

benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major regulatory actions with economically significant effects (\$100 million or more in any 1 year). This document will prevent the enrollment of new home health providers and Part B non-emergency ground ambulance suppliers in Medicare, Medicaid, and CHIP in certain states. Though savings may accrue by denying enrollments, the monetary amount cannot be quantified. Since the imposition of the initial moratoria on July 31, 2013, 1,147 HHAs and 19 ambulance companies in all geographic areas affected by the moratoria had their applications denied. We have found the number of applications that are denied after 60 days declines dramatically, as most providers and suppliers will not submit applications during the moratoria period. Therefore, this document does not reach the economic threshold, and thus is not considered a major action.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any one year. Individuals and states are not included in the definition of a small entity. CMS is not preparing an analysis for the RFA because it has determined, and the Secretary certifies, that this document will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if an action may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, CMS defines a small rural hospital as a hospital that is located outside of a metropolitan statistical area (MSA) for Medicare payment purposes and has fewer than 100 beds. CMS is not preparing an analysis for section 1102(b) of the Act because it has determined, and the Secretary certifies, that this document will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any regulatory action whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately \$146 million. This document will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed regulatory action (and subsequent final action) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Because this document does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this document was reviewed by the Office of Management and Budget.

Dated: December 28, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Request for Information

AGENCY: Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Request for information (RFI).

SUMMARY: This Request for Information (RFI) seeks recommendations for future work with and on behalf of American Indian and Alaska Native (AI/AN) leadership, tribes, tribal organizations, and populations in accord with ACF's vision of "children, youth, families, individuals, and communities who are resilient, safe, healthy, and economically secure."

DATES: Submit responses by March 10, 2017.

ADDRESSES: Written comments may be submitted through any of the methods specified below. However, electronic submission is preferred. Please do not submit duplicate comments.

■ **Electronic submission** through <https://www.regulations.gov> portal. Follow the instructions for submitting electronic comments. Attachments, if any, should be in Microsoft Word or Microsoft Excel. You can find this RFI by typing ACF-2016-0002 in the Search window. Then click on the "Comment Now!" button on the Search Results page. This will open up a Comment form where you can enter your comment on the form, attach files (up to 10MB each), as well as your personal information, when applicable. Be sure to complete all required fields. Please note that information entered on the web form may be viewable publicly. Once you reach the "Your Preview" screen, the information that will be viewable publicly is displayed directly on the form under the section titled: "This information will appear on *Regulations.gov*." To complete your comment, you must first agree to the disclaimer and check the box. This will enable the "Submit Comment" button. Upon completion, you will receive a Comment Tracking Number for your comment. To learn more about comment submission, visit the Submit a Comment section of the "How to Use *Regulations.gov*" pages.

■ **Electronic submission** through email to ANAComments@acf.hhs.gov.

All comments received before the close of the comment period will be available for public inspection, including any information that is included in a comment. All electronically submitted comments posted through the <https://www.regulations.gov> portal received before the end of the comment period will be available at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Camille Loya, Director, Division of Policy, Administration for Native Americans, Camille.Loya@acf.hhs.gov, 202-401-5964.

SUPPLEMENTARY INFORMATION:

I. Background information

Executive Order 13175, dated November 6, 2000, established policymaking criteria applicable to federal agencies, to the extent permitted by law, when formulating and implementing policies that have tribal implications, including special requirements for legislative proposals and consultation. Subsequently, President Obama issued a Presidential Memorandum on Tribal Consultation, dated November 5, 2009, affirming that "meaningful dialogue between Federal officials and tribal officials has greatly improved Federal policy toward Indian

tribes.” Finally, ACF recently issued the *ACF Principles for Working with Federally Recognized Indian Tribes*, effective October 20, 2016, that affirmed ACF’s commitment to receive input from elected tribal representatives as well as “to otherwise ensure human services coordination around issues affecting AI/AN populations.”

Consistent with the above affirmative statements of the value of feedback from AI/AN partners and stakeholders, ACF is requesting information from AI/AN tribes, tribal organizations, and stakeholders (including grantees). The purpose is to identify issues and challenges facing AI/AN populations as well as to inform ACF of tribes’ and tribal organizations’ recommendations, promising practices, and innovations to address the needs of AI/AN children, youth, families, and communities. This information may, in turn, be used by ACF in the development of future rulemaking and technical assistance, formation of legislative proposals and research agendas, and strategic planning in consultation with tribes.

II. Request for Information

As President Obama stated in his Presidential Proclamation—National Native American Heritage Month (2016):

Let us continue to build on the advancements we have made, because enduring progress will depend on our dedication to honoring our trust and treaty responsibilities. With sustained effort and unwavering optimism, we can ensure a vibrant and resilient Indian Country filled with possibility and prosperity.

In this RFI, we seek feedback and recommendations related to how ACF partners with tribes and how to make progress in the future. The following questions are not exhaustive, and we encourage commenters to provide any additional information they believe relevant to ACF’s work with and on behalf of American Indians and Alaska Natives. You may provide general comments, respond to all questions posed in section II of this RFI, or respond to one or more questions. If you respond to any of the questions in section II, please identify the number that corresponds to the question(s) you are responding to. Include our agency name and the docket number on all submissions. Please do not include confidential information, or otherwise sensitive or protected information with your responses.

(1) Are there challenges to AI/AN tribes and tribal organizations posed by non-federal match or cost sharing requirements in any applicable ACF programs? Please be specific as to the program or programs you are referring to

as well as provide as much detail as possible in describing challenges or difficulties posed and any specific recommendations you wish to provide.

(2) Are there challenges to AI/AN tribes and tribal organizations posed by administrative cost caps required under some ACF grant programs? Please be specific as to the program or programs you are referring to as well as provide as much detail as possible in describing challenges or difficulties posed and any specific recommendations you wish to provide.

(3) Are there instances for which you believe waiver authority, additional waiver authority allowed under block grants, would benefit tribes under any ACF programs? Please be specific as to the program or programs you are referring to as well as provide as much detail as possible in describing challenges or difficulties posed and any specific recommendations you wish to provide.

(4) For ACF programs that currently have waiver authority for tribes, do you recommend ACF streamline the processes under which AI/AN tribes and tribal organizations apply for or request waivers of statutory or regulatory requirements across ACF grant programs? Please be specific as to the program or programs you are referring to as well as provide as much detail as possible in describing where you believe additional streamlining is needed, along with any specific recommendations you wish to provide.

(5) Are there regulatory or administrative barriers that present challenges to AI/AN tribes and tribal organizations in the implementation of ACF grant programs? Please be specific about what those regulatory or administrative barriers are as well as recommendations for addressing them.

(6) Can you identify practices, policies, and procedures in ACF or elsewhere that are particularly effective in meeting the needs of AI/AN tribes, tribal organizations, families, and communities? Please be specific as to the program or programs you are referring to as well as provide as much detail as possible in describing effective and responsive practices, policies, and procedures.

(7) Related to data, what would you recommend ACF either collect (if it does not already) or analyze that would be most useful to inform our work with AI/AN tribes and tribal organizations? Please be specific and provide as much detail as possible.

(8) Do you have recommendations for how ACF could better share data related to AI/AN grantee program performance, outcomes, and sustainability? Please be

specific, including recommended use of technological or other means of data sharing.

(9) Are there elements of the application process that could potentially discourage AI/AN tribes or organizations from applying for ACF grants? If so, please specify what those elements are and explain why those elements could potentially discourage prospective AI/AN applicants and any recommendations for addressing such barriers.

III. Response to Comments

Because of the large number of public comments we normally receive, we are not able to acknowledge or respond to them individually. However, comments will be accepted on this RFI through <https://www.Regulations.gov> where you will be able to track your own comments and view other comments we receive.

Dated: January 3, 2017.

Mark H. Greenberg

Acting Assistant Secretary for Children and Families.

Dated: January 3, 2017.

Stacey Ecoffey,

Acting Deputy Assistant Secretary for Native American Affairs and Acting Commissioner Administration for Native Americans.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-2537]

Submission of Quality Metrics Data; Revised Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice of revised draft guidance availability that appeared in the **Federal Register** of November 25, 2016. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice of revised draft guidance availability published on November 25, 2016 (81 FR 85226). Submit either electronic or written comments by March 27, 2017.