered an incomplete application. The commenter concluded that the state failed to include any information in the application on the impact of the amendment on cost neutrality. The demonstration is budget neutral because it does not include expenditure authority, and CMS has concluded that the waiver authorities granted for the demonstration are unlikely to result in any increase in federal Medicaid expenditures. The demonstration will not include a budget neutrality expenditure limit, and no further test of budget neutrality is required at this time.

The commenter also questioned how the amendment will align with current demonstration evaluation design, including proposed hypotheses and research questions, and how the state will evaluate the impact of the amendment on the outcomes for the proposed beneficiary population. As mentioned above, the state will be required to make necessary updates to incorporate the amendment component into the demonstration's monitoring and evaluation deliverables. Monitoring will support tracking the state's progress towards its demonstration goals for the new demonstration population via a set of process and quality metrics associated with, for example, enrollment, access to care, quality of care, and grievances and appeals. Similarly, the state's evaluation will ensure a thorough assessment of whether the amendment is effective in producing the desired outcomes for beneficiaries and the Medicaid program overall.

The commenter also indicated that the amendment application does not address what is being tested and therefore, does not meet the objectives of Medicaid. The amendment application proposes to test if these mechanisms will result in better coordination of dental care for children to promote oral health, increase access to services, reduce administrative barriers for providers and streamline billing. CMS will work with the state to identify appropriate hypotheses and research questions to evaluate the demonstration component, including the following hypotheses proposed by the state:

1. The benefit structure will increase regular use of recall dental exams over the study period.
2. The benefit structure will not be perceived by dentists as a barrier to providing care.
3. Beneficiary outreach will improve access to a regular source of dental care.

After careful review of the public comments submitted during the federal comment period and the information received from the state public comment period, CMS has concluded that the demonstration is likely to advance the objectives of Medicaid, because it is likely to promote better coordination of dental care for children, thereby helping to improve oral health in an accessible and cost-effective manner.

*Other Information*

The award is subject to CMS receiving written acceptance of this award within 30 days of the date of this approval letter. Your project officer is Ms. Wanda Boone-Massey who is available to answer any questions concerning implementation of the state's section 1115(a) demonstration and her contact information is as follows:

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

We appreciate your state's commitment to improving the health of people in Iowa, and we look forward to our continued partnership on the Iowa Wellness Plan section 1115(a) demonstration. If you have any questions regarding this approval, please contact Ms. Teresa DeCaro, Acting Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (410) 786-9686.

Sincerely,

[redacted]

Anne Marie Costello
Acting Deputy Administrator and Director

Enclosures

cc: Laura D'Angelo, State Monitoring Lead, Medicaid and CHIP Operations Group

**CENTERS FOR MEDICARE & MEDICAID SERVICES**

**WAIVER AUTHORITY**

**NUMBER:** **11-W-00289/7**

**TITLE:** **Iowa Wellness Plan Section 1115 Demonstration**

**AWARDEE:** **Iowa Department of 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 effective from January 1, 2020 through December 31, 2024.

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 Iowa Wellness Plan section 1115 demonstration.

1. **Premiums** — **Section 1902(a)(14) insofar as it incorporates Section 1916**

   To the extent necessary to enable the state to charge premiums beyond applicable Medicaid limits to the Iowa Wellness Plan demonstration populations above 50 percent of the federal poverty level and to enable the state to charge premiums for all Dental Wellness Plan enrollees above 50 percent of the federal poverty level. Combined premiums and cost-sharing is subject to a quarterly aggregate cap of 5 percent of family income.

2. **Methods of Administration** — **Section 1902(a)(4) insofar as it incorporates 42 CFR 431.53**

   To the extent necessary to relieve the state of the responsibility to assure transportation to and from providers for individuals in the demonstration for the new adult group beneficiaries. Medically frail beneficiaries and those eligible for EPSDT services are exempt from this waiver of NEMT.

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

   To the extent necessary to permit the state to provide reduced cost sharing for the newly eligible population through an $8 copay for non-emergency use of the emergency department.

This copay will not apply to other Medicaid populations; copays applied to other Medicaid populations will not be imposed on this population.

To the extent necessary to enable the state to vary dental benefits based on premium payment and engagement in healthy behaviors, as provided for in the STCs.

**4. Proper and Efficient Administration** **Section 1902(a)(17)**

To the extent necessary to permit the state to contract with a single dental benefit plan administrator to provide dental services to beneficiaries affected by the Iowa Wellness Plan section 1115 demonstration.

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

To the extent necessary to permit the state to require enrollees to receive dental services through a carved-out contracted dental benefit with no access to other providers.

**6. Amount, Duration and Scope of Services** **Section 1902(a)(10)(B)**

To the extent necessary to enable the state to provide benefit packages to demonstration populations that differ from the state plan benefit package. To the extent necessary to enable the state to provide different dental benefits to Dental Wellness Plan enrollees subject to the requirements in the STCs.

**7. Retroactive Eligibility and (a)(34)** **Section 1902(a)(10)**

To the extent necessary to enable the state not to provide three months of retroactive eligibility for state plan populations. The waiver of retroactive eligibility does not apply to pregnant women (and during the 60-day period beginning on the last day of the pregnancy), infants under age 1, and (effective January 1, 2020) children under 19 years of age. The earliest that a retroactive eligibility period for children under age 19 will begin will be January 1, 2020, for an application filed on or after January 1, 2020.

The waiver of retroactive eligibility also does not apply to applicants who are eligible for nursing facility services based on level of care, who had been a resident of a nursing facility in any of the three months prior to an application, and who are otherwise eligible for Medicaid. For persons who are exempted from the waiver due to eligibility for nursing facility services, retroactive eligibility would be provided for any particular months in which the applicant was a nursing facility resident.

**CENTERS FOR MEDICARE & MEDICAID SERVICES**

**SPECIAL TERMS AND CONDITIONS**

**NUMBER:** **11-W-00289/7**

**TITLE:** **Iowa Wellness Plan**

**AWARDEE:** **Iowa Department of Human Services**

## I. PREFACE

The following are the Special Terms and Conditions (STCs) for the Iowa Wellness Plan section 1115(f) Medicaid demonstration (hereinafter "demonstration") to enable Iowa to operate this demonstration. Pursuant to authority in section 1115 of the Act, the Centers for Medicare & Medicaid Services (CMS) has granted waivers of certain requirements under section 1902(a) of the Social Security Act (the Act). 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. Enrollment activities for the new adult group began on October 1, 2013 for the Iowa Wellness Plan with eligibility effective January 1, 2014. The demonstration is statewide and is approved through December 31, 2024.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Populations Affected
V. Dental Delivery System
VI. Benefits
VII. Healthy Behaviors, Premiums, and Cost Sharing
VIII. Appeals
IX. General Reporting Requirements
X. Monitoring Calls and Discussions
XI. Evaluation of the Demonstration

## II. PROGRAM DESCRIPTION AND OBJECTIVES

The Iowa Wellness Plan (IWP) demonstration was first implemented on January 1, 2014, at the same time that Iowa's expansion of Medicaid to the new adult group took effect. The Iowa Wellness Plan (IWP) demonstration initially sought to promote responsible health care decisions among the ACA expansion population by coupling a monthly required financial contribution with an incentive to earn an exemption from the monthly contribution requirement by actively seeking preventive health services.

As initially approved, the demonstration also provided authority for a waiver of non-emergency medical transportation for the ACA expansion population. The NEMT waiver was scheduled to sunset on December 31, 2014, with the possibility of extending based on an evaluation of its impact on access to care. After reviewing initial data on the impact of the waiver on access, CMS approved an extension of the NEMT waiver through July 31, 2015. Thereafter, CMS and the state established criteria necessary for the state to continue the NEMT waiver beyond July 31, 2015. Specifically, the state agreed to compare survey responses of the persons affected by the waiver to survey responses of persons receiving "traditional" Medicaid benefits through the state plan. Iowa conducted the analysis and found that the survey responses of the two populations did not have statistically significant differences. In light of those results, CMS approved a second amendment through June 30, 2016. Based on the state's ongoing analysis and evaluation of the impact of the NEMT waiver on access to covered services, the waiver of NEMT was extended again, and is still part of the demonstration. According to the most current analysis, the Iowa Health and Wellness Plan Evaluation Interim Summative Report, April 2019, reported unmet need for transportation was not statistically different for Medicaid members (12 percent) and IWP members (11 percent). There was no statistical difference between Medicaid and IWP in reported worry about the cost of transportation with around 8 percent of each reporting that they worried "a great deal" about their ability to pay for the cost of transportation to or from a health care visit.

On May 1, 2014, CMS approved the state's request to amend the IWP demonstration to include a Dental Wellness Plan (DWP) component, which at that time provided tiered dental benefits, based on beneficiary completion of periodic exams, to the ACA expansion population. All dental benefits covered under the DWP were optional, not mandatory.

Currently, the demonstration still includes an incentive program intended to improve the use of preventive services and encourage health among the ACA expansion population. Under this program, beginning in year two of a beneficiary's enrollment, the state requires monthly premiums for beneficiaries in the ACA expansion population with household incomes above 50 percent up to and including 133 percent of the federal poverty level (FPL). However, beneficiaries with a premium requirement who complete a wellness exam and health risk assessment (HRA) will have their premium waived for the following benefit year. The premium amounts may not exceed $5 per month for non-exempt beneficiaries with household incomes above 50 percent up to and including 100 percent of the FPL, and $10 per month for non-exempt beneficiaries with household incomes over 100 percent up to and including 133 percent of the FPL. Exempt

beneficiaries include those who completed the wellness exam and HRA, beneficiaries who are medically frail, members of the Health Insurance Premium Payment (HIPP) population, and beneficiaries who self-attest to a financial hardship. IWP premiums are permitted in lieu of other cost sharing except for an $8 copay for non-emergency use of the emergency department. Beneficiaries subject to premiums are allowed a 90-day grace period to make payment. The nonpayment of these premiums will result in a collectible debt. Individuals with household income over 100 percent of the FPL will be disenrolled for nonpayment. Enrollees with household income at or under 100 percent of the FPL cannot be disenrolled for nonpayment of a premium, nor can an individual be denied an opportunity to re-enroll due to nonpayment of a premium. Persons who are disenrolled for nonpayment can reapply at any time; however, their outstanding premium payments will remain subject to recovery. Monthly premiums are subject to a quarterly aggregate cap of 5 percent of household income.

On February 23, 2016, CMS approved the State's request to implement a managed care delivery system for the medical and dental services affected by the IWP demonstration, concurrent with the §1915(b) High Quality Healthcare Initiative Waiver, effective April 1, 2016.

On November 23, 2016, CMS extended the demonstration for three years under section 1115(e) of the Act, through December 31, 2019. This initial extension was approved with no program modifications. Subsequently, the state submitted two amendment requests during the renewal period. The first amendment, approved by CMS on July 27, 2017, modified the Dental Wellness Plan (DWP) component of the demonstration based on analysis of independent evaluation findings and stakeholder feedback. Through this amendment, the state implemented an integrated dental program for all Medicaid enrollees aged 19 and over, including the new adult group (ACA expansion population), parent and other caretaker relatives, and mandatory aged, blind, and disabled individuals. The tiered benefit structure was removed, and instead, the state established an incentive structure to encourage uptake of preventive dental services. Enrollees with household income above 50 percent of the FPL are required to contribute financially toward their dental health care costs through $3 monthly premium contributions in order to maintain comprehensive dental benefits. Dental premiums are waived in the first year of the individual's enrollment. Dental premiums will continue to be waived in subsequent years if enrollees complete an oral health risk assessment and obtain a preventive dental service in the prior year. Failure to make monthly dental premium payments results in the enrollee being eligible for only a basic dental services package for the remainder of the benefit year, but beneficiaries will not be disenrolled for failure to pay premiums and the past due amounts. The following eligibility groups are exempt from Dental Wellness Plan premiums, and will not have their benefits reduced in their second year of enrollment, notwithstanding any failure to complete state-designated healthy behaviors (i) pregnant women; (ii) individuals whose medical assistance for services furnished in an institution is reduced by amounts reflecting available income other than required for personal needs; (iii) 1915(c) waiver enrollees; (iv) individuals receiving hospice care; (v) American Indians/ Alaska Natives (AI/AN) who are eligible to receive or have received an item or service furnished by an Indian health care provider or through referral under contract health services; (vi) breast and cervical

cancer treatment program enrollees; and (vii) medically frail enrollees (referred to as medically exempt in Iowa). Additionally, persons who self-attest to financial hardship or who are exempt as described in 42 CFR 447.56 will have no dental premium obligation. The program thus creates incentives for enrollees to appropriately utilize preventive dental services, maintain oral health, and prevent oral disease. This program is also intended to create incentives for members to establish a dental home, because it encourages the receipt of preventive dental services. As was the case before this amendment, all dental benefits covered under the DWP are optional, not mandatory.

On August 2, 2017, Iowa, as directed by its legislature, submitted a request to amend the demonstration to waive retroactive eligibility for all Medicaid beneficiaries. On October 26, 2017, CMS approved the state's amendment request for a waiver of retroactive eligibility for all Medicaid beneficiaries except for pregnant women (and during the 60-day period beginning on the last day of the pregnancy), and infants under one year of age. Under the currently approved demonstration, unless an exemption applies, an applicant's coverage would begin on the first day of the month in which the application is submitted, or as otherwise allowed under the state plan.

On June 20, 2019, Iowa submitted a renewal application under section 1115(f) for a five-year extension, and requested one change to the existing terms and conditions. In accordance with Iowa Senate File 2418 (2018), the state requested to exempt applicants from the waiver of retroactive eligibility who are eligible for both Medicaid, and nursing facility services based on level of care, and who had been a resident of a nursing facility in any of the three months prior to submitting an application. For persons who are exempted from the waiver of retroactive eligibility due to eligibility for nursing facility services, retroactive eligibility is, and would continue to be, provided for those particular months in which the applicant was a nursing facility resident. The state already applies this exemption, for applications filed on or after July 1, 2018.

CMS approved the 1115(f) extension on November 15, 2019, including the change requested by Iowa to the retroactive eligibility waiver. In extending the approval period, CMS also updated the waiver of retroactive eligibility to exempt children under 19 years of age. The earliest that a retroactive eligibility period for children under age 19 will begin will be January 1, 2020, for an application filed on or after January 1, 2020.

In an abundance of caution, CMS also updated the waiver of retroactive eligibility to include a waiver of section 1902(a)(10) of the Act, to the extent that section 1902(a)(10) imposes a requirement of retroactive eligibility. CMS has also updated the monitoring and evaluation sections of the STCs to align those sections with CMS' current approach to monitoring and evaluation for section 1115 demonstrations, and to specify that CMS has the authority to require the state to submit a corrective action plan if monitoring or evaluation data indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid. The STCs further specify that any such corrective action plan, submitted by the state, could include a temporary suspension of implementation of demonstration programs, in circumstances where data indicate substantial, sustained directional change, inconsistent with state targets (such as substantial, sustained trends indicating increases in disenrollment, difficulty accessing services, provider uncompensated care costs, or unpaid medical bills). These updates will better aid the

state in measuring and tracking the demonstration's impact on Iowans affected by it, and give CMS additional tools to protect beneficiaries if necessary. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

Consistent with sections 1115(f)(6) and 1915(h) of the Act, CMS approved a 5-year extension approval period because the demonstration (specifically, the DWP component) provides medical assistance to beneficiaries dually eligible for Medicare and Medicaid.

On February 25, 2021, Iowa submitted an amendment to the Iowa Wellness Plan to provide dental benefits to children through Prepaid Ambulatory Health Plans (PAHPs). The amendment sought to allow the state to better coordinate dental care for children, helping to promote oral health in an accessible and cost-effective manner. There are no proposed changes to children's dental benefits, they will remain exempt from the incentive structure required for adult enrollees in the Dental Wellness Plan (DWP), and all enrollees under 21 years of age will continue to be eligible for medically necessary services in accordance with federal early and periodic screening, diagnostic and treatment (EPSDT) requirements.

## III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Laws.** The state must comply with all applicable federal civil rights laws relating to non-discrimination in services and benefits in its programs and activities. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (ACA).

2. **Compliance with Medicaid and CHIP Law, Regulation, and Policy.** All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and written policy not expressly waived or identified as not applicable in the waiver document (of which these terms and conditions are part), apply to the demonstration.

3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is explicitly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes of an operational nature without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.

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

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

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS 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 on non-compliance with these STCs, including, but not limited to, failure by the state to submit required reports and other deliverables in a timely fashion according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

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

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

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

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

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

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

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

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

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

are available.

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

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

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

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

g. Federal Financial Participation (FFP). If the project is terminated or any relevant waivers are suspended by the state, FFP must be limited to normal closeout costs associated with the termination or expiration of the demonstration, including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

**10. Withdrawal of Waiver or Expenditure Authority.** CMS reserves the right to withdraw waivers and/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. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and must 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 authorities, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling participants.

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

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

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

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

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

15. **Common Rule Exemption.** The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program—including public benefit or service programs, procedures for

obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs or procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. The Secretary has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(b)(5).

## IV. POPULATIONS AFFECTED

16. **Waiver of Retroactive Eligibility Population.** The waiver of retroactive eligibility applies to individuals who are eligible for Medicaid under the state plan (including all modified adjusted gross income (MAGI) and Non-MAGI related groups), with certain exceptions described below.

    a. The state assures that it will provide outreach and education about how to apply for and receive Medicaid coverage to the public and to Medicaid providers, particularly those who serve vulnerable populations that may be impacted by the retroactive eligibility waiver and those disenrolled for nonpayment of premiums. The waiver of retroactive eligibility does not apply to pregnant women (and during the 60 day period beginning on the last day of the pregnancy), infants under one year of age, or children under nineteen years of age. The earliest that a retroactive eligibility period for children under age 19 will begin will be January 1, 2020, for an application filed on or after January 1, 2020.
    b. The waiver of retroactive eligibility also does not apply to applicants who are eligible for nursing facility services based on level of care, who had been a resident of a nursing facility in any of the three months prior to an application, and who are otherwise eligible for Medicaid. For individuals exempted from the retroactive eligibility waiver on the basis of nursing facility eligibility, retroactive eligibility would be provided for those particular months in which the applicant was a nursing facility resident.

17. **Iowa Wellness Plan Population.** The Iowa Wellness Plan premium incentive program intended to improve the use of preventive services and encourage health is targeted for individuals who are eligible in the new adult group under the state plan that is described in 1902(a)(10)(A)(i)(VIII) of the Act, and 42 CFR 435.119, and includes those persons up to and including 133 percent of the FPL.

18. **Dental Wellness Plan Population.** The Dental Wellness Plan (DWP) is targeted to all Medicaid populations identified in Table 1 below:

**Table 1: Dental Wellness Plan eligible populations**

| Eligibility Group Name | Social Security Act and CFR Citations | Income Level | Age Requirements |
|---|---|---|---|
| **New Adult Group** | 1902(a)(10)(A)(i)(VIII)<br>42 CFR. 435.119 | 0-133% FPL | |

<table>
<tr><td>Parents and Other Caretaker Relatives</td><td>1902(a)(10)(A)(i)(I)<br>1931(b) and (d) 42 CFR 435.110</td><td><table><tr><th>Household Size</th><th>Monthly Income Limit</th></tr><tr><td>1</td><td>$447</td></tr><tr><td>2</td><td>$716</td></tr><tr><td>3</td><td>$872</td></tr><tr><td>4</td><td>$1,033</td></tr><tr><td>5</td><td>$1,177</td></tr><tr><td>6</td><td>$1,330</td></tr><tr><td>7</td><td>$1,481</td></tr><tr><td>8</td><td>$1,633</td></tr><tr><td>9</td><td>$1,784</td></tr><tr><td>10</td><td>$1,950</td></tr></table></td><td></td></tr>
<tr><td>Transitional Medical Assistance</td><td>408(a)(11)(A)<br>1931(c)(2)<br>1925<br>1902(a)(52)</td><td>First 6 months: N/A<br>Additional 6 months:<br>0-185% FPL</td><td rowspan="9">19 and over</td></tr>
<tr><td>Pregnant Women</td><td>1902(a)(10(A)(i)(III) and (IV)<br>1902(a)(10)(A)(ii)(I), (IV) and (IX)<br>1920<br>43 CFR 435.116</td><td>0-375% FPL</td></tr>
<tr><td>Mandatory Aged, Blind and Disabled Individuals</td><td>42 CFR 435.120 through<br>42 CFR 435.138</td><td>SSI Limit</td></tr>
<tr><td>Optional Eligibility for Individuals who Meet Income & Resource of Cash Assistance Programs</td><td>1902(a)(10)(A)(ii)(I)<br>42 CFR 435.210</td><td>SSI Limit</td></tr>
<tr><td>Optional Eligibility for Individuals who would be Eligible for Cash Assistance if they Were not in Medical Institutions</td><td>1902(a)(10)(A)(ii)(IV)<br>42 CFR 435.211</td><td>SSI FBR</td></tr>
<tr><td>Institutionalized Individuals</td><td>1902(a)(10)(A)(ii)(V)</td><td>300% SSI FBR</td></tr>
<tr><td>Medicaid for Employed People</td><td>1902(a)(10)(A)(ii)(XIII)</td><td>250% FPL</td></tr>
<tr><td>Former Foster Care Children up to Age 26</td><td>1902(a)(10)(A)(i)(IX)<br>42 CFR 435.150</td><td>N/A</td></tr>
<tr><td>Independent Foster Care Adolescents</td><td>1902(a)(10)(A)(ii)(XVII)</td><td>254% FPL</td></tr>
</table>

| | | |
|---|---|---|
| **Reasonable Classifications of Children** | 42 CFR 435.222 | N/A |
| **§1915(c) HCBS Physical Disability** | 1902(a)(10)(A)(ii)(VI)<br>42 CFR 435.217 | 300% SSI FBR |
| **§1915(c) HCBS Health and Disability Waiver** | 1902(a)(10)(A)(ii)(VI)<br>42 CFR 435.217 | 300% SSI FBR |
| **§1915(c) HCBS Elderly Waiver** | 1902(a)(10)(A)(ii)(VI)<br>42 CFR 435.217 | 300% SSI FBR |
| **§1915(c) HCBS Intellectual Disability Waiver** | 1902(a)(10)(A)(ii)(VI)<br>42 CFR 435.217 | 300% SSI FBR |
| **§1915(c) HCBS AIDS Waiver** | 1902(a)(10)(A)(ii)(VI)<br>42 CFR 435.217 | 300% SSI FBR |
| **§1915(c) HCBS Brain Injury Waiver** | 1902(a)(10)(A)(ii)(VI)<br>42 CFR 435.217 | 300% SSI FBR |
| **Breast & Cervical Cancer Treatment Program** | 1902(a)(10)(A)(ii)(XVIII) | N/A |
| **Deemed Newborn Children** | 42 CFR §435.117 | N/A |
| **Infants and Children under Age 19** | 42 CFR §435.118 | Infants under 1: 375% FPL<br>Age 1 -5: 167% FPL<br>Age 6-18: 167% FPL |
| **Children with Adoption Assistance, Foster Care, or Guardianship Care Under Title IV-E** | 42 CFR §435.145<br>1902(a)(10)(A)(i)(I)<br>473(b)(3) | N/A |
| **Children with Non IV-E Adoption Assistance** | 42 CFR §435.277<br>1902(a)(10)(A)(ii)(VIII) | N/A |
| **Family Opportunity Act Children with Disabilities** | 1902(a)(10)(ii)(XIX) | 300% FPL |
| **§1915(c) Children's Mental Health Waiver** | 1902(a)(10)(A)(ii)(VI)<br>42 CFR §435.217 | 300% SSI FBR |

## V. DENTAL DELIVERY SYSTEM

**19. Overview**. The Iowa Wellness Plan will provide dental services through a managed care delivery system known as a Prepaid Ambulatory Health Plan (PAHP).

**20. Managed Care Requirements.** The state must comply with the managed

care regulations published at 42 CFR 438, except as waived herein. Capitation rates shall be developed and certified as actuarially sound, in accordance with 42 CFR 438.4. The certification shall identify historical utilization of services that are the same as outlined in the corresponding Alternative Benefit Plan and used in the rate development process.

21. **Managed Care Contracts.** No FFP is available for activities covered under contracts and/or modifications to existing contracts that are subject to 42 CFR 438 requirements prior to CMS approval of this demonstration authority as well as such contracts and/or contract amendments. The state shall submit any supporting documentation deemed necessary by CMS. The state must provide CMS with a minimum of 60 days to review and approve changes. CMS reserves the right, as a corrective action, to withhold FFP (either partial or full) for the demonstration, until the contract compliance requirement is met.

22. **Public Contracts**. Payments under contracts with public agencies, that are not competitively bid in a process involving multiple bidders, shall not exceed the documented costs incurred in furnishing covered services to eligible individuals (or a reasonable estimate with an adjustment factor no greater than the annual change in the consumer price index).

23. **Managed Care Dental Benefit Package.** Individuals enrolled in the Iowa Wellness Plan will receive from the managed care program the benefits as identified in Section VI of the STCs. Covered dental benefits should be delivered and coordinated in an integrated fashion.

**24. Enrollment Requirements.** The state may require any of the populations identified in Section IV to enroll in PAHPs pursuant to 42 CFR 438.

25. **Network Requirements**. The state must ensure the delivery of all covered dental benefits, including high quality care. Services must be delivered in a culturally competent manner, and the PAHP network must be sufficient to provide access to covered services to the low- income population. The following requirements must be included in the state's PAHP contracts:

    a. **Special Health Care Needs.** Enrollees with special health care needs must have direct access to a specialist, as appropriate for the individual's health care condition, as specified in 42 CFR 438.208(c)(4).

    b. **Out of Network Requirements.** The PAHP must provide demonstration populations with all demonstration program benefits under their contract and as described within these STCs and must allow access to non-network

providers when services cannot be provided consistent with the timeliness standards required by the state.

**26. Demonstrating Network Adequacy**. Annually, the PAHP must provide adequate assurances that it has sufficient capacity to serve the expected enrollment in its service area and offers an adequate range of providers necessary to provide covered services for the anticipated number of enrollees in the service area.

a. The state must verify these assurances by reviewing demographic, utilization and enrollment data for enrollees in the demonstration as well as:
   i. The number and types of dentists and dental specialty providers available to provide covered services to the demonstration population;
   ii. The number of network providers accepting the new demonstration population; and
   iii. The geographic location of providers and demonstration populations, as shown through GeoAccess or similar software.
b. The state must submit the documentation required in subparagraphs i – iii above to CMS with initial PAHP contract submission as well as at each contract renewal or renegotiation, or at any time that there is a significant impact to the PAHP's operation, including service area expansion or reduction and population expansion.

## VI. BENEFITS

**27. Iowa Wellness Plan Benefits.** Individuals in the IWP populations described in STC 17 will receive benefits described in the Iowa Wellness Plan alternative benefit plan (ABP).

**28. Dental Wellness Plan Benefits.**

a. **Benefits in First Year of Enrollment**. Individuals enrolled in the Dental Wellness Plan will receive all available dental benefits described in the state plan or alternative benefit plan, as applicable.

b. **Benefit Requirements After First Year of Enrollment**. Individuals enrolled in the Dental Wellness Plan may continue to receive all benefits described in the state plan or the alternative benefit plan, as applicable, subject to the requirements set forth below.

   i. **Dental Premium.** Beneficiaries will be required to pay a monthly dental premium starting in year 2 of enrollment in the demonstration to maintain full dental benefits, as specified in STC 30.
   ii. **Healthy Behaviors.** Beneficiaries will not be charged a monthly dental premium if they complete state-designated healthy behaviors

in the prior year of enrollment.

iii. **Penalty.** Beneficiaries who do not make a premium payment or complete healthy behaviors will receive basic dental benefits as outlined in the state plan and alternative benefits plan.

iv. **Appeal Rights.** Beneficiaries will be able to challenge any denial in whole or in part, limited authorization of service, termination of a previously authorized service, or failure of a plan to act within the required timeframe as described in Section VII of the STCs.

c. **Dental Appointments.** The state must take action to assist beneficiaries in accessing services if they report to the state, in a timely manner, that they were not able to secure a dental appointment through a PAHP. The state must provide member hotline assistance to individuals seeking dental care who were unable to secure an appointment with a dental provider.

d. **EPSDT.** All beneficiaries under 21 years of age will continue to be eligible for medically necessary dental services in accordance with federal EPSDT requirements.

**29. Non-Emergency Medical Transportation (NEMT).** Individuals in the new adult group shall not receive any benefit in the form of an administrative activity or service to assure non-emergency transportation to and from providers. Medically frail beneficiaries and those eligible for EPSDT services are exempt from this waiver.

## VII. HEALTHY BEHAVIORS, PREMIUMS AND COST SHARING

**30. Iowa Wellness Plan and Dental Wellness Plan Premiums**. The premiums and cost-sharing features of the demonstration are designed to incentivize the uptake of preventive services, which could improve beneficiary health and thereby reduce the costs of providing coverage, thus improving the financial sustainability of Iowa's Medicaid program. The state has the authority to charge premiums in accordance with the CMS approved protocols described in STC 34, which are binding upon the state**.** The state may request changes to the approved protocols; any changes must be accepted by CMS. Any change will require advance notice to members. All modifications to the premium policies must be captured through the immediate next Annual Monitoring Report.

a. No premium will be charged for the first year of enrollment in the Iowa Wellness Plan or the Dental Wellness Plan.

b. All premiums permitted by this paragraph are subject to the exemptions and waivers described in STC 31.

c. Monthly premium amounts for the Iowa Wellness Plan may not exceed $5/month for nonexempt households with income above 50 percent up to and

including 100 percent of the FPL and $10/month for nonexempt households with income over 100 percent up to and including 133 percent of the FPL. Monthly premium amounts for the Dental Wellness Plan may not exceed $3/month for nonexempt households with income above 50 percent of the FPL. Combined premiums and cost-sharing is subject to a quarterly aggregate cap of 5 percent of household income.

d. Enrollees in the Iowa Wellness Plan and the Dental Wellness Plan will be allowed a 90-day premium grace period.

e. Iowa Wellness Plan enrollees with income up to and including 100 percent FPL and all Dental Wellness Plan beneficiaries may not be disenrolled for nonpayment of a premium, nor can an individual be denied an opportunity to re-enroll due to nonpayment of a premium.

f. Individuals with income over 100 percent of the FPL may be disenrolled from the IWP for nonpayment. Persons disenrolled for nonpayment can reapply at any time; however, their outstanding premium payments will remain subject to recovery.

g. After the 90 day grace period, unpaid Iowa Wellness Plan and Dental Wellness Plan premiums may be considered a collectible debt owed to the State of Iowa and, at state option, subject to collection by the state, with the following exception:

h. If, at the member's next annual renewal date, the member does not apply for renewed eligibility, and the member has no claims for services delivered after the month of the last premium payment, unpaid premiums shall not be considered a collectible debt by the state.

i. Enrollees with a premium requirement who complete state-designated healthy behaviors will have their premium waived for the following benefit year.

**31. Premium Exemptions**.

a. **Iowa Wellness Plan**. Enrollees will be exempt from a monthly contribution obligation under the following conditions:

i. For all individuals enrolled in the Iowa Wellness Plan, premiums are waived in the first year of the individual's enrollment. Premiums will continue to be waived in subsequent years if enrollees complete healthy behaviors in their prior annual period, as outlined in the state's approved Healthy Behavior Incentive Protocol.

ii. Premiums may only be assessed on non-exempt individuals as described in 42 CFR 447.56.

iii. Medically frail and members in the HIPP population are not subject to premiums.

iv. All individuals who self-attest to a financial hardship will have no premium obligation. The opportunity to self-attest will be made available with each invoice.

b. **Dental Wellness Plan.** Enrollees will be exempt from a monthly contribution obligation for dental benefits under the following conditions:

i. For all individuals enrolled in the Dental Wellness Plan, premiums are waived in the first year of the individual's enrollment. Premiums will continue to be waived in subsequent years if enrollees complete healthy behaviors in the prior year.

ii. Premiums may only be assessed on non-exempt individuals as described in 42 CFR 447.56.

iii. The following eligibility groups will be exempt from Dental Wellness Plan premiums, and will not have their benefits reduced in their second year of enrollment, notwithstanding any failure to complete state-designated healthy behaviors as described in STC 33 (i) pregnant women; (ii) individuals whose medical assistance for services furnished in an institution is reduced by amounts reflecting available income other than required for personal needs; (iii) 1915(c) waiver enrollees; (iv) individuals receiving hospice care; (v) American Indians/Alaska Natives (AI/AN) who are eligible to receive or have received an item or service furnished by an Indian health care provider or through referral under contract health services; (vi) breast and cervical cancer treatment program enrollees; and (vii) medically frail enrollees (referred to as medically exempt in Iowa) ; (viii) Deemed Newborn Children (ix) Infants and Children under Age 19; (x) Children with Adoption Assistance, Foster Care, or Guardianship Care Under Title IV-E; (xi) Children with Non IV-E Adoption Assistance; (xii) Family Opportunity Act Children with Disabilities; (xiii) §1915(c) Children's Mental Health Waiver; and (ix) 19 and 20 year olds eligible for EPSDT services.

iv. All individuals who self-attest to a financial hardship will have no dental premium obligation. The opportunity to self-attest will be made available with each invoice.

**32. Copayment for non-emergency use of the emergency department.** Individuals in the IWP populations described in STC 17 are subject to premiums in lieu of other cost sharing except that the state may impose a copayment for non-emergency use of the emergency room consistent with its approved state plan and with all federal requirements that are set forth in statute, regulation and policies, including exemptions from cost-sharing set forth in 42 CFR 447.56.

**33. Healthy Behaviors.**

a. **Iowa Wellness Plan.** The state has the authority to implement the Healthy Behaviors component pursuant to the CMS approved protocols described in STC 34. Enrollees who do not complete required healthy behaviors will be required to pay their monthly premiums beginning in the next enrollment year.

i. **General Description.** All individuals subject to premiums who are enrolled in the Iowa Wellness Plan will have premiums waived during the 1st year of enrollment and will be eligible to receive a waiver of monthly premium contributions required in the 2nd year of enrollment if enrollees complete healthy behaviors during the first year. For each subsequent year, nonexempt enrollees will have the opportunity to complete healthy behaviors to continue to waive financial contributions, i.e. healthy behaviors performed in year 2 of enrollment will be permitted to waive premiums for year 3.

ii. **Healthy Behaviors.** The conditions to be met by a nonexempt individual in year 1 of enrollment as a condition for not being liable for monthly contributions in year 2 are completing a health risk assessment and wellness exam (annual exam). A health risk assessment is considered part of the individual's medical record and is afforded all associated privacy and confidentiality protections afforded to such documents by federal and state law, regulations, and policy. The state must provide outreach and education to beneficiaries to inform them of the incentives that can be used to avoid premiums and the consequences of nonpayment of those premiums if due.

iii. **Grace Period.** Nonexempt individuals will be given a 30-day healthy behavior grace period. If the individual completes the required healthy behaviors in the first 30 days of a year when premiums are due, no premiums will be due for the remainder of the year.

b. **Dental Wellness Plan.** Members who complete dental healthy behaviors each year of enrollment will continue to receive full dental benefits without ever being subject to monthly dental premiums.

i. General Description. All individuals in the Dental Wellness Plan who are subject to premiums will have premiums waived in year 1 of enrollment and will be eligible to receive a waiver of monthly premium contributions required in year 2 of enrollment to maintain full dental benefits if enrollees complete dental healthy behaviors during year 1 of enrollment. For each subsequent year, nonexempt enrollees will have the opportunity to complete dental healthy

behaviors to continue to waive financial contributions (e.g. healthy behaviors performed in year 2 will be permitted to waive premiums for year 3).

ii. Healthy behaviors. The conditions to be met by a nonexempt individual in year 1 of enrollment as a condition of maintaining full dental benefits without liability for monthly premium contributions in year 2 are completing an oral health risk assessment and preventive dental service. The state must provide outreach and education to beneficiaries to inform them of the incentives that can be used to avoid premiums and the consequences of nonpayment of those premiums if due. Additionally, any future changes to state-designated healthy behaviors will be thoroughly communicated to enrollees in order to provide thorough opportunity for enrollees to maintain full dental benefits without liability for monthly contributions. Self-assessments submitted are considered part of the individual's medical record and afforded all associated privacy and confidentiality protections afforded to such documents by federal and state law, regulations, and policy.

**34. Iowa Wellness Plan Healthy Behaviors and Premiums Protocols.** The state has the authority to implement the Healthy Behaviors and Premiums component in accordance with the CMS approved protocol, which is binding upon the state**.** The state may request changes to the approved Healthy Behaviors and Premiums Protocols; any changes must be accepted by CMS. Any change will require advance notice to members. All modifications to the Healthy Behaviors and Premiums Protocols must be captured through the immediate next Annual Monitoring Report.

The state's approved Healthy Behaviors and Premiums Protocols detail**:**

a. The purpose and objectives of the Healthy Behaviors Incentive program.
b. The methodology for obtaining, and content of, the health risk assessment used to identify unhealthy behaviors such as alcohol abuse, substance use disorders, tobacco use, obesity, and deficiencies in immunization status.
c. The criteria to be met for completing a wellness exam.
d. The process by which an enrollee is deemed compliant with healthy behaviors in year 1.
e. A list of stakeholders consulted in the development of the protocol.
f. A description of how healthy behaviors will be tracked and monitored at the enrollee and provider levels, including standards of accountability for providers.
g. A description of how the state will notify and educate enrollees about the Healthy Behaviors Incentives program.

In addition, the approved protocol delineates:

a. The process by which the state will identify individuals who are exempt from the premium requirements.
b. The notices beneficiaries will receive regarding premiums and/or Healthy Behaviors and the schedule for such notices.
c. The process by which beneficiaries will be able to remit payment, including ways individuals who cannot pay by check will be accommodated.
d. The process by which the state will collect past due premiums.
e. The approved protocol also describes criteria by which the state will monitor premiums and thresholds for modification and/or termination of premium collection in the event of unintended harm to beneficiaries.
f. The state's approved Future Year Healthy Behaviors Incentives Protocol describes the following Healthy Behaviors Incentive Program standards:
    i. A description of any provisions that will be provided to assist enrollees in addressing unhealthy behaviors identified through the health risk assessment.
    ii. A description of selected healthy behaviors to be met by an individual in year 1 (or subsequent years) in order to be deemed compliant with healthy behaviors resulting in a waiver of monthly contributions in year 2 (or subsequent years).

Iowa will further evaluate, define and refine healthy behavior requirements for subsequent years of the demonstration. Iowa must obtain CMS approval before the state can introduce new requirements to enrollees.

## VIII. APPEALS

**35.** Beneficiary safeguards of appeal rights will be provided by the state, including fair hearing rights. No waiver will be granted related to appeals. The state must ensure compliance with all federal and state requirements related to beneficiary appeal rights. Pursuant to the Intergovernmental Cooperation Act of 1968, the state may submit a State Plan Amendment delegating certain responsibilities to the Iowa Insurance Division or another state agency. Dental services appeals are governed by the contract between the state and the dental Prepaid Ambulatory Health Plans (PAHPs).

## IX. GENERAL REPORTING REQUIREMENTS

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

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

a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).

b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action as an interim step before applying the deferral, if corrective action is proposed in the state's written extension request.

c. If CMS agrees to an interim corrective process in accordance with subsection (b), and the state fails to comply with the corrective action steps or still fails to submit the overdue deliverable(s) that meets the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.

d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement for submitting deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the standards outlined in these STCs, the deferral(s) will be released.

e. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

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

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

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

**39. Implementation Plan.** The state must submit an Implementation Plan to CMS no later than 90 calendar days after the effective date of the demonstration. The Implementation Plan must cover at least the key policies being tested under this demonstration, including premiums and the waiver of retroactive eligibility. The state must include premiums in the implementation plan only to the extent it needs to provide information in addition to the information already included in the approved Healthy Behaviors and Premiums Protocols. Once determined complete by CMS, the Implementation Plan will be incorporated into the STCs, as Attachment B. At a minimum, the Implementation Plan must include definitions and parameters of key policies, and describe the state's strategic approach to implementing the policies, including timelines for meeting milestones associated with these key policies. Other topics to be discussed in the Implementation Plan include application assistance, reporting, and processing; notices; coordinated agency responsibilities; coordination with other insurance affordability programs; appeals; renewals; coordination with other state agencies; beneficiary protections; and outreach.

**40. Monitoring Protocol.** The state must submit to CMS a Monitoring Protocol no later than 150 calendar days after the effective date of the demonstration. Once approved, the Monitoring Protocol will be incorporated into the STCs, as Attachment C.

At a minimum, the Monitoring Protocol will affirm the state's commitment to conduct quarterly and annual monitoring in accordance with CMS' template. Any proposed deviations from CMS' template should be documented in the Monitoring Protocol. The Monitoring Protocol will describe the quantitative and qualitative elements on which the state will report through quarterly and annual monitoring reports. For quantitative metrics (e.g., performance metrics as described in STC 41b below), CMS will provide the state with a set of required metrics, and technical specifications for data collection and analysis covering the key policies being tested under this demonstration, including but not limited to premiums, incentives for healthy behaviors, and waiver of retroactive eligibility. The state is also expected to describe its plans for capturing data and information pertaining to the NEMT waiver policy, including but not limited to data and other information about beneficiary understanding of and experience with transportation in accessing covered services, particularly services that beneficiaries must obtain to avoid premiums. The Monitoring Protocol will specify the methods of data collection and timeframes for reporting on the state's progress as part of the quarterly and annual monitoring reports. For the qualitative elements (e.g., operational updates as described in STC 41a below), CMS will provide the state

with guidance on narrative and descriptive information which will supplement the quantitative metrics on key aspects of the demonstration policies. The quantitative and qualitative elements will comprise the state's quarterly and annual monitoring reports.

41. **Monitoring Reports.** The state must submit three (3) Quarterly Reports and one (1) Annual Report each DY. The fourth quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual Report. The Quarterly Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The Annual Report (including the fourth-quarter information) is due no later than ninety (90) calendar days following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.
    a. Operational Updates - Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

    Performance Metrics - Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration goals for the following key policies under this demonstration, including premiums, incentives for healthy behaviors, and the waiver of retroactive eligibility. For premiums, this will also include metrics related to premium payment/non-payment, such as individuals subject to premium requirements, individuals whose premiums have been waived due to compliance with healthy behaviors, individuals exempt due to hardship, individuals with overdue premiums, information about the state's collection activities, and individuals over 100 percent up to and including 133 percent of the FPL who are disenrolled due to premium non-payment. The state will report applicable monitoring metrics to cover the waiver of retroactive eligibility policy, including "unpaid medical bills", using information found on the beneficiary

enrollment application.

The required monitoring and performance metrics must be included in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

The state is also expected to provide information regarding the NEMT waiver about beneficiary understanding of and experience with transportation in accessing covered services, particularly services that beneficiaries must obtain to avoid premiums. In addition, the state must provide metrics pertaining to access to care generally.

b. Financial Reporting Requirements - Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs for this demonstration should be reported separately on the CMS-64.

c. Evaluation Activities and Interim Findings - Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.

**42. Corrective Action Plan Related to Monitoring.** If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where monitoring data indicate substantial sustained directional change, inconsistent with state targets (such as substantial, sustained trends indicating increases in disenrollment, difficulty accessing services, or unpaid medical bills). A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS will withdraw an authority, as described in STC 10, when metrics indicate substantial, sustained directional change, inconsistent with state targets, and the state has not implemented corrective action. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

**43. Close Out Report**. Within 120 calendar days after the expiration of the demonstration, the state must submit a draft Close-Out Report to CMS for comments.

a. The draft report must comply with the most current guidance from CMS.
b. The state will present to and participate in a discussion with CMS on the Close-Out Report.
c. The state must take into consideration CMS' comments for incorporation into the final Close-Out Report.

d. The final Close-Out Report is due to CMS no later than thirty (30) calendar days after receipt of CMS' comments.
e. A delay in submitting the draft or final version of the Close-Out Report may subject the state to penalties described in STC 36.

## X. MONITORING CALLS AND DISCUSSIONS

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

**45. Post Award Forum.** Pursuant to 42 CFR 431.420(c), One year from the last post award forum the state shall afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least thirty (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 must also post the most recent annual report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Report.

## XI. EVALUATION OF THE DEMONSTRATION

**46. Cooperation with Federal Evaluators.** As required under 42 CFR 431.420(f), the state shall cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to: commenting on design and other federal evaluation documents; providing data and analytic files to CMS; entering into a data use agreement that explains how the data and data files will be exchanged; and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state shall include in its contracts with entities that collect, produce or maintain data and files for the demonstration, that they make data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 36.

**47. Independent Evaluator.** Upon approval of the demonstration, the state must arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to study the

effectiveness of the demonstration, as will be delineated in the approved evaluation design (see STC 48). The state must require the independent party to sign an agreement that the independent party will conduct the demonstration evaluation in an independent manner in accordance with the CMS-approved Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

**48. Draft Evaluation Design.** The state must submit, for CMS comment and approval, a draft Evaluation Design, no later than 180 calendar days after the effective date of the demonstration.

Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The draft Evaluation Design must be developed in accordance with the following CMS guidance (including but not limited to):

a. Attachment D (Developing the Evaluation Design) of these STCs.
b. All applicable evaluation design guidance, including guidance on premiums and waivers of retroactive eligibility.
c. Any applicable CMS technical assistance on applying robust evaluation approaches, including establishing appropriate comparison groups and assuring causal inferences in demonstration evaluations.

**49. Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an Attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the Monitoring Reports. Once CMS approves the evaluation design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

**50. Evaluation Questions and Hypotheses.** Consistent with Attachments D and E (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. The evaluation must outline and address well-crafted hypotheses and research questions for all key demonstration policy components covering applicable demonstration populations that support understanding the demonstration's impact and its effectiveness in achieving the goals. The evaluation must assess the impact of the demonstration on beneficiary coverage, access to and quality of care, and health outcomes. Each demonstration component should have at least one evaluation question and hypothesis. In addition, CMS's expectations for evaluating waivers pertaining to premiums, NEMT and retroactive eligibility, and for other eligibility and coverage policies, are more extensive as

follows. Hypotheses for healthy behavior incentives and premiums must relate to (but are not limited to) the following areas: beneficiary understanding of and experience with premiums as an incentive, the interface between incentives to seek out preventive care and premiums, and consequences of these demonstration policies, including non-compliance with premiums and healthy behavior requirements, on coverage (including employer-sponsored health insurance and no coverage for those who separate from the demonstration) and health outcomes. Hypotheses for the waiver of retroactive eligibility must relate to (but are not limited to) the following outcomes: likelihood of enrollment and enrollment continuity; likelihood that beneficiaries will apply for Medicaid when they believe they meet the criteria for Medicaid; enrollment when people are healthy, or as soon as possible after meeting eligibility criteria; and health status (as a result of greater enrollment continuity). Hypotheses to evaluate the NEMT waiver policy must include (but are not limited to): effects on access to covered services, including access to the services that beneficiaries must obtain to avoid premiums. The state must also investigate cost outcomes for the demonstration as a whole, including but not limited to: administrative costs of demonstration implementation and operation, Medicaid health service expenditures, and provider uncompensated costs. In addition, the state must use results of hypothesis tests and cost analyses to assess demonstration effects on Medicaid program sustainability.

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

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

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

expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.

c. If the state is seeking to extend the demonstration, the draft Interim Evaluation Report is due when the application for extension is submitted. If the state would make changes to the demonstration in its application for extension, the report should include how the evaluation design would be adapted to accommodate the proposed policy changes. If the state is not requesting an extension for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration (i.e., by December 31, 2023). For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
d. The state must submit the revised Interim Evaluation Report sixty (60) calendar days after receiving CMS's comments on the draft Interim Evaluation Report Once approved by CMS, the state must post the final Interim Evaluation Report to the state's website within thirty (30) calendar days of approval by CMS.
e. The Interim Evaluation Report must comply with Attachment E (Preparing the Evaluation Report) of these STCs.

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

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

**54. Corrective Action Plan Related to Evaluation**. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. A state corrective action plan could include a temporary suspension of implementation of demonstration programs, in circumstances where evaluation findings indicate substantial, sustained directional change inconsistent with state targets (such as substantial, sustained trends indicating increases in disenrollment, difficulty accessing services or unpaid medical bills). A corrective action plan may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10. CMS would further have the ability to suspend implementation of the demonstration should corrective actions not effectively resolve these concerns in a timely manner.

**55. State Presentations for CMS**. CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the interim evaluation, and/or the summative evaluation.

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

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

**58. Schedule of Demonstration Period Deliverables**

| **Schedule of Deliverables for the Demonstration Period** | | |
|---|---|---|
| **Date** | **Deliverable** | **STC** |
| 30 calendar days after approval date- | State acceptance of demonstration Waivers, STCs, and Expenditure Authorities | Approval letter |
| 90 calendar days after the effective date-<br>**March 31, 2020** | Implementation Plan | STC 39 |
| 150 calendar days effective date-<br>**May 30, 2020** | Monitoring Protocol | STC 40 |
| 180 calendar days after effective date-<br>**June 29, 2020.** | Draft Evaluation Design | STC 48 |
| 60 days after receipt of CMS comments | Revised Draft Evaluation Design | STC 49 |
| 30 calendar days after CMS Approval | Approved Evaluation Design published to state's website | STC 49 |
| With extension application or by | Draft Interim Evaluation Report | STC 52 c |

| | | |
|---|---|---|
| **December 31, 2023**, whichever is earlier | | |
| 60 days after receipt of CMS comments | Revised Interim Evaluation Report | STC 52 d |
| Within 18 months after **December 31, 2024** | Draft Summative Evaluation Report | STC 53 |
| 60 calendar days after receipt of CMS comments | Revised Summative Evaluation Report | STC 53 |
| Monthly Deliverables | Monitoring Call | STC 44 |
| Quarterly monitoring reports due 60 calendar days after end of each quarter, except 4th quarter | Quarterly Monitoring Reports<br>(Dates for 1st year only)<br>1st Report Due - May 30, 2020<br>2nd Report Due - August 29, 2020<br>3rd Report Due - November 29, 2020 | STC 41 |
| Annual Deliverables - (90) calendar days following the end of the DY (4th quarter) | Annual Monitoring Reports<br>(Date for 1st year only)<br>1st Report Due- March 31, 2021 | STC 41 |

**Attachment A**
**Healthy Behaviors and Premiums Protocols**

**Attachment B**
**Implementation Plan**

**Attachment C**
**Monitoring Protocol**

**Attachment D**
**Developing the Evaluation Design**

## Introduction

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

## Expectations for Evaluation Designs

CMS expects Evaluation Designs to be rigorous, incorporate baseline and comparison group assessments, as well as statistical significance testing. Technical assistance resources for constructing comparison groups and identifying causal inferences are available on Medicaid.gov: https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html. If the state needs technical assistance using this outline or developing the Evaluation Design, the state should contact its demonstration team.

All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

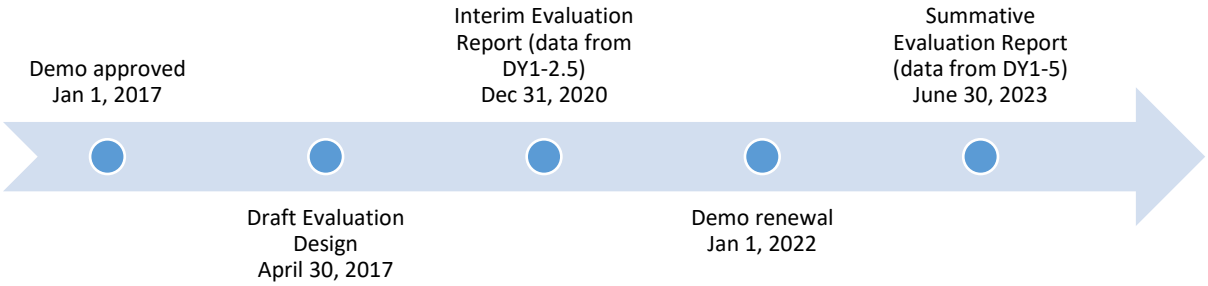
The format for the Evaluation Design is as follows:

A. General Background Information;
B. Evaluation Questions and Hypotheses;
C. Methodology;
D. Methodological Limitations; and
E. Attachments.

## Submission Timelines

There is a specified timeline for the state's submission of Evaluation Design and Reports. (The graphic below depicts an example of this timeline for a 5-year demonstration period). In addition, the state should be aware that section 1115 evaluation documents are public

records. The state is required to publish the Evaluation Design to the state's website within thirty (30) days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.




**Required Core Components of All Evaluation Designs**

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

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

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

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

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

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

5) A description of the population groups impacted by the demonstration.

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

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

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

3) Identify the state's hypotheses about the outcomes of the demonstration:
   a. Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
   b. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

**C. Methodology –** In this section, the state is to describe in detail the proposed research methodology. The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

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

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

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

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

4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:
    a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
    b. Qualitative analysis methods may be used, and must be described in detail.
    c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
    d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
    e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
    f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

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

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

6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:
    a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.
    b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
    c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
    d. The application of sensitivity analyses, as appropriate, should be considered.

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

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

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

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

CMS recognizes that there may be certain instances where a state cannot meet the rigor of an evaluation as expected by CMS. In these instances, the state should document for CMS why it is not able to incorporate key components of a rigorous evaluation, including comparison groups and baseline data analyses. Examples of considerations include when the demonstration is considered successful without issues or concerns that would require more regular reporting, such as:

a. The demonstration is operating smoothly without administrative changes; and
b. There are no or minimal appeals and grievances; and

c. There are no state issues with CMS 64 reporting or budget neutrality; and
d. There are no Corrective Action Plans (CAP) for the demonstration.

## E. Attachments

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

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

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

## Attachment E
## Preparing the Evaluation Report

### Introduction

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

### Expectations for Evaluation Reports

All states with Medicaid section 1115 demonstrations are required to conduct evaluations that are valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. With the following kind of information, states and CMS are best poised to inform and shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

When submitting an application for renewal, the Interim Evaluation Report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

### Intent of this Attachment

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

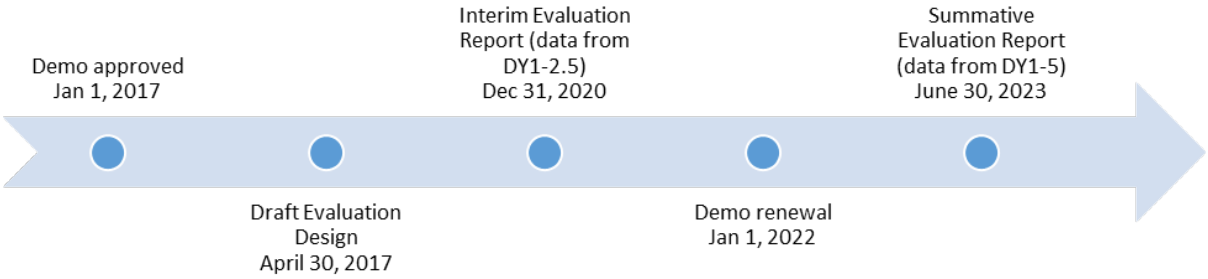
The format for the Interim and Summative Evaluation reports is as follows:

A. Executive Summary;
B. General Background Information;

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

**Submission Timelines**

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline for a 5-year demonstration). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish the evaluation design and reports to the state's website within thirty (30) days of CMS approval, as per 42 CFR 431.424(d). CMS will also publish a copy to the Medicaid.gov website.




**Required Core Components of Interim and Summative Evaluation Reports**

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

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

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

1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
5) A description of the population groups impacted by the demonstration.

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

1) Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.
2) Identify the state's hypotheses about the outcomes of the demonstration;
    a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
    b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
    c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

**D. Methodology** – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design. The evaluation Design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

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

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

1) *Evaluation Design*—Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?

2) *Target and Comparison Populations*—Describe the target and comparison populations; include inclusion and exclusion criteria.

3) *Evaluation Period*—Describe the time periods for which data will be collected.

4) *Evaluation Measures*—What measures are used to evaluate the demonstration, and who are the measure stewards?

5) *Data Sources*—Explain where the data will be obtained, and efforts to validate and clean the data.

6) *Analytic methods*—Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).

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

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

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

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

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

2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:
    a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

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

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

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

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

**J. Attachment**

1) Evaluation Design: Provide the CMS-approved Evaluation Design