CENTERS FOR MEDICARE AND MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: **11-W-00289/5**

TITLE: **Iowa Health and Wellness Plan**

AWARDEE: **Iowa Department of Human Services**

I. PREFACE

The following are the Special Terms and Conditions (STCs) for the Iowa Health and Wellness Plan section 1115(a) Medicaid demonstration (hereinafter "demonstration") to enable Iowa to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted a waiver of a requirement 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 population began on October 1, 2013 for the Iowa Health and Wellness Plan with eligibility effective January 1, 2014. The demonstration will be statewide and is approved through December 31, 2016.

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. Benefits
VI. Evaluation
VII. Monitoring

II. PROGRAM DESCRIPTION AND OBJECTIVES

Under the approved Health and Wellness Plan demonstration, for the new adult population that is eligible under the state plan group described in section 1902(a)(10)(A)(i)(VIII) and is not affected by the Marketplace Choice Plan demonstration, the state will be relieved of its responsibility to assure non-emergency transportation to and from providers for a one year period. Through this demonstration, the state will test and evaluate the effect of this change in state responsibilities on beneficiary access and utilization of services, and overall health status.
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III. GENERAL PROGRAM REQUIREMENTS

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

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

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

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**

   a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as well as a modified allotment neutrality worksheet for the demonstration as necessary to comply with such change. The modified budget neutrality agreement will be effective upon the implementation of the change.

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

5. **State Plan Amendments.** The state will not be required to submit Title XIX or XXI state plan amendments 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 may be required, except as otherwise noted in these STCs. In all such instances the Medicaid state plan governs.

   Should the state amend the state plan to make any changes to eligibility for any population affected by the demonstration, upon submission of the state plan amendment, the state must notify CMS for demonstration staff in writing of the pending state plan amendment, and request any necessary corresponding technical corrections to the demonstration.

6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, enrollee rights, delivery systems, cost sharing, evaluation design, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject

to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and FFP will not be available for changes to the demonstration that have not been approved through the amendment process set forth in STC **7** below.

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 herein. 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 15, prior to submission of the requested amendment;

b. A data analysis worksheet which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include 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 detail 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;

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

d. A detailed description of the amendment including impact on beneficiaries, with sufficient supporting documentation and data supporting the evaluation hypotheses as detailed in the evaluation design in STC 23; and

e. If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.

8. Extension of the Demonstration. States that intend to request demonstration extensions under sections 1115(e) or 1115(f) are advised to observe the timelines contained in those statutes. Otherwise, no later than 12 months prior to the expiration date of the demonstration, the governor or chief executive officer of the State must submit to CMS either a demonstration extension request or a transition and phase-out plan consistent with the requirements of STC 9.

a. Compliance with Transparency Requirements at 42 CFR §431.412.

b. As part of the demonstration extension requests the State must provide documentation of compliance with the transparency requirements 42 CFR §431.412 and the public notice and tribal consultation requirements outlined in STC 15.

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

a. Notification of Suspension or Termination: The State must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The State must submit its notification letter and a draft plan to CMS no less than six (6) months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft plan to CMS, the State must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In addition, the State must conduct tribal consultation in accordance with its approved tribal consultation State Plan Amendment. Once the 30-day public comment period has ended, the State must provide a summary of each public comment received the State's response to the comment and how the State incorporated the received comment into the revised plan.

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

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

d. Phase-out Procedures: The State must comply with all notice requirements found in 42 CFR §431.206, §431.210, and §431.213. In addition, the State must assure all appeal and hearing rights afforded to demonstration participants as outlined in 42 CFR §431.220 and §431.221. If a demonstration participant requests a hearing before the date of action, the State must maintain benefits as required in 42 CFR §431.230. In addition, the State must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category. 42 CFR §435.916.

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

10. Post Award Forum. Within six months of the demonstration's implementation, and annually thereafter, the State will afford the public with an opportunity to provide meaningful comment

on the progress of the demonstration. At least 30 days prior to the date of the planned public forum, the State must publish the date, time and location of the forum in a prominent location on its website. The State can either use its Medical Care Advisory Committee, or another meeting that is open to the public and where an interested party can learn about the progress of the demonstration to meet the requirements of this STC. The State must include a summary of the comments in the quarterly report associated with the quarter in which the forum was held. The State must also include the summary in its annual report.

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

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

    a. Expiration Requirements: The state must include, at a minimum, in its demonstration expiration plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility for the affected beneficiaries, and ensure ongoing coverage for eligible individuals, as well as any community outreach activities.

    b. Expiration Procedures: The state must comply with all notice requirements found in 42 CFR Sections 431.206, 431.210 and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration participants as outlined in 42 CFR Sections 431.220 and 431.221. If a demonstration participant requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR Section 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category as discussed in October 1, 2010, State Health Official Letter #10-008.

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

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

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

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

15. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the State Notice Procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994). The state must also comply with the tribal consultation requirements in section 1902(a)(73) of the Act as amended by section 5006(e) of the American Recovery and Reinvestment Act (ARRA) of 2009, the implementing regulations for the Review and Approval Process for Section 1115 demonstrations at 42 CFR Section 431.408, and the tribal consultation requirements contained in the state's approved state plan, when any program changes to the demonstration are proposed by the state.

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

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

    c. The state must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

16. **Federal Financial Participation (FFP).** No federal matching for administrative or service expenditures for this demonstration will take effect until the effective date identified in the demonstration approval letter.

IV. POPULATIONS AFFECTED

17. Iowa Wellness Plan Population.

The Iowa Health and Wellness Plan is targeted for 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, who are not affected by the Marketplace Choice Plans demonstration, and who receive the ABP that is the Iowa Wellness plan.

V. BENEFITS

18. Iowa Health and Wellness Plan Benefits. Individuals affected by this demonstration will receive benefits described in the State's alternative benefit plan for the new adult group as set forth in the State ABP State plan.

19. Non-Emergency Medical Transportation (NEMT). The Iowa Wellness Plan will not benefit from any administrative activity or service to assure non-emergency transportation to and from providers. This waiver authority will sunset after one year, to allow for reevaluation of this authority to allow for the state and CMS to consider the impact on access to care.

20. Healthy Behaviors Incentives Standards. The Health and Wellness Plan program will promote healthy behaviors through education and engagement of beneficiaries and providers, and includes an incentive component that is intended to promote healthy behaviors. By March 31, 2014, the state shall submit for approval a protocol related to Healthy Behavior Incentives, including

i) The purpose and objectives of the Healthy Behaviors Incentive program.

ii) The methodology for obtaining, and criteria for, healthy behaviors to be met in order for incentives to be provided.

iii) The process by which an enrollee is deemed to have met healthy behaviors.

iv) The positive incentives that could be used for other health-related purposes, and the amount of positive incentives that can be earned on an annual basis.

v) A list of stakeholders utilized in the development of the protocol.

vi) A description of how healthy behaviors will be tracked and monitored at the enrollee and provider levels, including standards of accountability for providers.

vii) A description of how the state will notify and educate enrollees about the Healthy Behaviors Incentives program.

VI. EVALUATION

21. Submission of Draft Evaluation Design. The state shall submit a draft evaluation design to CMS no later than 60 days after the award of the demonstration. CMS shall provide comment within 30 days of receipt from the state.

22. Submission of Final Evaluation Design. The state shall provide the Final Evaluation Design within 30 days of receipt of CMS comments of the Draft Evaluation Design. If CMS finds that the Final Evaluation Design adequately accommodates its comments, then CMS will approve the Final Evaluation Design within 30 days.

23. Evaluation Requirements. The State shall engage the public in the development of its evaluation design. The evaluation design shall incorporate a final evaluation and will discuss the following requirements as they pertain to each:

a. The scientific rigor of the analysis;
b. A discussion of the goals, objectives and specific hypotheses that are to be tested;
c. Specific performance and outcomes measures used to evaluate the demonstration's impact;
d. Data strategy including sources of data, sampling methodology, and how data will be obtained;
e. The unique contributions and interactions of other initiatives; and
f. How the evaluation and reporting will develop and be maintained.

The demonstration evaluation will meet the prevailing standards of scientific and academic rigor, as appropriate and feasible for each aspect of the evaluation, including standards for the evaluation design, conduct, interpretation and reporting of findings. The demonstration evaluation will use the best available data; use controls and adjustments for and reporting of the limitations of data and their effects on results; and discuss the generalizability of results.

The State shall acquire an independent entity to conduct the evaluation. The evaluation design shall discuss the State's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications the entity must possess, how the State will assure no conflict of interest, and a budget for evaluation activities.

24. Evaluation Design. The Evaluation Design shall include the following core components to be approved by CMS:

a. Research questions and hypotheses: This includes a statement of the specific research questions and testable hypotheses that address the goals of the demonstration. At a minimum, the research questions shall address the goals of improving access, improving quality of care thereby leading to enhanced health outcomes, and lowering costs. The research questions will be examined using appropriate comparison groups and studied in a time series.

   The following are among the hypotheses to be considered in development of the evaluation design and will be included in the design as appropriate:

   i. Not assuring non-emergency transportation has no impact on healthy behaviors and does not pose a barrier to access to care.
   ii. Health and Wellness enrollees will use preventative care services at a greater rate.

iii. Health and Wellness beneficiaries will have satisfactory access and experience without a non-emergency transportation benefit.
iv. Additional types of payments above the regular fee-for-service payment for Primary Care Physicians (PCPs) incentive wellness activities in Health and Wellness enrollees will increase preventative services at a greater rate.

b. Study Design: The design will consider through its research questions and analysis plan the appropriate application of the following dimensions of access and quality including consumer satisfaction and other indicators of consumer experience.

c. The design will include a description of the quantitative and qualitative study design (e.g., cohort, controlled before-and-after studies, interrupted time series, case-control, etc.), including a rationale for the design selected. The discussion will include a proposed baseline and approach to comparison; examples to be considered as appropriate include the definition of control and/or comparison groups or within-subjects design, use of propensity score matching and difference in differences design to adjust for differences in comparison populations over time. The discussion will include approach to benchmarking, and should consider applicability of national and state standards. The application of sensitivity analyses as appropriate shall be considered.

d. Study Population: This includes a clear description of the populations impacted by each hypothesis, as well as the comparison population, if applicable. The discussion may include the sampling methodology for the selected population, as well as support that a statistically reliable sample size is available.

e. Access, Service Delivery Improvement, Health Outcome, Satisfaction and Cost Measures: This includes identification, for each hypothesis, of quantitative and/or qualitative process and/or outcome measures that adequately assess the effectiveness of the demonstration. Nationally recognized measures should be used where appropriate. Measures will be clearly stated and described, with the numerator and dominator clearly defined. To the extent possible, the State will incorporate comparisons to national data and/or measure sets. A broad set of performance metrics will be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation, for meaningful use under HIT, and from the Medicaid Core Adult sets. 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.

f. Data Collection: This discussion shall include a description of the data sources; the frequency and timing of data collection; and the method of data collection. The following shall be considered and included as appropriate:
i. Medicaid encounter and claims data,
ii. Enrollment data,
iii. Provider Network data,
iv. Consumer and provider surveys, and
v. Other data needed to support performance measurement relative to access and quality metrics.

g. Assurances Needed to Obtain Data: The design report will discuss the State's arrangements to assure needed data to support the evaluation design are available including from health plans.

h. Data Analysis: This includes a detailed discussion of the method of data evaluation, including appropriate statistical methods that will allow for the effects of the demonstration to be isolated from other initiatives occurring in the State. The level of analysis may be at the beneficiary, provider, and program level, as appropriate, and shall include population stratifications, for further depth. Sensitivity analyses shall be used when appropriate. Qualitative analysis methods shall also be described, if applicable.

i. Timeline: This includes a timeline for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables.

j. 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; how the state will assure no conflict of interest, and a budget for evaluation activities.

25. Public Access. The State shall post the final approved Evaluation Design on the State Medicaid website within 30 days of approval by CMS.

26. Electronic Submission of Reports. The State shall submit all required plans and reports using the process stipulated by CMS, if applicable.

27. Cooperation with Federal Evaluators. Should CMS undertake an evaluation of the demonstration or any component of the demonstration, the State shall cooperate fully with CMS and its contractors. This includes, but is not limited to, submitting any required data to CMS or the contractor in a timely manner and at no cost to CMS or the contractor.

28. Cooperation with Federal Learning Collaboration Efforts. The State will cooperate with improvement and learning collaboration efforts by CMS.

29. Evaluation Budget. A budget for the evaluation shall be provided with the 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 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 design or if CMS finds that the design is not sufficiently developed.

30. Final Evaluation and Implementation. The State must implement the evaluation design, and submit to CMS a draft of the evaluation 120 days after the expiration of the demonstration. CMS shall provide comments within 60 days of receipt of the draft

evaluation. Within 60 days of receipt of comments from CMS, a revised final report must be submitted.

31. Deferral for Failure to Provide Final Evaluation Reports on Time. The State agrees that when Final Evaluation Reports are due, CMS may issue deferrals in the amount of $5,000,000 if they are not submitted on time to CMS or are found by CMS not to be consistent with the evaluation design as approved by CMS.

XIV. MONITORING

32. Evaluation Monitoring Protocol. The State shall submit for CMS approval a draft monitoring protocol no later than 60 days after the award of the demonstration. The protocol is subject to CMS approval. CMS shall provide comment within 30 days of receipt from the State. The State shall provide the final protocol within 30 days of receipt of CMS comments. If CMS finds that the final protocol adequately accommodates its comments, then CMS will approve the final protocol within 30 days.

a. The monitoring protocol, including metrics and network characteristics shall align with the CMS approved evaluation design.

b. The State shall make the necessary arrangements to assure that the data needed from the health plans, and data needed from other sources, are available as required by the CMS approved monitoring protocol.

c. The monitoring protocol and reports shall be posted on the State Medicaid website within 30 days of CMS approval.

33. Quarterly Evaluation Operations Report. The State will provide quarterly reports to CMS. The reports shall provide sufficient information for CMS to understand implementation progress of the demonstration and whether there has been progress toward the goals of the demonstration The reports will document key operational and other challenges, to what they attribute the challenges and how the challenges are being addressed, as well as key achievements and to what conditions and efforts they attribute the successes.

34. Rapid Cycle Assessments. The State shall specify for CMS approval a set of performance and outcome metrics, including their specifications, reporting cycles, level of reporting (e.g., the State, health plan and provider level, and segmentation by population) to support rapid cycle assessment in trends under the Health and Wellness Plan, and for monitoring and evaluation of the demonstration.