DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 431

[CMS-2325-F]

RIN 0938-AQ46

Medicaid Program; Review and Approval Process for Section 1115 Demonstrations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will implement provisions of section 10201(i) of the Patient Protection and Affordable Care Act of 2010 that set forth transparency and public notice procedures for experimental, pilot, and demonstration projects approved under section 1115 of the Social Security Act relating to Medicaid and the Children's Health Insurance Program (CHIP). This final rule will increase the degree to which information about Medicaid and CHIP demonstration applications and approved demonstration projects is publicly available and promote greater transparency in the review and approval of demonstrations. It will also codify existing statutory requirements pertaining to seeking advice from Indian health care providers and urban Indian organizations for section 1115 demonstration projects, and for the first time impose as regulatory requirements tribal consultation standards that were previously only published as guidance documents.

DATES: These regulations are effective on [OFR--please insert date 60 days after publication in the Federal Register].

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SUPPLEMENTARY INFORMATION:

I. Background

A. Section 1115 Demonstrations

1. Overview

Section 1115 of the Social Security Act (the Act) allows the Secretary of the Department of Health and Human Services (the Secretary) to waive selected provisions of section 1902 of the Act for experimental, pilot, or demonstration projects (demonstrations), and to provide Federal Financial Participation (FFP) for demonstration costs which would not otherwise be considered as expenditures under the Medicaid State plan, when the Secretary finds that the demonstrations are likely to assist in promoting the objectives of Medicaid. Section 2107(e) of the Act states that the waiver authorities in section 1115 of the Act apply to the Children's Health Insurance Program (CHIP) in title XXI of the Act in the same manner as they apply to the Medicaid program in title XIX of the Act.

States have used section 1115 demonstrations for different reasons. Some States have tested new approaches to providing coverage or improving the scope or quality of benefits in ways that would not otherwise be permitted under the statute. For example, some States have used section 1115 demonstrations to expand eligibility to individuals who would not otherwise qualify for benefits, or to establish innovative service delivery systems. Other demonstrations have constrained eligibility or benefits in ways not otherwise permitted by statute. For example, some demonstrations have provided for a more limited set of benefits than the statute requires for a specified population, implemented cost-sharing at levels that exceed statutory requirements, or included enrollment limits. Some demonstrations have involved financing approaches that are not contemplated in titles XIX or XXI of the Act.

As such, demonstrations can have a significant and varied impact on beneficiaries, providers, States, Tribes and local governments. They can also influence policy making at the

State, Tribal and Federal level, by introducing new approaches that can be a model for other States and lead to programmatic changes nationwide. In light of the impact demonstration projects can have, the Congress has determined that the process by which States apply for and the Federal government reviews demonstrations should assure public input. From time to time that process has come under criticism. In recent years, the Congress, the Government Accountability Office (GAO), and the stakeholders representing a range of interests affected by the Medicaid and CHIP programs have raised concerns regarding the need for greater transparency in the submission, review, and approval of demonstration applications.

2. Prior Guidance Related to Public Notice

In the September 17, 2010 **Federal Register** (75 FR 56946), we published the "Review and Approval Process for Section 1115 Medicaid Demonstrations" proposed rule. In the September 17, 2010 proposed rule, we detailed the prior guidance that we have provided including the September 27, 1994 **Federal Register** notice entitled "Medicaid Programs; Demonstration Proposals Pursuant to Section 1115(a) of the Social Security Act; Policies and Procedures"(59 FR 49249) that provided general principles and guidelines governing demonstration projects and provided for a public notice process that was designed to ensure that interested parties would have an opportunity to provide input into the design and review of a State demonstration application.

In 2002, we issued a letter to State Medicaid directors, State Medicaid Director Letter (SMDL) #02-007, to encourage States to facilitate public participation in the development of demonstration applications in an effort to ensure adherence to the public notice procedures outlined in the September 27, 1994 **Federal Register** notice.

In 2002, the GAO issued a report entitled "Medicaid and SCHIP – Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns," finding that HHS had not consistently followed its September 27, 1994 **Federal Register** notice process. GAO

specifically noted that, since 1998, HHS had not complied with the **Federal Register** notice procedures. GAO recommended that the HHS Secretary provide for a public process that, at a minimum, included publishing notices of demonstrations in the **Federal Register** and a 30-day comment period.

In a subsequent 2007 report entitled *"*Medicaid Demonstration Waivers: Lack of Opportunity for Public Input during the Federal Approval Process Still a Concern,*"* the GAO examined demonstration projects in two States and found that HHS did not provide opportunity for public input at the Federal level during the Federal review process. It determined that the States that submitted the demonstration applications made efforts to obtain public input to comply with HHS' September 27, 1994 **Federal Register** notice, but that stakeholders in those States reported lacking access to information during the Federal review process about parts of the demonstration applications that had a significant impact on beneficiaries or having inadequate time to review and comment on the applications. GAO reiterated its longstanding concerns about the lack of public input into section 1115 demonstrations and restated its recommendation for a process that assures public input.

In a January 21, 2009 Memorandum to the Heads of Executive Departments and Agencies, President Obama established the Federal government's commitment to transparency, participation, and collaboration. Noting that public input can promote efficiency, effectiveness, and accountability in government, the President committed Federal agencies to disseminating information quickly and accessibly, and to ensure increased opportunities for the public to participate in policymaking. The Memorandum required each Federal agency to establish an Open Government plan, and on April 7, 2010, HHS announced its plan to achieve transparency, participation, and collaboration. HHS is committed to timely and responsive administration of the Medicaid and CHIP programs and seeks to assure transparency, input, and collaboration,

while also being mindful of the need to avoid duplicative processes and unnecessary administrative burdens and delays.

In May 2010, we met with more than 20 representatives of stakeholder organizations including organizations advocating on behalf of the elderly, people with disabilities and other low income populations, as well as organizations representing health care providers regarding transparency in the demonstration approval process. We also held a listening session open to officials from all 50 States, the District of Columbia, and U.S. Territories.

3. Guidance Related to Tribal Consultation and Seeking Advice from Indian Health Care Providers and Urban Indian Organizations.

To foster greater notice and a meaningful opportunity for input, in 2000, the Administration issued Executive Order 13175 regarding "Consultation and Coordination with Indian and Tribal governments." This Executive Order applies to the programs operated by the Federal government and, since States administer Medicaid and CHIP, we have issued guidance to States to conduct consultation with Tribes prior to implementing 1115 demonstration or 1915 waiver requests. Executive Order 13175 mandated the establishment of regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have "tribal implications," which are defined as policies or actions "with substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." On November 5, 2009, President Obama issued a Memorandum for the Heads of Executive Departments and Agencies reiterating the importance of Executive Order 13175 and requiring a detailed plan for compliance with its provisions.

In July 2001, we issued a letter to State Medicaid Directors (SMDL #01-024) that provided direction to States to allow federally-recognized Tribes to participate in the planning and development of Medicaid and CHIP demonstration applications and extensions through a

consultation process. The guidance encouraged States to provide information to tribal governments at least 60 days prior to implementation and to provide 30 days for tribes to comment on a State's planned demonstration request. The letter also articulated principles of consultation, such as respect for the sovereign rights of Tribes. In this final rule, we establish consultation procedures that allow States to meet simultaneously both the new statutory requirements pertaining to Indian health care providers and urban Indian organizations, as well as the new statutory requirements that pertain to the public at large under the Affordable Care Act.

4. Changes Made by the Recovery Act and the Affordable Care Act

Section 5006 of the American Recovery and Reinvestment Act of 2009 (Recovery Act) (Pub. L. 111-5, enacted on February 17, 2009), among other protections for Indian beneficiaries in Medicaid and CHIP, required States to seek advice from Indian health programs and urban Indian health organizations concerning Medicaid and CHIP policies before submitting a Medicaid or CHIP State plan amendment, demonstration request or application that would directly affect Indian health programs and urban Indian health organizations. This provision was effective July 1, 2009, and was summarized in a letter to State Medicaid Directors dated January 22, 2010 (SMDL # 10-001).

Section 10201(i) of the Patient Protection and Affordable Care Act of 2010 (Pub. L 111-148, enacted March 23, 2010) (the Affordable Care Act) amended section 1115 of the Act by adding a new subsection (d) to require the Secretary to issue regulations that would ensure the public has adequate opportunities to provide meaningful input into the development of State demonstration projects, as well as in the Federal review and approval of State demonstration applications and renewals. The Affordable Care Act also requires periodic evaluations and implementation reports to ensure that information on the outcomes of demonstration projects is available to the public.

Specifically, new section 1115(d) of the Act provides that these procedural requirements must include review standards pertaining to the goals of demonstration programs, the impact of the demonstration project on costs and coverage, and the plans of the State to ensure that the demonstration will comply with applicable requirements specified in title XIX and XXI of the Act. The statute requires the establishment of a process to provide for public notice and comment on the State level and at the Federal level once an application for a demonstration is received by the Secretary. These public notice and comment processes are meant to ensure a meaningful level of public input. The statute also requires the Secretary to implement reporting requirements for States with approved demonstrations, and to establish a process for the periodic evaluation of demonstration projects. Under section 1115(d)(3) of the Act, the Secretary is required to report annually to the Congress on actions taken for applications for demonstration projects.

In the September 17, 2010 proposed rule, we proposed to implement section 1115(d) of the Act to ensure transparency at each stage of the demonstration development and review process without interfering with the timely submission and review of demonstration proposals. We also proposed to codify the requirements of section 5006 of the Recovery Act that apply to demonstrations.

5. Findings Related to Section 1115 Demonstration Evaluations

We recognize the importance of public availability and understanding of information about the impact and operations of health insurance and health insurance programs, including Medicaid and CHIP. Because demonstration projects are approved to pilot or experiment with new approaches, it is particularly important to evaluate such projects and to share lessons learned. Demonstration evaluations can document policies that succeed or fail and the degree to which they do so informs decisions about the demonstration at issue, as well as the policy efforts of other States and at the Federal level. In particular, evaluations of the impact of demonstration

program features that depart from the statutory requirements can inform future decisions with regard to new approaches to coverage and care.

More public involvement, understanding, and access to demonstration project evaluations will also provide greater understanding of demonstration effectiveness, and compliance. Public involvement can benefit all aspects of the evaluation process, including the process for submission of evaluation designs, approval of demonstration evaluations, and the submission of evaluation reports. Therefore, we are, as part of this transparency rule, codifying our existing policies to ensure greater transparency, communication, and collaboration in the evaluation aspect of the section 1115 demonstration process.

II. Summary of the Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

The September 17, 2010 proposed rule addressed the Affordable Care Act provisions requiring transparency in the process of developing and approving demonstrations. We received a total of 33 timely comments on the September 17, 2010 (75 FR 56946) proposed rule.

A. Basis and Purpose (§431.400)

To incorporate the policies and implement the statutory provisions described above, we proposed to add a new subpart G under 42 CFR part 431 to implement the provisions of section 1115(d) of the Act, as amended by section 10201 of the Affordable Care Act. Subpart G includes guidance related to the development of demonstration applications, public notice for States and the Department, monitoring, compliance, evaluation of demonstration projects, and the submission of reports to the Secretary.

We did not receive any comments opposing this new subpart, see no other reason to change our proposed additions, and therefore, we are finalizing these provisions subject to the changes described below.

B. Definitions (§431.404)

In §431.404, we define the terms "demonstration," "Indian health program," "public notice," and "section 1332 waiver" that are used in new subpart G under 42 CFR part 431.

We received the following comment concerning the proposed Definitions:

Comment: One commenter requested that CMS include the definition of "Indian Health Program" under the Indian Health Care Improvement Act (IHCIA).

Response: We have included the IHCIA definition of "Indian Health Program" in the final rule.

C. State Public Notice Process (§431.408)

We recognize that demonstrations can have a significant impact on beneficiaries, providers, and States. Demonstrations can also influence policy making at the State and Federal level, by testing new approaches that can be models for programmatic changes nationwide or in other States. For these reasons and under section 10201(i) of the Affordable Care Act, in §431.408, we proposed to establish a process that promotes transparency, facilitates public involvement and input, and encourages sound decision-making as demonstration applications are designed at the State level. We are also mindful that States have developed their own State-specific procedures for public involvement in policy and program decision-making. Furthermore, Medicaid is a jointly administered Federal/State program. Accordingly, we have attempted to craft our requirements in ways that assure achievement of these statutory objectives while minimizing administrative burden.

We received the following comments concerning the proposed State public notice and comment period.

1. State Public Notice and Comment Period

Comment: While several commenters expressed support for the 30-day public notice period before the section 1115 demonstration application is submitted to CMS, many commenters stated that the period should be expanded to 45 or 60 days. One commenter

suggested as an alternative providing a 60-day comment period for new demonstration applications and a 30-day comment period for extensions of existing demonstrations.

Response: One of the goals of this regulation is to balance the need for transparency with the need for timely development, review, and approval of demonstrations. While we appreciate the commenters' suggestions regarding the length of the State comment period, we believe that 30 days strikes an appropriate balance between providing for increased transparency and ensuring timely submission of demonstration applications. In addition, we note that the Administrative Procedure Act has for many decades used 30 days as the normal minimum length for comments on proposed Federal rules. Moreover, our standards are minimums and States may exceed them at their discretion.

Comment: One commenter expressed concern that 20 days is not enough time for States to hold hearings and then analyze and incorporate the comments raised at the hearing into the demonstration application.

Response: The timeframes included in the final rule are the minimum timeframes that the State must follow. Our intention was to provide the State with as much flexibility as possible during the public notice process while maintaining our goal of increased transparency and timely procession of applications.

Comment: One commenter was concerned as to how States should discuss differing opinions between a local chapter and the National chapter of a stakeholder association in the document of consultation activities under §431.408(b).

Response: The State should include a summary of all comments aired in the consultation process, and may describe this type of situation in its report addressing the key issues raised in that process and how it took those comments into consideration, including comment on both sides of the issue, when finalizing its application. Neither Federal nor State governments are bound to follow public comments, but simply to consider them before making final decisions.

Comment: One commenter requested that the State produce a summary report on comments it received and how the comments influenced the content of the application, if at all.

Response: The information that the commenter wanted in a summary report was included in the proposed rule as part of the application submitted to CMS at §431.412(a)(1)(viii). Since this application is publicly available, the commenter will have access to this information and an additional required report is unnecessary.

2. Statement of Public Notice and State Public Input Procedures

Comment: One commenter recommended that CMS revise the regulation to bring it into compliance with the cost-sharing provisions of the Medicaid Act, as amended by the Deficit Reduction Act (DRA) of 2005.

Response: This comment is beyond the scope of this rulemaking document, and therefore, we are not addressing it in this final rule.

Comment: One commenter recommended that CMS require the State to publish its public notice in both the State Register and local newspapers.

Response: By requiring the demonstration application and hearing notice to be posted on the main page of the State's Web site, we believe it is unnecessary to also require notice in both the State Administrative Register and newspapers with significant circulation. We have accordingly retained State discretion to choose either its Administrative Register or newspaper (or both) as vehicles to provide public notice in addition to requiring notice on the main page of the State's Web site. We have also required States to use additional approaches, such as electronic mailing lists to provide public notice. Of course, it is likely that news media, other media, and advocacy organizations will use their own means to spread this information.

Comment: One commenter recommended that CMS require States to seek input from providers; similar to the tribal consultation requirement.

Response: While we understand the commenter's concern, we did not revise the language in this rule to require States to seek input from providers similar to the manner in which they conduct tribal consultation. There are specific requirements to seek advice from Indian health providers and urban Indian organizations outlined in the statute, and therefore, this rule needs to meet the statutory ARRA protections. Other providers will have an opportunity to offer their views in the process for public input along with other interested parties. The purpose of the public comment process is to provide all stakeholders an ample opportunity to comment.

Comment: Many commenters recommended that States be required to include a list of waiver and expenditure authorities in their applications, and requested that this list be included in the State's public notice as well.

Response*:* We are accepting this recommendation but we note that the public notice will not be considered deficient if the waivers and expenditure authorities granted to facilitate the demonstration are different than those the State contemplates. The actual waivers and expenditure authorities awarded will be based on CMS analysis of the waivers and expenditure authorities that are actually needed to accomplish demonstration objectives.

Comment: One commenter requested that CMS clarify that the financial analysis of changes to the demonstration requested by the State is for renewal applications only.

Response: We agree with this comment, and have included language to this effect in the final rule. The distinction was clear in the proposed §431.412 and we have revised the final rule at §431.408 to be consistent.

Comment: One commenter noted that it is unclear in the regulation whether the entire public notice document, that is, all the elements prescribed in §431.408(a)(1), must be published, or whether it can be an abbreviated notice referencing a Web site where the full document can be found.

Response: We have revised the language in §431.408(a)(2)(ii) to clarify that the public notice document published in either the State's Administrative Record or significant newspapers may be abbreviated, that is, the notice may include a summary of the elements found in §431.408(a)(1) for purposes of publication; however, the abbreviated notice must provide an active link to a Web site where the public notice may be viewed in its entirety.

Comment: Several commenters noted that public input would be more meaningful if it occurred before the State completed the process of drafting a complete demonstration application, and recommended that CMS allow the State to not post a complete application. The commenters noted that the 30-day Federal comment period would provide a full opportunity for public comment on the complete application once it had been submitted to CMS.

Response: While we appreciate the commenter's concern about ensuring the public has the opportunity to provide input on a proposed demonstration project, we believe that the public must have a specific proposal to respond to to provide meaningful input. We have outlined the required application content in §431.412(a)(1). The State may also post a draft application that contains sufficient information for the public to provide meaningful input. To provide a full opportunity for public review, there must be at least a 30-day period for public input before the draft application is submitted to CMS. This opportunity for input prior to submission of an application to CMS allows the public to participate in the State's process for developing the application. That opportunity is separate from the opportunity for public comment on the final application under consideration in the Federal review process.

Comment: One commenter requested that CMS require the State to provide summaries of quality data that do not contain patient information and that are detailed enough to allow for public analysis and comment, as well as to provide information on historical expenditures.

Response: The information requested by the commenter is already included in the regulations at §431.428(a)(4). We do not believe it is necessary to include this information in the public notice requirement.

Comment: One commenter requested that the State include specific Federally-Qualified Health Center (FQHC) related waivers, and the rationale and justification for such waivers in the public notice.

Response: FQHCs play a critical role in serving Medicaid beneficiaries. We are accommodating the commenter's concern in the revision discussed above requiring the State to identify specific waiver and expenditure authorities, as well as requiring a broad program description. We believe this information is sufficient to initiate a dialogue between the State and interested FQHCs on the rationale and justification for the State's proposal.

Comment: One commenter suggested that CMS include language in §431.408(a)(1)(iii) expressly referring to a time period of at least 30 days for the submission of comments.

Response: We agree with this comment, and have included such language in the final rule.

Comment: One commenter recommended that Medicaid providers affected by the proposed demonstration be required to post information in a conspicuous location so that affected individuals would have an opportunity to comment.

Response: While we appreciate the commenter's desire to involve the provider community, we believe this suggestion would cause an undue administrative burden on providers.

Comment: One commenter requested that CMS require the State to include a link to CMS' Web site on the Web page containing information on the demonstration application.

Response: We agree with this comment, and have included such a requirement in the final rule.

3. Language Requirements

Comment: Several commenters requested further guidance on how CMS plans to ensure that beneficiaries with limited English proficiency will be able to access published information regarding the proposed demonstration. One commenter recommended that CMS utilize the Department of Health and Human Services' Limited English Proficiency (LEP) guidance in selecting languages for translations of published information.

Response: States are subject to various civil rights requirements regarding communication, for both language and disability. These include Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act, and the Americans with Disabilities Act. There are regulations under each of these statutes and, in the case of Title VI, detailed guidance published by the Department of Health and Human Services regarding services to individuals with Limited English Proficiency. We agree with the commenter that this guidance establishes reasonable practices that States are expected to follow.

Comment: One commenter requested that CMS clarify that all documents posted to both the State and CMS Web sites be accessible to individuals with disabilities.

Response: As stated above, there are long-standing regulations in place that govern State practices not only for the activities addressed by this regulation, but also for all programs and activities performed by States and other recipients of Federal financial assistance and, in the case of the Americans with Disabilities Act, State programs and services regardless of Federal financial assistance. States are responsible for compliance and knowing their responsibilities as it relates to accessibility of information and documents for individuals with disabilities. Other Federal agencies (the HHS Office for Civil Rights and the Department of Justice) are responsible for any necessary clarification and enforcement.

4. Electronic Mailing List

Comment: One commenter requested clarification that the electronic mailing lists' purpose is to provide notification that a demonstration application is available for public review and comment.

Response: The electronic mailing lists' purpose is to provide notification that a demonstration application is available for public comment.

Comment: Several commenters expressed concern regarding how an interested party could sign up for the electronic mailing list at the State and Federal levels, as well as how the State and CMS would ensure notification to all interested parties, including Medicaid and CHIP beneficiaries.

Response: The use of such services will depend on State decisions. It is usual practice for links for, or instructions on how to, register for electronic mailing lists to be included, in appropriate places, on State Web sites so that individuals and advocacy groups may easily register for the electronic mailing lists. We will establish notification procedures on our Web site and other venues such as press notifications, as appropriate.

Comment: One commenter requested that the State explain how the electronic mailing list would work while another commenter suggested that the State's Web site provide a way for interested persons to be added to a mailing list. Another commenter expressed concern that the requirement to publish a notice in the newspaper of widest circulation (in each city or county with a population of 50,000 or more) appears to be optional if the State uses an electronic mailing list to notify interested parties. The commenter stated that many people with low-incomes and/or disabilities do not have access to email.

Response: We have revised §431.408(a)(2)(ii) to clarify that the State must publish its public notice in the newspaper of widest circulation in each region of the State that contains a city with a population of 100,000 or more or in the State's Register, and that it must also utilize a mechanism such as an electronic mailing list to notify interested parties. It is important to ensure

that the public notice is not entirely Web-based because there are individuals who may have limited access to, or facility with, Web-based information. On the other hand, there are large numbers of persons who use the Internet who do not subscribe to newspapers. We understand that any of these mechanisms are not necessarily going to reach all consumers and encourage the State, providers and advocacy groups to appropriately transmit the information to affected consumers.

Comment: One commenter recommended that the State's primary care association be automatically included in CMS' electronic mailing list.

Response: As we discuss below, we intend to automatically include all interested national organizations in the Federal electronic mailing list for the Federal public notice process. We would also like to clarify that regional, State and local organizations may request to be included on the notification mechanism at any time.

5. Public Hearings

Comment: While several commenters expressed support for the public hearings, the commenters requested that CMS clarify language to ensure the public has an opportunity to speak at the hearings.

Response: We agree with this comment, and have included language at §431.408(a)(3).

Comment: One commenter expressed concern that two public hearings may not be adequate for larger States, and recommended that CMS require four public hearings with the option of waiving two hearings for smaller States.

Response: We appreciate, and agree with, the commenter's concern that all interested parties across the State are afforded the same opportunity to provide input on a proposed demonstration project. In lieu of adding two additional public hearings, however, we have revised the language in the rule to require the State to utilize technology, that is, telephonic and/or Web conferencing capabilities, to ensure statewide access to the public hearing, including

in rural areas of the State. States remain free, of course, to conduct additional hearings, decisions that we expect will vary widely depending on geography, law, and customary practice in each State.

Comment: One commenter requested that CMS clarify what constitutes two public hearings, that is, the commenter questioned if the hearings have to be held in separate locations, separate dates and times, and if the State utilizes teleconferencing. Another commenter requested that CMS require the State to teleconference the hearing to at least five separate locations.

Response: We have included clarifying language in this final rule outlining that the two public hearings must be held on different dates and in different locations, and that the State must utilize telephonic and/or Web conferencing capabilities that normally provide essentially unlimited geographic access. While we agree that interested parties in rural portions of a State should be afforded the opportunity to provide meaningful input on a proposed demonstration project, we will not prescribe the number of locations to which the State must teleconference the hearing if for some reason it is infeasible to cover the entire State.

Comment: One commenter recommended that CMS require the State to ensure that the State's primary care association and at least two FQHCs have the opportunity to speak.

Response: While we understand the commenter's concern that the State's primary care association and FQHCs have the opportunity to speak, we believe that any interested party should be afforded the opportunity to provide comments on the demonstration. We have also clarified in §431.408(a)(3) that the public must have an opportunity to speak and provide meaningful input at the public hearings.

6. Tribal Consultation

Comment: While we received general support for tribal consultation, one commenter stated that it is not clear what CMS means by "publication" when requiring States to conduct

tribal consultation at least 60 days prior to "publication" or submission of an application. The commenter also noted that the inclusion of both "publication" and submission is confusing. If "publication" refers to the date of State public notice, then the reference to the "submission" date is unnecessary because submission will occur after the public notice.

Response: We agree with the commenter's concern, and have clarified the language in §431.408(b)(1) to read "submission" rather than "publication or submission of an application."

Comment: One commenter requested that CMS define acceptable consultation activities.

Response: We have clarified the language in §431.408(b)(2) by including a reference to SMDL # 01-024 which outlines acceptable tribal consultation activities. We also believe that States and tribes can determine how best to conduct such consultation, if they enter into agreements acceptable to both the State and the tribes. We think it likely that details will vary not only from State to State (reflecting the huge diversity among States as to tribal and Indian health presence), but also from demonstration to demonstration. We note that States are required in their applications to present information on their consultations, on issues raised, and on State decisions as to what to propose to CMS. We can and will reject applications that fail to provide appropriate consultation.

Comment: One commenter requested that CMS define "direct impact," and another commenter requested that CMS change "direct impact" to "direct effect," as well as include a definition for "direct effect."

Response: We have changed "direct impact" to "direct effect" in §431.408(b)(1) to be more consistent with the language specified in section 5006(e) of ARRA. We also acknowledge that States may work with tribes, Indian health providers and urban Indian organizations to define direct effect in a manner that meets the needs of all the parties when they have entered into a formal consultation policy with tribes or when they have defined direct effect in the State

plan which outlines the process for seeking advice from Indian health providers and urban Indian organizations in the State.

D. Application Procedures

In reviewing section 1115 demonstration applications, CMS requests information from States to determine the nature, scope, and impact of the demonstration request. In this rule, we are requiring application components consistent with current practice both for new demonstrations and for the extension of an existing demonstration, in an effort to make the application process consistent and transparent.

Under §431.412(a), we define when a State request for a new demonstration will be considered complete for the purposes of initiating the Federal review process described below.

Section 431.412(b) describes the application procedures that States must follow when submitting an application for a new demonstration or a request to extend an existing demonstration under section 1115 of the Act. This provision establishes a process for the State to submit an application, and for CMS to confirm that the application is complete, which in turn initiates the Federal comment and decision-making period. We developed these procedures because they represent a standardized approach that will be helpful to States, stakeholders, and CMS in the review of section 1115 demonstrations. While it is not a requirement for an initial section 1115 demonstration request, we strongly encourage that the Governor submit the demonstration request to the Secretary.

Generally, demonstrations may be extended up to 3 years under sections 1115(a), 1115(e), and 1115(f) of the Act; however, section 1915(h), as amended by section 2601 of the Affordable Care Act, allows section 1115 demonstrations to be extended up to 5 years at the Secretary's discretion if the demonstration provides medical assistance to dually eligible beneficiaries. As sections 1115(e) and (f) of the Act provide for a substantially streamlined Federal review process, the timeframes constrain Federal review of the demonstration and

consequently the time under which CMS can consider public input. In §431.412(c), at least 30 days prior to a State's submission of a request for review under those sections, the State will issue public notice of its intent to seek an extension under those sections and receive public comment on the proposed extension of the demonstration for at least 30 days. In addition, the State must provide a written summary to CMS of the issues raised in the public comment period and how the State considered those issues when developing the demonstration extension application.

The application prerequisites for the extension of a demonstration, codify current practice guidelines employed by CMS in the review of an existing section 1115 demonstration, which are consistent with the required timeframes in section 1115(e) and 1115 (f) of the Act. In §431.412(c), a demonstration extension request will be considered only if it is submitted no later than 12 months prior to the expiration date of the demonstration when requesting an extension under section 1115(e) of the Act or 6 months (or in some cases longer) when requesting an extension under a section 1115(a) or (f) of the Act.

In §431.412(c), a demonstration extension request or phase out plan will be sent from the Governor of the State to the Secretary of HHS, as required by the statute, to extend a demonstration under sections 1115(e) and (f) of the Act. However, if an extension application includes substantial changes to the existing demonstration, CMS may, at our discretion, treat the application as an application for a new demonstration.

We received the following comments on the proposed application procedures.

1. Concept Paper

Comment: One commenter requested that the language outlined in the background section regarding the submission of a pre-application concept paper to CMS be included in the final rule.

Response: We agree with this comment, and have included language in the final rule.

Comment: One commenter requested further guidance regarding the process of submitting to CMS a pre-application concept paper and/or conferring with CMS about intent to seek a demonstration prior to submitting a completed application.

Response: The purpose of a concept paper is to engage both the State and CMS in early dialogue on a potential demonstration project. We will not be issuing further guidance on this topic as our intent is not to be prescriptive on the process.

2. Application Templates

Comment: One commenter requested that CMS develop and provide standard demonstration applications for States to use.

Response: We appreciate the commenter's suggestion, and may consider it outside of the content of rulemaking.

3. Application Content – Initial Demonstration Applications

Comment: While several commenters were in support of the proposed application content, several other commenters requested that the demonstration applications should include demographic information on the demonstration population, as well as information on how the demonstration population will be impacted, particularly if the demonstration population is comprised of vulnerable or medically-underserved individuals. One commenter suggested that CMS require the State to provide details on how it will mitigate adverse health consequences, including outreach and education efforts to assist the vulnerable and medically-underserved populations in obtaining services and to raise awareness.

Response: The State is required to include a description of how current or new beneficiaries will be impacted by the demonstration, as well to describe how the individuals will be impacted by the various programmatic features of the demonstration in its public notice as outlined in §431.408(a)(1)(i)(A) and (B).

Comment: One commenter requested that demonstration applications proposing to reduce eligibility or benefits should contain explanations of the benefit/eligibility limit(s), the number of people affected and consequences of the reduction.

Response: We believe that we have already addressed the commenter's concern in §431.412(a)(1)(ii) of this final rule.

Comment: Regarding the inclusion of financial data, one commenter requested that States determine per capita cost per value and how the demonstration would change the total costs and revenues for the State's Medicaid program.

Response: To support analysis needed to establish budget neutrality, we require States to submit historical Medicaid expenditure data for all populations that will be affected by a proposed demonstration. In most cases, States must show on the basis of reasonable with- and without-waiver cost projections that the proposed demonstration will not cost the Federal government more than the program could have cost in the demonstration's absence. Once the demonstration is operational, we require States to report their actual expenditures, which are tracked and compared to the without-waiver estimates (which may be adjusted to account for caseload changes), to ensure that the demonstration remains budget neutral. Any Federal funding received by the State in excess of the without-waiver estimate must be returned to CMS.

Comment: One commenter requested that the State describe specific FQHC related waivers, the rationale and justification for such waivers, if/why such waivers are necessary for the project to achieve its goal, how the demonstration would be adversely affected if the FQHC waiver was not approved, the financial impact on the FQHCs and their ability to provide services, and the written responses and testimony provided by FQHCs during the State public notice process.

Response: FQHCs play a critical role in serving Medicaid beneficiaries. We believe that the current language in the regulation addresses the commenter's request by requiring the State

to include information in its application related to the specific expenditure and waiver authorities it is requesting, a narrative description of the proposed project, and identification of key issues, such as those discussed by the commenter, raised during the State's public comment period.

4. Application Submission – Initial Demonstration Applications

Comment: One commenter requested that the date of electronic submission be deemed as the official submission date.

Response: The official submission date is the date in which the State's application was received by the Secretary. We have revised the language in the final rule incorporating this change.

5. Application Procedures – Initial Demonstration Applications

Comment: One commenter requested clarification regarding when CMS would use its discretion to direct an additional 30-day public comment period.

Response: Each demonstration application is unique, and as such, we cannot provide specifics on when we would require an additional 30-day period. We would decide this on a case-by-case basis, but intend to only direct an additional 30-day period when the State has made significant changes to the demonstration relative to the proposal it provided for public input prior to submitting it to CMS.

Comment: One commenter noted that the application procedures section addressed new demonstration applications and extensions, and requested clarification on which notice and comment requirements apply to renewals of existing demonstration projects.

Response: We use "renewal of an existing demonstration" and "extension of an existing demonstration" interchangeably. In order to prevent additional confusion, we have revised the language in the final rule to make it more consistent, by using the word "extension" rather than "renewal."

6. Application Content – Demonstration Extension Requests

Comment: One commenter stated that the implementation date of a demonstration program is subject to the Federal approval date of the Demonstration and of an information system's Advance Planning Document (APD). The commenter requested that CMS use the implementation date rather than the approval date when requiring a demonstration extension request.

Response: While we appreciate the commenter's suggestion, APDs are not generally associated with section 1115 demonstrations. Approval dates and implementation dates sometimes differ because a State may need Federal approval before moving forward with steps toward implementation. Generally, when the implementation date is different from the approval date, the Special Terms and Conditions will indicate the implementation date. For demonstration extensions, an APD would be less likely because the State has already implemented the demonstration. The extension, and the timing for the extension application request, would need to date from the expiration of the prior approval period, to avoid a gap in approved operation.

Comment: One commenter expressed concern that important issues would not be included in the State's report of key issues raised during the public comment period. The commenter recommended that CMS delete the word "key" as it is subjective.

Response: We have revised the language by deleting the word "key" in §431.412(a)(1) and §431.412(c)(2).

Comment: One commenter requested greater flexibility when providing the summaries of various quality reports to prevent the submission of irrelevant reports.

Response: We are committed to ensuring that Medicaid beneficiaries receive quality care, and as such, believe the current quality reporting requirements reflect our commitment to quality care.

Comment: One commenter requested that States include their 416 EPSDT/CHIP reports when submitting their demonstration extension requests.

Response: We agree with the commenter, and have revised the language in the final rule.

7. Application Submission –Demonstration Extension Requests

Comment: Several commenters requested clarification regarding the availability of short-term extensions of existing demonstrations, even if initiated less than 12 months prior to the expiration of an existing demonstration. One of these commenters suggested adding language authorizing the Secretary to consider extension requests during the period when a successor demonstration project is under review.

Response: We agree with the commenters, and have incorporated clarifying language into this final rule.

Comment: Several commenters expressed concern over the requirement for States to submit demonstration extension requests 12 months prior to expiration. One commenter suggested that this timeframe be reduced to 6 months.

Response: While we understand the commenter's concern over the timeframe, the 12-month requirement is currently included in the Special Terms and Conditions (STCs) in the majority of the existing demonstrations. The 12-month period gives both the State and CMS adequate time for review. However, we have amended our regulatory language to allow States to submit an extension request 6 months prior to the expiration of a demonstration when requesting an extension under section 1115(a) or (f) of the Act when the Special Terms and conditions do not impose a longer requirement.

Comment: One commenter requested that CMS incorporate language to allow the submitting party of a demonstration extension to include a Governor's designee.

Response: We need to have an assurance that the demonstration is fully supported by State law and State executive authority. As a result, it is our current policy to require the State Governor to submit all new demonstration applications and demonstration extension requests.

8. Demonstration Approval

Comment: One commenter requested that CMS provide an explanation as to the considerations and conclusions reached by CMS that resulted in the agency granting waivers relating to FQHCs and particularly the conclusions reached by CMS as to the impact such waivers would have on the viability of the FQHCs and their continuing capacity to serve Medicaid beneficiaries.

Response: While we understand the commenter's concern regarding the granting of waivers impacting FQHCs, each individual section 1115 demonstration is the product of extensive discussion between the State and CMS about the particular circumstances of the State. We expect the public comments will inform these discussions, but do not believe it is feasible to explain considerations regarding conclusions reached with respect to a particular component of a demonstration.

9. Stakeholder Involvement

Comment: One commenter proposed language for CMS to add to ensure States include a description of current or anticipated mechanisms for stakeholder involvement beyond the comment periods outlined in the rule.

Response: While we appreciate the commenter's suggestion to require States to include how they will continue stakeholder involvement in the demonstration project, we believe the new post-implementation public forum, as well as already established forums such as Medical Care Advisory Committees (MCAC) that are required for each State to advise the Medicaid agency according to §431.12, provide sufficient level of stakeholder involvement. We

encourage States to use these and any additional steps they find most useful to ensure stakeholder involvement.

E. Federal Public Notice and Approval Process (§431.416)

We proposed timeframes and action steps to communicate to States and concerned stakeholders the current status and sequential steps in the demonstration review process. This approach standardizes and improves transparency in the section 1115 demonstration review process. In addition, by clearly communicating this process, we will minimize confusion around the demonstration review process, satisfy key stakeholders' need for information and improve communication at the Federal level.

In §431.416(a), within 15 days of receipt of a complete demonstration application for a new demonstration project or an extension of an existing demonstration project, we proposed we would send the State a written notice.

In §431.416(b)(2), we proposed to create and solicit subscription to an electronic mailing list for the widespread distribution of information to individuals and organizations interested in demonstration applications.

Under §431.416(d), we proposed to publish all comments electronically. We will review and consider all comments, but will not provide written responses to public comments.

Under §431.416(e), we proposed to not render a final decision on a demonstration application until at least 45 days after notice of receipt of a completed application.

Under §431.416(f), we proposed to maintain, and publish on our Web site, an administrative record.

To ensure that States and the Federal Government are able to respond quickly to emergencies and unanticipated disasters, in §431.416(g) we proposed to provide a good cause exception to bypass, in whole or in part, the Federal and State notice and comment processes to expedite a decision on a proposed demonstration application or renewal.

We received the following comments concerning the Federal public notice and approval process:

1. Federal Receipt of Demonstration Application

Comment: One commenter recommends that CMS publish the notification of receipt of a State's application to its Web site within the same 15-day timeframe in which the State will be notified of receipt for the public to have access to the information at approximately the same time as the State.

Response: We agree with this comment, and have revised the language in this final rule.

2. Federal Review of Demonstration Applications

Comment: Many commenters expressed support for the 45-day Federal review timeframe; however, some commenters sought clarification regarding a maximum Federal review timeframe and asked whether CMS had a defined process to extend waivers pending review.

Response: Although CMS endeavors to review demonstration requests expeditiously, given the complex and individual nature of each demonstration application, we do not have a maximum allowed timeframe for review. We intend to continue our current practice of providing temporary extensions of existing demonstrations should additional time be required to renew an existing demonstration.

3. Federal Public Comment Period and Process

Comment: One commenter requested clarification on CMS' intended use of any public comment it receives on a State's demonstration application, and whether CMS will make that public comment available to the State prior to publishing those comments on the Web site.

Response: We intend to use the Federal comment period to allow the public the opportunity to provide meaningful input on a State's demonstration application, as well as to ensure that the State has addressed all public comments raised during its public notice period.

We will not provide the State with advance notice of the comments prior to publishing them on our Web site.

Comment: Several commenters believed that the Federal comment period should be longer than 30 days. Some commenters suggested expanding the period to 45 or 60 days while other commenters suggested that CMS increase the comment period on an individual basis.

Response: One of the goals of this regulation is to balance the need for transparency with the need for timely review and approval. While we appreciate the commenters' suggestions regarding the length of the Federal comment period, we believe that 30 days strikes the appropriate balance between transparency and timeliness. The public may submit comments after the Federal comment period has ended; however, we cannot assure that late comments will be considered in the Federal review process. We encourage the public to ensure all comments are submitted during the Federal comment period to ensure that we have an opportunity to review such comments before we render a final decision on a State's demonstration application. We will not render a final decision until 45 days after receipt of a State's demonstration application, and will attempt to ensure that comments submitted after the Federal comment period had ended are considered in the final decision.

Comment: One commenter recommended that CMS publish the State's plan for accepting public comments at the same time that the application and associated concept papers, that is, the start of the Federal comment period, is published.

Response: The State's application will already include the public comments received during its public comment period and how the State took those comments into consideration at the start of the Federal comment period.

Comment: Many commenters acknowledged that CMS would not be able to provide an individualized written response to each comment; however, they requested that CMS provide a summary report of the public comments received and how they have been addressed. One

commenter urged CMS to reconsider its position of not responding to individual comments. Another commenter requested that CMS provide written response to public comments relating to waivers of FQHC service and payment protections.

Response: We will post on the CMS Web site page for the application a list of the issues raised during the Federal public notice process as outlined in §431.416(c)(2). We may include a summary report of frequently raised issues in our regular status updates.

Comment: One commenter requested that providers have direct access to CMS during the Federal public comment period.

Response: While we understand the commenter's concern that providers have the opportunity to provide written comments to CMS, we believe that the Federal public comment period outlined in this rule affords all interested parties the same opportunity to provide comments. We currently meet with interested parties regarding a State's demonstration application, and expect to continue to do so to the extent we deem appropriate and feasible. The Federal government's own rulemaking procedures under the Administrative Procedure Act emphasize written comments for many reasons, among them the value of written comments in allowing the sharing of commenters' precise views and rationale for those views among the various officials involved in various stages of review, the value of a written record, and the desirability of members of the public having access to the views of all other commenters.

4. Public Disclosure

Comment: Several commenters requested that when CMS publishes updates on State submissions that it posts all materials that the State has submitted as part of the application process. One commenter recommended that CMS clarify that it will post this information on a regular basis, and that the information will include submissions that are pending or have been rejected and not limited to those that have been approved.

Response: We are committed to promoting greater transparency during the demonstration review process, and will post the demonstration application per §431.416(b), as well as status updates on all submissions on a regular basis.

Comment: One commenter proposed draft language to ensure that CMS post copies of requests from CMS to the State for additional information and the State's responses to those requests, along with timeframes for the public to comment, as well as draft STCs.

Response: While we are committed to promoting greater transparency during the demonstration review process, we also need to protect frank and candid discussions between the State and CMS. While a demonstration application is under review, we believe that publication of these discussions would inhibit the free flow of information. As detailed under §431.416(f), we will maintain, and publish on our public Web site, an administrative record that will include sufficient documentation to address substantive issues relating to the approval.

Comment: One commenter requested that CMS clarify that all documents posted to both the State and CMS Web sites be accessible to individuals with disabilities.

Response: Individuals with disabilities will have access to demonstration materials. The Federal government's Web sites are subject to specific accessibility responsibilities and practices dictated by section 508 of the Rehabilitation Act. States are subject to other statutes, including section 504 of the Rehabilitation Act, the Americans with Disabilities Act, and in many cases State-specific statutes. Clarification of those statutes, if needed, is the responsibility of the agencies that administer those statutes. We are committed to ensuring that individuals with disabilities have access to demonstration materials, and believe that the current language in the final rule accomplishes this goal. We intend to issue specific guidance on electronic formats that will be accessible to individuals with disabilities.

Comment: One commenter requested that the State include a link to the CMS Web site on its Web site.

Response: We agree with this comment, and have revised this final rule accordingly.

5. Administrative Record

Comment: Several commenters requested that we include, at a minimum, the following information in the administrative record: State's application; public comments received during the Federal comment period and CMS' responses; and specific requirements related to the approved demonstration, such as implementation reviews, complaints, documents regarding suspensions or terminations, and evaluations on how the demonstration is impacting beneficiaries. One commenter requested that all information regarding the demonstration be posted as the administrative record given that it can be obtained through a Freedom of Information Act request. Another commenter suggested that we amend the proposed language to require the inclusion of evidence that the Secretary properly considered and accounted for the impact of the demonstration project on the human participants.

Response: We appreciate the commenters' suggestions regarding the content of the administrative record, and we believe we have set forth documentation that should comprehensively set forth the basis, purpose, and conditions for the approved demonstration. Regarding the impact of a demonstration project on human participants, relevant regulations at 45 CFR 46.101(b)(5) contain an exemption for research and demonstration projects that are approved by agency heads, and are designed to study, evaluate, or otherwise examine: a public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs. We believe most, if not all, section 1115 demonstration projects will fit within this exception. Entities that may receive Medicaid funding under section 1115 demonstration projects will still have to review whether the human subject protection regulations are applicable to them. For example, while a State might not be subject to these regulations when conducting a demonstration to pay for

services furnished through clinical trials, a research institution conducting such trials may be subject to these regulations.

Comment: One commenter requested clarification that the administrative record will be publicly accessible on CMS' Web site.

Response: Yes, the administrative record will be publicly available on our Web site. We have revised the regulatory language to clarify our intent.

6. Disaster Exemption

Comment: Many commenters requested that CMS limit the public notice exception to natural or man-made disasters such as earthquakes, floods, or terrorist attacks or a public health disaster and not extend beyond these events. One commenter suggested that CMS post an explanation of the reasons for the exception on the CMS Web site, along with a timeline for accepting public comments on emergency measures.

Response: We have revised the language in the final rule to clarify that the public notice exemption applies only to natural disasters, public health emergencies, or other emergency threats to human lives. Should we approve a State's disaster exemption request, we will post the approval letter on our Web site within 15 days of approval and the revised timeline for public comment, if applicable.

Comment: Several commenters requested that CMS incorporate proposed language excluding demonstration applications seeking to restrict eligibility and/or reduce benefits or increase cost-sharing for beneficiaries from a disaster exception.

Response: We understand the commenters' concern on this issue; however, the purpose in providing an exception to public notice during a disaster is to enable the State to move nimbly during the response period. In most disaster cases, we grant authorities to States allowing them to expedite processes to ensure coverage to populations impacted by the disaster. We expect that

in such cases States will seek to maintain or expand affordable coverage for affected populations.

Comment: Several commenters requested that CMS provide greater flexibility when providing exceptions to address legislative activities and the State legislature's schedule. One commenter expressed concern at potentially having to repeat the public notice process when the nature of the demonstration changes as a result of legislative action.

Response: We understand that demonstration projects may be impacted by legislative changes; however, we believe the language in the final rule provides States flexibility in the public notice process should a change occur. Changes that do not substantially change the nature and scope of the demonstration project will not cause the State to repost the application for additional public comment. We may, at our discretion, require the State to repost for an additional 30-day public comment period should the revised demonstration application contain substantial changes to the initial application. We believe that the additional 30-day comment period is necessary if the State takes action to substantially delay the approval process.

F. Monitoring and Compliance (§431.420)

As section 1115 demonstrations have a significant impact on beneficiaries, States and the Federal government, we are establishing processes and methodologies to assure we have adequate and appropriate information regarding the effectiveness of section 1115 demonstrations. Under §431.420(a), we proposed that States must comply with all applicable Federal laws, regulations, policy statements and Departmental guidance unless a law or regulation has specifically been waived or determined not applicable under the demonstration. Under section 1115 CMS has no authority to waive requirements that are not contained in parts of the Social Security Act specifically enumerated in that section, or otherwise delegated to CMS for this purpose. For example, CMS has no authority to exempt a State from laws or regulations

administered by another Federal Department or agency. We have reworded the language to clarify this and to emphasize the limited scope of section 1115 demonstrations.

Under §431.420(b), as part of the special terms and conditions of any demonstration project, we proposed that States will conduct periodic reviews related to the implementation of the demonstration.

Under §431.420(c), we proposed that States will publish the date, time, and location of the public forum in a prominent location on the State's public Web site at least 30 days prior to the date of the planned public forum.

Under §431.420(d), we proposed to affirm the Secretary's right to suspend or terminate a demonstration, in whole or in part, any time before the date of expiration, whenever it determines that the State has materially failed to comply with the terms of the demonstration project.

In §431.420(f), should we undertake an independent evaluation of any component of the demonstration, we proposed the State must cooperate fully with CMS or the independent evaluator selected by CMS. The State must submit all necessary data and information to CMS or the independent evaluator.

We received the following comments concerning monitoring and compliance:

1. Implementation Reviews

Comment: One commenter requested additional detail concerning the implementation review, that is, what the review should entail, how such a review is to be conducted and reported, etc.

Response: The State must comply with the implementation review requirement as outlined in the demonstration's STCs.

Comment: One commenter noted that the regulation does not address quarterly reports, and asked if the implementation reviews replaced these reports.

Response: States will be required to comply with requirements, such as the submission of quarterly reports, found in their STCs. Implementation reviews will not replace these requirements.

2. Complaints

Comment: One commenter asked if complaints will be shared with the State or if the State would be given the opportunity to respond to such complaints. The commenter recommended that CMS share all complaints received with the State as outlined in §431.420(b)(2).

Response: We believe it is in the best interests of States, the Federal government, providers and beneficiaries to share such complaints with the State to ensure that any appropriate corrective action occurs. As such, we have revised the language in the final rule to reflect this.

Comment: One commenter proposed language to the monitoring and compliance section clarifying that CMS will publish information on its Web site explaining how to file a complaint and that documented complaints will be reviewed by CMS.

Response: While it is current practice for complaints to be submitted, reviewed and responded to by the Regional Office which works most closely with the State in question, we are committed to ensuring that all documented complaints are reviewed and responded to by CMS. We will provide guidance on our Web site on how the public can file complaints with CMS.

3. Post Award Public Forum

Comment: While many commenters expressed support for the post award public forum, the commenters requested that CMS clarify language to ensure the public has opportunity to speak at the post award public forum.

Response: We agree with this comment, and have included language in the final rule.

Comment: One commenter stated that the post-award public forum is onerous, particularly in combination with the periodic implementation review requirement, and

recommended that CMS allow States to utilize forums already established to receive comments from the public regarding the Medicaid programs.

Response: We believe that the post-award public forum is important in accomplishing greater transparency, ensuring meaningful public input into the implementation process, and is an important aspect of the evaluation component established by the law. The final rule allows the State to use already established forums to comply with this requirement.

Comment: One commenter noted that the proposed rule is inconsistent with the Medical Care Advisory Committee (MCAC) regulations at §431.12 which requires each State to have a MCAC and to assure that the MCAC has the opportunity to participate in policy development. As such, the commenter recommended that CMS remove the optional use of the State's MCAC in §431.408(a)(3) and §431.420(c), and require the State to include its MCAC in the development of the State's demonstration application.

Response: We disagree with the commenter. We believe that it is more appropriate to give the State the choice of venue in holding the public forum. States have different ways in which they structure and organize their oversight and advisory structures. In some States, the MCAC meetings are not open to the public but other types of panels are open to public comment. This regulation does not in any way limit the MCAC's role in policy development.

Comment: One commenter expressed concern that 6 months may not be enough time to see the impact and outcomes of a demonstration, and recommended that CMS require the forum to be held 12 months after implementation rather than 6 months.

Response: Our intent in requiring the forum within 6 months of implementation is to allow the public to provide initial feedback on implementation. This is beneficial to both the State and the beneficiaries as it will allow the State to address any problems associated with the initial implementation of the demonstration.

Comment: One commenter requested that CMS require States to summarize the comments imparted at the forum and immediately submit the summary for CMS review.

Response: We believe that the current requirement is sufficient and accomplishes our goal of balancing transparency with minimal administrative burden to the State. We have revised language in §431.420(c) requiring the State to provide a summary of the forum in the quarterly report associated with the quarter in which the forum was held, as well as in the State's annual report.

4. General

Comment: While we did receive several comments supporting the monitoring and compliance provisions of this rule, we also received several comments requesting the deletion of §431.420(a)(2) as it conflicts with §431.420(d).

Response: We agree with this comment, and have revised the language in the final regulation.

Comment: One commenter requested that CMS define "interpretive policy statement" and "interpretive guidance" as specified in §431.420(a)(1).

Response: These terms have the same meaning, and we are revising the rule to use only the term "interpretive guidance" to refer to HHS or CMS guidance on the Federal interpretation of applicable Federal laws and regulations that have been communicated to the State through CMS manuals, letters to State Medicaid Directors, or other communications giving State notice of the Federal interpretation.

Comments: One commenter requested that a State receive advance notification of monitoring and compliance issues, with a chance for the State to appeal any finds for noncompliance, termination, or suspension.

Response: We will promptly notify the State of any monitoring and compliance issues. To the extent that there are consequences for the State, and available appeal processes, the special terms and conditions will describe those details.

Comment: A few commenters requested that CMS clarify that demonstrations may be terminated only if the State fails to materially comply with the agreed upon terms and conditions.

Response: We have clarified the language in the rule to provide that the Secretary may suspend or terminate a demonstration if the State fails to materially comply with the agreed upon terms and conditions. We also added language clarifying that the Secretary may also withdraw waivers or expenditure authorities based on a finding that the demonstration project is not likely to achieve the statutory purposes. The terms and conditions for the demonstration will detail any notice and appeal rights for the State for a termination, suspension or withdrawal of waivers or expenditure authorities.

G. Evaluation Requirements (§431.424)

In §431.424(a), we proposed that the Secretary may use a broad range of evaluation strategies developed by States but subject to Secretarial approval in the application of evaluation techniques for measuring the effectiveness and usefulness of demonstration projects as models that help shape health care delivery and policy.

In §431.424(b), we proposed the criteria that should be included in demonstration evaluations.

In §431.424(c), we proposed that States submit and receive CMS approval of a design for an evaluation of the demonstration (or extension) and publish to the State's public Web site the draft demonstration evaluation design within 30 days of CMS approval.

In §431.424(d), in the event the State submits a request to extend the demonstration beyond the current approval period under the authority of sections 1115(a), (e), or (f) of the Act, we proposed that the State shall include an interim evaluation report as part of the State's request

for each subsequent renewal. State evaluations must be published on the State's public Web site within 30 days of submission to CMS.

In §431.424(e), we proposed that States will publish the approved demonstration evaluation design on the State's public Web site within 30 days of CMS approval.

In §431.424(f) regarding Federal evaluations, we proposed that States must comply with all requirements set forth in this subpart.

In §431.424(g), we proposed that we will post, or provide a link to the State's public Web site, all evaluation materials, including research and data collection, on our Web site for purposes of sharing findings with the public within 30 days of receipt of materials.

We received the following comments on the evaluation requirements.

1. Evaluation Design Plan

Comment: Several commenters suggested that the evaluation design plan could be strengthened by incorporating some of the components referenced in the section governing annual reports. In particular, the commenters stated that the evaluation designs should evaluate how the demonstration impacts the outcome of care, quality of care, cost of care, and access to care for demonstration populations, where appropriate.

Response: While we appreciate the commenters' suggestion, we believe that the State should have flexibility, subject to CMS approval, in determining which indicators that it would like to evaluate when designing the demonstration's evaluation plan in light of the different kinds of demonstrations that are approved. Additionally, we believe that the indicators mentioned in the commenters' suggestion are inherent to an evaluation design plan.

Comment: Several commenters requested that language protecting beneficiaries' privacy be included in §431.424(a)(2).

Response: We agree with this comment, and have included language in the final rule. We note that existing Federal statutes, most notably the Privacy Act and HIPAA, prevent

disclosure of protected personal information. In addition, the release, disclosure, or use of personal information is governed by the requirements 42 CFR 431, subpart F.

Comment: Due to the fact that some information required in the evaluation section is contingent upon the selection of potential contractors, one commenter requested that the evaluation information be submitted to CMS at a conceptual level including as much information as is available with more detailed information following selection of the contracting entity. The commenter recommended that an exemption allowance be considered for demonstration projects that will be implemented by contracted staff.

Response: We understand the commenter's concern, and it is current practice to allow States to revise their evaluation design plans once a contractor has been selected, if necessary. We do not believe such a procedure is inconsistent with the proposed regulations, and thus we are not making any revisions to these final regulations. On the issue of the "exemption allowance," we do not see any basis for a broad exemption from evaluation requirements.

2. General

Comment: Given the fact that data necessary to fully evaluate a demonstration may not be available until well after the demonstration ends, one commenter questioned if CMS would consider extending the evaluation's due date beyond the waiver expiration in such cases.

Response: It is our practice to include language in the STCs requiring the State to submit an evaluation 120 days after the expiration of the demonstration. We will decide on a case-by-case basis to extend this timeframe should a State need additional time to comply.

Comment: One commenter expressed concern over the difficulty in isolating the effects of the demonstration from other changes occurring in the State at the same time, and would need to exclude some demonstration participants from the "other changes." The commenter believed that this would result in a more complicated evaluation design that would be difficult and

expensive to implement, and requested that the evaluation requirement be deleted from the final rule.

Response: The purpose of a demonstration is to test new approaches to coverage, delivering care, improving quality, etc. Evaluation is required to measure the effectiveness and usefulness of the demonstration as a model to help shape health care delivery and policy.

Comment: One commenter requested that data collection comply with the Office of Management and Budget's (OMB) 1997 revised standards for the collection of race and ethnicity data.

Response: We will ensure that data collected during the evaluation of the demonstration project complies with OMB's 1997 revised standards for the collection of race and ethnicity data, as appropriate. As a technical matter, these standards apply only to data collection by the Federal government itself, and of course they can only be used when feasible, which is not always the case in research and evaluation activities, such as studies using medical or administrative records that do not use the OMB categories.

Comment: One commenter stated that while it is helpful for the public to comment on the evaluation parameters, CMS should require the State to provide opportunity for public review and comment on the State's evaluation design.

Response: The public is afforded the opportunity to comment on the evaluation design plan as the State must publish its application on its Web site or a demonstration specific Web page as outlined in §431.412(a)(2)(i). The evaluation design plan is a required component of the State's application.

Comment: One commenter requested that CMS include a deadline for publishing the evaluation design and reports on both the State and CMS Web sites.

Response: We agree with this comment, and have included language in the final rule.

H. Reporting Requirements (§431.428)

In order for CMS to effectively monitor the implementation of a demonstration, we proposed that States will submit an annual report, as described in §431.428(a).

In §431.428(b), we proposed that States will submit a draft annual report to CMS no later than 90 days after the end of each demonstration year. Within 60 days of receipt of comments from CMS, the State will submit a final annual report for the demonstration year to CMS. The draft and final annual reports are to be published on the State's public Web site.

We received the following comments concerning annual reporting:

1. Annual Reports

Comment: One commenter requested that we clarify the "grievances and appeals" component of the annual report. The commenter requested clarification of what information is required under the "grievances and appeals" component, and whether the reference is intended to mean appeals under 42 CFR part 431, subpart E and/or 42 CFR part 438, subpart F relating to the waivers and expenditure authorities granted as part of the demonstration project.

Response: The State should provide a summary of the types of grievances and appeals, and include any trends discovered, the resolution of the grievances and appeals, and any actions taken, or to be taken, to prevent other occurrences.

Comment: Several commenters requested clarification regarding CMS' intent to require the State to publish draft annual reports on its Web site. One commenter recommended that CMS remove this requirement from the final regulation, and only require the State to publish a final annual report.

Response: The overarching goal of this regulation is to increase the degree to which information about section 1115 demonstrations is publicly available. By requiring the State to publish the draft annual report on its Web site, we believe this requirement is in line with the goal of this final rule.

Comment: One commenter expressed concern over conducting annual beneficiary satisfaction surveys as they are costly and time consuming. The commenter requested that CMS consider biannual member satisfaction surveys.

Response: While we did not specifically request an annual beneficiary satisfaction survey, we have clarified the language regarding this requirement. An annual survey is not required.

Comment: Many commenters recommended that CMS post the State's annual report on its Web site.

Response: The State's annual report will be included in the administrative record as outlined in §431.416(f). We will also provide a link to the State's public Web site to assure public access to the State's annual report.

Comment: One commenter requested that CMS specify a timeframe for it to provide comments on the annual report.

Response: Given the complex and individual nature of each demonstration application, we do not have a specified timeframe for review.

Comment: One commenter expressed concern about the lack of flexibility for annual recordkeeping and reporting, as well as the discrepancies in timeframes between existing STCs and this rule.

Response: We have revised the language to clarify that States may also follow the timeframes for submitting their annual reports as specified in their STCs.

Comment: One commenter requested that CMS remove quality as a distinct requirement in the annual report.

Response: We are committed to ensuring that Medicaid beneficiaries receive quality care, and as such, believe the current quality reporting requirements are in line with our commitment to quality care.

I. General Comments

1. Demonstration Amendments

Comment: Several of the commenters requested clarification on whether the regulation would apply to section 1115 demonstration amendments. One commenter suggested that if the regulation did apply to amendments, CMS should establish a threshold for the types of changes that would require public notice.

Response: This regulation and the statutory changes that it implements, do not address section 1115 demonstration amendments. We will provide further guidance in a separate issuance on when a State must solicit public input on demonstration amendments, including whether a demonstration amendment would result in a new demonstration project.

Comment: One commenter recommended that CMS require advance notice and opportunity for public comment if the State proposes substantive changes to an approved waiver demonstration.

Response: While we appreciate the commenter's concern for additional public notice on demonstration amendments, this regulation does not apply to section 1115 demonstration amendments.

2. American Recovery and Reinvestment Act (ARRA)

Comment: The commenter requested additional regulatory action to codify section 5006(e) of ARRA for all Medicaid and CHIP policy changes.

Response: We have addressed the requirements in section 5006(e) of ARRA to seek advice from Indian health providers and urban Indian organizations for section 1115 demonstrations, but the overall implementation of consultation requirements is beyond the scope of this rulemaking document, and therefore, we are not addressing it in this final rule. Regardless, the ARRA provides States appropriate flexibility in the methods they choose to use,

as is appropriate given the wide array of situations among the States where there are Federally-recognized tribes, Indian health providers, or urban Indian organizations.

3. Current CMS Web Site

Comment: Several commenters requested that CMS provide the public with more information on its Web site about section 1115 demonstrations that are currently being considered for extensions and new section 1115 demonstrations that have been submitted.

Response: We appreciate the commenters' suggestion, and are reviewing our current Web site operating procedures to ensure we meet the requirements of the regulation.

4. Operational Protocols

Comment: One commenter expressed concern that the public will not be able to comment on operational protocols as these are sometimes used to make significant changes to the demonstration. The commenter requested that CMS provide the public opportunity to comment on these protocols should it allow states to make changes to the demonstration through the submission of these protocols.

Response: We no longer require States to submit operational protocols; it is our current practice to include all operational requirements in the special terms and conditions upon which approval of the demonstration project is contingent. Therefore, this comment is beyond the scope of this rulemaking.

5. General/Unrelated

Comment: While several commenters expressed support for the proposed regulation, several others expressed concern that the regulation would be too cumbersome by requiring additional staff time and resources, which are under considerable strain due to current State fiscal pressures.

Response: One of the goals of this regulation is to balance the need for transparency with respect to administrative burden. While we understand the commenters' concerns regarding

the additional staff time and resources, we believe that this regulation strikes an appropriate balance between transparency and administrative burden by providing the State with flexibility in the manner in which it publishes its public notice, as well as the venues it selects to hold the public hearings. In addition, by making public documents available on the Web, States and the Federal government are likely to have fewer requests for public documents, and therefore, can expect a reduction in staff time devoted to such activities.

Comment: One commenter recommended that CMS grandfather operational section 1115 demonstrations that were in place prior to the issuance of these regulations, and only require them to comply with the new regulation upon renewal.

Response: We intend to apply the procedural requirements in these regulations to extensions of current operational section 1115 demonstrations, and would not require States with current operational 1115 demonstrations to meet public process requirements prior to the next extension

Comment: Several commenters provided instances where there were typographical or referencing errors in the proposed rule.

Response: We agree with these comments, and have made the appropriate changes to the final rule.

Comment: One commenter urged that CMS apply the principles of this regulation to Medicare demonstrations.

Response: This comment is beyond the scope of this rulemaking document, and therefore, we are not addressing it in this final rule.

Comment: One commenter recommended that the Department of Health and Human Services should align procedures for public notice and comment as required by the section 1332(a)(4)(B) of the Affordable Care Act.

Response: Section 1332(a)(5) of the Affordable Care Act requires coordination of the application process for demonstration projects under that section with the existing application process under section 1115 (and certain other waiver authorities).

Comment: One commenter urged that CMS apply the principles of this regulation to State Plan Amendment approvals.

Response: This comment is beyond both the scope of this rulemaking document and statute, and therefore, we are not addressing in this final rule. Moreover, the review of State plan amendments is entirely different than the review of a proposed demonstration. Approval of State plan amendments that comply with the regulatory framework is non-discretionary and there is a regulatory timeframe for federal review. In contrast, approval of section 1115 demonstration projects, including the timeframe, is discretionary with the Secretary.

III. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

A. Coordination with Section 1332 Waivers (§431.402)

We have deleted this provision from the final rule, but we plan to work closely with the States considering submitting multiple waivers to promote coordination across them to meet a State's specific circumstances and minimize administrative complexity while ensuring that the integrity of the review and approval processes is maintained.

B. Definitions (§431.404)

We have added the definition of "Indian Health Program" to make it consistent with the definition found in the Indian Health Care Improvement Act.

C. State Public Notice Process (§431.408)

We have amended §431.408(a)(1)(i) to clarify that a demonstration application or extension request contains sufficient level of detail to ensure meaningful input from the public.

We have further clarified in §431.408(a)(1)(i)(C) that a financial analysis of changes to the demonstration must be included in a demonstration extension request.

We have added §431.408(a)(1)(i)(E) requiring the State to include in its public notice specific waiver and expenditure authorities that the State believes to be necessary to authorize the demonstration.

We have amended §431.408(a)(1)(iii) clarifying that comments need only be accepted by the State within a minimum 30-day time period.

We have amended §431.408(a)(2)(i) requiring the State to include a link to relevant Medicaid demonstration page(s) on the CMS Web site on its Web site, and have clarified language that the State may publish an abbreviated notice in a newspaper or the State's Register.

We have clarified in §431.408(a)(2)(ii) that the State must also publish an abbreviated public notice which must include a summary description of the demonstration, the location and times of the two public hearings, and an active link to the full public notice document on the State's Web site in either the State's Administrative Record or significant newspaper. We have amended language requiring the State to publish its notice in the newspaper of widest circulation in each city with a population of 100,000 or more. We have added §431.408(a)(2)(iii) requiring the State to utilize a mechanism, such as an electronic mailing list, to notify interested parties of a demonstration application in addition to publishing an abbreviated public notice in either the State's Administrative Record or significant newspapers.

We have amended §431.408(a)(3) to clarify that the two public hearings must be held on separate dates and at separate locations, and must provide the public throughout the State an opportunity to provide comments. We further clarify that the State must use telephonic and/or Web conference capabilities for at least one public hearing to ensure statewide accessibility to the hearing unless it can document that it has met this requirement.

We have added a technical amendment to §431.408(a)(3)(i) revising the CFR citation that governs the Medical Care Advisory Committee to read "§431.12."

We have amended language in §431.408(b)(1) to clarify that, for a new demonstration project, or an extension of an existing demonstration, that has or would have a direct effect on tribes, Indians, Indian health programs, or urban Indian health organizations, the State must undertake a consultation process with Tribes and seek advice from affected Indian health providers and urban Indian health organizations that includes advance notice of the application with the anticipated effect on tribes and Indian health providers, and an opportunity for input in a timeframe that allows adequate time for State consideration of any issues raised. This process should be consistent with the guidance set forth in the State Medicaid Director Letter dated July 17, 2001 (#01-024) unless the State has a different established policy with the tribes and/or a different process for seeking advice from the Indian health providers and urban Indian organizations any State process under its approved Medicaid State plan.

We have revised, in §431.408(b)(3), the term "a renewal of a previously approved demonstration project" to read "an extension of an existing demonstration project."

D. Application Procedures (§431.412)

We have amended language in §431.412(a)(1)(viii) deleting the word "key" as well as clarifying that the State must provide written evidence on how it considered public comments when developing the demonstration application.

To ensure flexibility, we have deleted specific reference to "Section 508 of the American with Disabilities Act" and substituted language requiring that State submissions be in formats that are accessible to individuals with disabilities.

We have added a new §431.412(a)(3) to clarify that this section does not preclude a State from submitting a pre-application concept paper to CMS or from conferring with CMS about its intent to seek a demonstration prior to submitting a completed application.

We have amended §431.412(b)(1) to clarify that we will include the date in which the Secretary received the State's demonstration application in the written notice informing the State receipt of the submitted application.

We have amended §431.412(c) to clarify that States must submit an extension request 12 months prior to the expiration date of a demonstration when requesting an extension under section 1115(e) of the Act or 6 months prior to the expiration date of a demonstration when requesting an extension under section 1115(a) or (f) of the Act, unless a longer time frame is specified in the Special Terms and Conditions for the original demonstration.

We have revised §431.412(c)(2)(iv) to include the CMS 416 EPSDT/CHIP report as an example of other documentation regarding access to care, in its extension request.

We have revised §431.412(c)(2)(vii) deleting the word "key" as well as clarifying that the State must provide written evidence on how it considered public comments when developing the demonstration application.

We have added a new §431.412(c)(4) clarifying that the Secretary may extend an existing demonstration project on a temporary basis for the period during which a successor demonstration is under review, without regard to the date when the application was submitted.

E. Federal Public Notice and Approval Process (§431.416)

We have amended §431.416(a)(i) to clarify that we will include the State's official demonstration application submission date received by the Secretary in the written notice informing the State of receipt of the submitted application. We will also publish the written notice on our Web site within the 15-day timeframe.

We have amended §431.416(d) to clarify that we will publish all written comments.

We have amended §431.416(f)(2) to clarify that we will publish the administrative record on our Web site, or provide a link to the State's public Web site to ensure public access to all demonstration documents.

We have added another administrative record element in the new paragraph §431.416(f)(1)(ii)to include the State's disaster exception request, the CMS' response letter, and revised public notice timeline, if applicable.

We have clarified in §431.416(f)(1)(iii) that written public comments will be included in the administrative record.

We have added another administrative record element in §431.416 (f)(1)(vi) to include any written request(s) for additional information that CMS sends to the State.

We have clarified in §431.416(f)(1)(v) that if an application is approved, the final State response to written CMS requests for additional information will be included in the administrative record.

We have added §431.416(f)(1)(vi) to include the disapproval letter sent to the State should its application be denied.

We added in §431.416(f)(1)(vii) the phrase "as applicable."

We have clarified §431.416(f)(1)(viii) to include specific requirements related to the approved and agreed upon terms and conditions, such as implementation reviews, evaluation design, quarterly progress reports, annual reports, and interim and/or final evaluation reports.

We have added another administrative record element in §431.416(f)(1)(ix) to include any applicable notices of the demonstration's suspension or termination.

We have added §431.416 paragraph(f)(2) to clarify that we will provide a link to the State's public Web site to ensure the public has access to all demonstration related documentation.

We have revised, in §431.416(g), the term "demonstration renewal" to read "demonstration extension request." We have also deleted the term "economic" from §431.416(g).

We have revised §431.416(g)(i) to read "The State acted in good faith, and in a diligent, timely, and prudent manner."

F. Monitoring and Compliance (§431.420)

We have amended §431.420(a)(1) to delete "policy statement" and change "policy" to "guidance."

We have amended §431.420(a)(2) to clarify that the States must comply with the terms and conditions set forth by the Secretary, and to make the paragraph more consistent with §431.420(d).

We have added §431.420(b)(3) clarifying that we will promptly share with the State complaints that it has received, and that we will notify the State of any applicable monitoring and compliance issues.

We have amended §431.420(c) to clarify that the public forum must allow the public an opportunity to provide comments, as well as to require the State to include a summary report of the public forum in the quarterly report associated with the quarter in which the forum was held. We also clarify that the public forum must be held within 6 months after the demonstration's implementation date.

We have amended §431.420(c)(1)(i) revising the CFR citation that governs the Medical Care Advisory Committee to read §431.12.

We have amended §431.420(d) to clarify that the Secretary may suspend or terminate a demonstration, and that the Secretary may also withdraw waivers or expenditures authorities based on a finding that demonstration project is not likely to achieve the statutory purposes.

G. Evaluation Requirements (§431.424)

We have revised §431.424(b)(2) requiring the State to ensure that the evaluation process protects beneficiary privacy.

We have amended §431.424 (c)(1) requiring the State to publish its evaluation design plan on its Web site within 30 days of CMS approval.

We have amended §431.424 (d) requiring the State to publish its evaluations on its Web site within 30 days of submission to CMS.

We have clarified in §431.424 (g)that we will post all evaluation materials, or provide a link to the State's public Web site, within 30 days of receipt.

H. Reporting Requirements (§431.428)

We have amended §431.428(a)(2) to include that any issues and/or complaints made by beneficiaries must be included in the annual report.

We have amended §431.428(a)(5) to clarify that the results of beneficiary satisfaction survey, if conducted during the reporting year, should be included in the annual report.

We have amended §431.428(b) requiring the State to publish its draft annual report on its public Web site within 30 days of submission to CMS.

We have amended §431.428(b)(2) requiring the State to publish its final annual report on its Web site within 30 days of approval by CMS.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.

- The accuracy of our estimate of the information collection burden.

- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

A. ICRs Regarding State Public Notice Process (§431.408)

Section 431.408 provides for a State to provide a public notice and comment period regarding applications for a demonstration project, or an extension of an existing demonstration project the State intends to submit to CMS for review and consideration. Section 431.408(a)(1) specifies that prior to submitting an application to CMS for a new demonstration project, or an extension of an existing demonstration project, the State must provide public notice, and a comment period for at least 30 days. The public notice must address the information requirements listed at §431.408(a)(1)(i) through (iv).

The burden estimate associated with this requirement is the time and effort necessary to develop and publish notice with a comment period that complies with the aforementioned information requirements. We estimate that, on average, each of the 15 States submitting applications for new demonstration projects, and extension of a previously approved demonstration project will require 80 hours to comply with the requirements in this section. The estimated annual burden associated with this section is 1200 hours at a cost of $120,000.

Section 431.408(a)(2) provides that States establish and maintain a readily identifiable link to a demonstration Web page on the public Web site of the State agency responsible for making applications for demonstrations, and provide a link to the appropriate demonstration Web page on the CMS Web site. The State public notice must appear in a prominent location on the demonstration Web page of the State's public Web site throughout the entire review process; and the public notice must appear in at least one of the publications listed in §431.408(a)(2)(i) and (ii).

The burden associated with this is the time and effort necessary to develop a notice and to publish it both on the Web site for State agency responsible for submitting demonstration applications and in at least one of the publications listed in §431.408(a)(2)(i) and (ii). While these requirements are subject to the PRA, we believe we addressed the burden estimates in our discussion of §431.408(a)(1).

Section 431.408(a)(3) requires that at least 20 days prior to submitting an application for new demonstration projects, or an extension of a previously approved demonstration project to CMS for review, the State must have conducted at least two public hearings regarding the State's demonstration application using at least two of the following public forums contained in this section. The two public hearings must be held on separate dates and in separate locations, and must afford the public an opportunity to provide comments. Additionally, the State must utilize teleconferencing or Web capabilities for at least one of the public hearings to ensure statewide accessibility. The burden associated with this is the time and effort necessary for a State to conduct at least two public hearings 20 days prior to submitting an application for a demonstration. While this requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(h)(4). Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration of the comment are not subject to the PRA.

Section 431.408(b) requires States with Federally-recognized Indian tribes, Indian health programs, urban Indian health organizations or all three of the aforementioned entities, to consult with the Indian tribes, and seek advice from Indian Health programs and urban Indian health organizations in the State, before submitting a demonstration application that has direct effects

on Indians and/or these entities and organizations. Section 431.408(b)(2) specifies that consultation activities must be conducted in a manner consistent with the State Medicaid Director Letter #01-024 regarding consultation with tribes and the approved State Plan Amendments for seeking advice from Indian health providers and urban Indian organizations. Section 431.408(b)(3) further specifies that when there is a direct effect on Indians, Indian tribes, Indian health providers or urban Indian organizations, the State must submit evidence to CMS that these requirements have been met. Section 431.408(b)(4) explains that documentation of the State's consultation activities must be included in the demonstration application, which must describe the notification process, the entities they sought advice from or consulted with, the date and location of these consultation or how advice was sought, issues raised, and the potential resolution for such issues.

The burden associated with the requirements in this section is both the time and effort necessary for a State to seek advice and/or conduct its tribal consultations and the time and effort necessary to notify CMS of the State's compliance with §431.408(b). We estimate that this requirement applies to 37 States but that no more than, on average, 15 States would be subject to this requirement in a given year. We further estimate that it will take each State a total of 40 hours to both conduct its tribal consultations, and seek advice from Indian health programs and urban Indian health organizations prior to submitting an application for a new demonstration project, or an extension of an existing demonstration project and to submit the aforementioned evidence to CMS. The estimated annual burden associated with these requirements is 600 hours at a cost of $60,000.

B. ICRs Regarding Application Procedures (§431.412)

Section 431.412(a) discusses the application process for Medicaid demonstration projects. A State's application for approval of a new demonstration project or an extension of an existing demonstration project must be submitted to CMS as both printed and electronic

documents. Electronic documents should be in formats accessible to individuals with disabilities. Section 431.412(b) further explains that applications for the initial approval of a demonstration will not be considered complete if they do not comply with the requirements contained at §431.412(b) and §431.408.

The burden associated with the requirements in §431.412 is the time and effort necessary for a State to develop and submit a complete initial application for a demonstration. We estimate that we will receive, on average, five applications annually. Similarly we estimate that it will take 400 hours for a State to develop and submit a complete demonstration application. The total estimated annual burden associated with the requirements in §431.412(b) is 2000 hours at a cost of $200,000.

Section 431.412(c) specifies that a State must submit a request to extend an existing demonstration under section 1115(e) of the Act at least 12 months prior to the expiration date of the demonstration or 6 months prior to the expiration date of the demonstration when requesting an extension under section 1115(a) or (f) of the Act, unless a longer time frame is specified in the Special Terms and Conditions for the original demonstration. An extension application, including an extension for the purpose of phasing out a demonstration, must be sent from the Governor of the State to the Secretary. Section 431.412(c)(2) further specifies that an application to extend an existing demonstration will be considered complete when the State provides the required information listed at §431.412(c)(2)(i) through (vii). The burden associated with the requirements in §431.412(c) is the time and effort necessary for a State to develop and submit a demonstration extension application. CMS estimates that, on average, 10 States will apply for extensions annually. We further estimate that it will take each State approximately 320 hours to develop and submit a demonstration extension application. The total estimated annual burden is 3200 hours at a cost of $320,000.

C. ICRs Regarding Monitoring and Compliance (§431.420)

According to Section 431.420(b), States will periodically perform reviews of the implementation of the demonstration. We estimate that it will take each State 80 hours annually to periodically review the demonstration's implementation. We also estimate that, on average, 15 States must comply with this requirement. The total estimated annual burden associated with this requirement is 1200 hours at a cost of $120,000.

Section 431.420(c) states that at least 6 months after the implementation date of the demonstration and annually thereafter, the State must hold a public forum to solicit comments on the progress of a demonstration project. Section 431.420(c)(3)(i) through (iii) further specifies that the public forum to solicit feedback on the progress of a demonstration project, must occur at a Medical Care Advisory Committee, or a commission, or other similar process, where meetings are open to members of the public, and would afford an interested party the opportunity to learn about and comment on the demonstration's progress. Additionally, as stated in §431.420(c)(3)(iii), the State must publish the date, time, and location of the public forum in a prominent location on the State's public Web site, at least 30 days prior to the date of the planned public forum.

The burden associated with these provisions includes the time and effort necessary to conduct public meeting and the time and effort necessary for a State to publish the date, time, and location of the public forum in a prominent location on the State's public Web site, at least 30 days prior to the date of the planned public forum. While these requirements are subject to the PRA, we believe the associated burden is exempt from the PRA. As discussed previously in this final rule, facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration of the comment are not subject to the PRA. Therefore, the burden associated

with the annual public hearing requirement is exempt. Similarly, we believe the time and effort necessary to a State to publish the date, time, and location of the public forum in a prominent location on the State's public Web site is a burden that would be incurred in the course of usual and customary State business practices and is therefore exempt from the PRA under 5 CFR 1320.3(b)(3).

D. ICRs Regarding Evaluation Requirements (§431.424)

As required in §431.424(c)(1), simultaneous to receiving CMS' approval of a new demonstration project, or a extension of a previously existing demonstration project, the State must receive CMS approval of a design for an evaluation of the demonstration project and publish this document to the State's public Web site within 30 days of submission to CMS. The draft evaluation must include information established in §431.424(c)(2). The burden associated with this requirement is the time and effort necessary to design an evaluation for a new demonstration. We estimate that it will take each State 160 hours to develop an evaluation. Similarly, we estimate that, on average, 15 States must comply with this requirement. We further estimate that the total estimated annual burden associated with this requirement is 2,400 hours at a cost of $240,000.

Section 431.424(d) specifies that in the event that the State requests to extend the demonstration beyond the current approval period under the authority of section 1115(a), (e), or (f) of the Act, the State must submit an interim evaluation report as part of the State's request for a subsequent extension of the demonstration. The burden associated with this is the time and effort necessary for a State to develop and submit an interim evaluation report. We estimate that each State will take 160 hours to comply with this requirement. Similarly, we estimate that, on average, 10 States must comply with this requirement. We further estimate that the total estimated annual burden associated with this requirement is 1,600 hours at a cost of $160,000.

Section 431.424(e) established that States will publish CMS-approved demonstration evaluation designs on their State public Web site within 30 days of CMS approval. We estimate that it will take 70 hours for each State to comply with this disclosure process. We further estimate that, on average, 15 States must comply with this provision. We further estimate that the total estimated annual burden associated with this requirement is 1,050 hours at a cost of $105,000.

E. ICRs Regarding Reporting Requirements (§431.428)

Section 431.428 establishes that States will submit annual reports to CMS documenting the information listed in §431.428(a) (1) through (11). As part of the submission process, §431.428(b) requires States to submit draft annual reports to CMS no later than 90 days after the end of each demonstration year. The burden associated with this reporting requirement is the time and effort necessary to submit draft annual reports to CMS. We estimate that, on average, 15 States must comply with this. We estimate that it will take 40 hours for each State to comply with this reporting requirement. We further estimate that the total estimated annual burden associated with this requirement is 600 hours at a cost of $60,000.

In §431.428(b)(1) establishes that within 60 days of receipt of comments from CMS, the State must submit to CMS the final annual report for the demonstration year. While this requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(h)(9). Facts or opinions obtained or solicited through non-standardized follow-up questions designed to clarify responses to approved collections of information are not subject to the PRA.

Section §431.428(b)(2) states that the draft and final annual reports must be published on the State's public Web site within 30 days of submission and approval to CMS, respectively. The burden associated with this is the time and effort it takes for a State to post the aforementioned information on the State's public Web site. We estimate that, on average, each

of the 15 States will require 4 hours to comply with this requirement. The total estimated annual burden associated with this requirement is 60 hours at a cost of $6,000.

TABLE 1: Estimated Annual Recordkeeping and Reporting Burden

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§431.408(a)(1)	0938-New	15	1	80	1,200	100	120,000	0	120,000
§431.408(b)	0938-New	15	1	40	600	100	60,000	0	60,000
§431.412(a) & (b)	0938-New	5	1	400	2,000	100	200,000	0	200,000
§431.412(c)	0938-New	10	1	320	3,200	100	320,000	0	320,000
§431.420	0938-New	15	1	80	1,200	100	120,000	0	120,000
§431.424(c)	0938-New	15	1	160	2,400	100	240,000	0	240,000
§431.424(d)	0938-New	10	1	160	1,600	100	160,000	0	160,000
§431.424(e)	0938-New	15	1	70	1,050	100	105,000	0	105,000
§431.428(b)	0938-New	15	1	40	600	100	60,000	0	60,000
§431.428(b)(2)	0938-New	15	1	4	60	100	6,000	0	6,000
Total		**130**	**10**		**13,910**		**1,391,000**		**1,391,000**

If you comment on these information collection and recordkeeping requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS-2325-F]

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

V. Regulatory Impact Statement

A. Statement of Need

Under Executive Order 12866 (58 FR 51735), a Federal agency should publish only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling need. This final rule implements statutorily required provisions of section 10201(i) of the Affordable Care Act, and of section 5006 of the American Recovery and Investment Act. This final rule will increase the degree to which information about Medicaid and CHIP demonstration applications and approved demonstration projects is publicly available and promote greater transparency in the review and approval of demonstrations.

B. Overall Impact.

We have examined the impact of this rule as required by Executive Order 13563 on Improving Regulation and Regulatory Review (January 18. 2011), Executive Order 12866 on Regulatory Planning and Review (September 1993),the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202

of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 13563 and 12866 direct agencies to assess all costs and 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). We believe that the total costs of this rule, including information collection costs, will be at least several million dollars annually, but are unlikely to exceed ten million dollars annually. Therefore, this rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief for small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule will not have a significant 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 a rule 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, we define a small rural hospital as a hospital that is located outside of Core-Based Statistical Area (for Medicaid) and

outside of a Metropolitan Statistical Area (for Medicare) and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule 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 (UMRA) (Pub. L. 104-4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. Because this rule does not mandate State participation in using section 1115 demonstrations, there is no obligation for the State to make any change to their existing programs. As a result, there is no mandate for the State. Therefore, we estimate this rule will not mandate expenditures in the threshold amount of $136 million in any 1 year.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication. We have sought in this rule to respect State's own processes for notifying the public of important policy changes and for obtaining public comment.

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

List of Subjects in 42 CFR Part 431

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and Recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 431--STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

2. Subpart G is added to part 431 to read as follows:

Subpart G – Section 1115 Demonstrations

Sec.

Subpart G – Section 1115 Demonstrations

§ 431.400 Basis and purpose.

(a) Basis. This subpart implements provisions in section 1115(d) of the Act, which requires all of the following:

(1) The establishment of application requirements for Medicaid and CHIP demonstration projects that provide for:

(i) A process for public notice and comment at the State level, including public hearings, sufficient to ensure a meaningful level of public input and that does not impose requirements that are in addition to, or duplicative of, requirements imposed under the Administrative Procedure Act, or requirements that are unreasonable or unnecessarily burdensome with respect to State compliance.

(ii) Requirements relating to all of the following:

(A) The goals of the program to be implemented or renewed under the demonstration project.

(B) Expected State and Federal costs and coverage projections of the State demonstration project.

(C) Specific plans of the State to ensure the demonstration project will be in compliance with titles XIX or XXI of the Act.

(2) A process for public notice and comment after a demonstration application is received by the Secretary that is sufficient to ensure a meaningful level of public input.

(3) A process for the submission of reports to the Secretary by a State relating to the implementation of a demonstration project.

(4) Periodic evaluation of demonstration projects by the Secretary.

(b) Purpose. This subpart sets forth a process for application and review of Medicaid and CHIP demonstration projects that provides for transparency and public participation.

§ 431.404 Definitions.

For the purposes of this subpart:

Demonstration means any experimental, pilot, or demonstration project which the Secretary approves under the authority of section 1115 of the Act because, in the judgment of the Secretary, it is likely to assist in promoting the statutory objectives of the Medicaid or CHIP program.

Indian Health Program means a program as defined at section 4(12) of the Indian Health Care Improvement Act, (Pub. L. 94-437).

Public notice means a notice issued by a government agency or legislative body that contains sufficient detail to notify the public at large of a proposed action, consistent with the provisions of § 431.408 of this subpart.

§ 431.408 State public notice process.

(a) General. A State must provide at least a 30-day public notice and comment period regarding applications for a demonstration project, or an extension of an existing demonstration project that the State intends to submit to CMS for review and consideration.

(1) Public notice and comment period. Prior to submitting an application to CMS for a new demonstration project or an extension of a previously approved demonstration project, the State must provide at least a 30-day public notice and comment period, and the public notice shall include all of the following information:

(i) A comprehensive description of the demonstration application or extension to be submitted to CMS that contains a sufficient level of detail to ensure meaningful input from the public, including:

(A) The program description, goals, and objectives to be implemented or extended under the demonstration project, including a description of the current or new beneficiaries who will be impacted by the demonstration.

(B) To the extent applicable, the proposed health care delivery system and the eligibility requirements, benefit coverage and cost sharing (premiums, co-payments, and deductibles) required of individuals that will impacted by the demonstration, and how such provisions vary from the State's current program features.

(C) An estimate of the expected increase or decrease in annual enrollment, and in annual aggregate expenditures, including historic enrollment or budgetary data, if applicable. This includes a financial analysis of any changes to the demonstration requested by the State in its extension request.

(D) The hypothesis and evaluation parameters of the demonstration.

(E) The specific waiver and expenditure authorities that the State believes to be necessary to authorize the demonstration.

(ii) The locations and Internet address where copies of the demonstration application are available for public review and comment.

(iii) Postal and Internet email addresses where written comments may be sent and reviewed by the public, and the minimum 30-day time period in which comments will be accepted.

(iv) The location, date, and time of at least two public hearings convened by the State to seek public input on the demonstration application.

(2) Statement of public notice and public input procedures. (i) The State shall publish its public notice process, public input process, planned hearings, the demonstration application(s), and a link to the relevant Medicaid demonstration page(s) on the CMS Web site in a prominent location on either the main page of the public Web site of the State agency responsible for making applications for demonstrations or on a demonstration-specific Web page that is linked in a readily identifiable way to the main page of the State agency's Web site. The State must maintain and keep current the public Web site throughout the entire public comment and review process.

(ii) The State shall also publish an abbreviated public notice which must include a summary description of the demonstration, the location and times of the two or more public hearings, and an active link to the full public notice document on the State's Web site in the State's administrative record in accordance with the State's Administrative Procedure Act, provided that such notice is provided at least 30 days prior to the submission of the demonstration application to CMS or in the newspapers of widest circulation in each city with a population of 100,000, or more, provided that such notice is provided at least 30 days prior to the submission of the demonstration application to CMS , or both.

(iii) The State must also utilize additional mechanisms, such as an electronic mailing list, to notify interested parties of the demonstration application(s).

(3) Public hearings. At least 20 days prior to submitting an application for a new demonstration project or extension of an existing demonstration project to CMS for review, the State must have conducted at least two public hearings, on separate dates and

at separate locations, regarding the State's demonstration application at which members of the public throughout the State have an opportunity to provide comments. The State must use telephonic and/or Web conference capabilities for at least one of the two required public hearings to ensure statewide accessibility to the public hearing unless it can document it has afforded the public throughout the State the opportunity to provide comment, such as holding the two public hearings in geographically distinct areas of the State. The State must use at least two of the following public forums:

(i) The Medical Care Advisory Committee that operates in accordance with § 431.12 of this subpart; or

(ii) A commission or other similar process, where meetings are open to members of the public; or

(iii) A State legislative process, which would afford an interested party the opportunity to learn about the contents of the demonstration application, and to comment on its contents; or

(iv) Any other similar process for public input that would afford an interested party the opportunity to learn about the contents of the demonstration application, and to comment on its contents.

(b) <u>Tribal consultation and seeking advice from Indian health providers and urban Indian organizations.</u> A State with Federally-recognized Indian tribes, Indian health programs, and/or urban Indian health organizations shall include a process to consult with the Indian tribes, and seek advice from Indian Health programs and urban Indian health organizations in the State, prior to submission of an application to CMS for a new

demonstration project, or an extension of a previously approved demonstration project, that has or would have a direct effect on Indians, tribes, on Indian health programs, or on urban Indian health organizations.

(1) For initial applications and applications extending existing demonstration projects that have a direct effect on Indians, tribes, Indian health programs, and urban Indian health organizations in the State, the State must demonstrate that it has conducted consultation activities with tribes and sought advice from Indian health programs and urban Indian health organizations prior to submission of such application.

(2) Consultation with Federally-recognized Indian tribes and solicitation of advice from affected Indian health providers and urban Indian organizations must be conducted in accordance with the consultation process outlined in the July 17, 2001 letter or the State's formal tribal consultation agreement or process and the process for seeking advice from Indian Health providers must be conducted as outlined in the State's approved Medicaid State Plan.

(3) Documentation of the State's consultation activities must be included in the demonstration application, which must describe the notification process, the entities involved in the consultation(s), the date(s) and location(s) of the consultation(s), issues raised, and the potential resolution for such issues.

§ 431.412 Application procedures.

(a) Initial demonstration application content. (1) Applications for initial approval of a demonstration will not be considered complete unless they comply with the public notice process set forth in § 431.408(a) of this subpart, and include the following:

(i) A comprehensive program description of the demonstration, including the goals and objectives to be implemented under the demonstration project.

(ii) A description of the proposed health care delivery system, eligibility requirements, benefit coverage and cost sharing (premiums, copayments, and deductibles) required of individuals who will be impacted by the demonstration to the extent such provisions would vary from the State's current program features and the requirements of the Act.

(iii) An estimate of the expected increase or decrease in annual enrollment, and in annual aggregate expenditures, including historic enrollment or budgetary data, if applicable.

(iv) Current enrollment data, if applicable, and enrollment projections expected over the term of the demonstration for each category of beneficiary whose health care coverage is impacted by the demonstration.

(v) Other program features that the demonstration would modify in the State's Medicaid and CHIP programs.

(vi) The specific waiver and expenditure authorities that the State believes to be necessary to authorize the demonstration.

(vii) The research hypotheses that are related to the demonstration's proposed changes, goals, and objectives, a plan for testing the hypotheses in the context of an evaluation, and, if a quantitative evaluation design is feasible, the identification of appropriate evaluation indicators.

(viii) Written documentation of the State's compliance with the public notice requirements set forth in §431.408 of this subpart, with a report of the issues raised by the public during the comment period, which shall be no less than 30 days, and how the State considered those comments when developing the demonstration application.

(2) CMS may request, or the State may propose application modifications, as well as additional information to aid in the review of the application. If an application modification substantially changes the original demonstration design, CMS may, at its discretion, direct an additional 30-day public comment period.

(3) This section does not preclude a State from submitting to CMS a pre-application concept paper or from conferring with CMS about its intent to seek a demonstration prior to submitting a completed application.

(b) Demonstration application procedures. A State application for approval of a new demonstration project or an extension of an existing demonstration project must be submitted to CMS as both printed and electronic documents. Electronic documents must be submitted in a format that will be accessible to individuals with disabilities.

(1) Consistent with § 431.416(a) of this subpart, within 15 days of receipt of a complete application, CMS will send the State a written notice informing the State of receipt of the submitted application, the date in which the Secretary received the State's demonstration application and the start date of the 30-day Federal public notice process set forth in § 431.416 of this subpart. The written notice--

(i) Is provided for purposes of initiating the Federal-level public comment period and does not preclude a determination that, based on further review, further information

is required to supplement or support the application, or that the application cannot be approved because a required element is missing or insufficient.

(ii) Does not prevent a State from modifying its application or submitting any supplementary information it determines necessary to support CMS' review of its application.

(2) Within 15 days of receipt of a demonstration application that CMS determines is incomplete, CMS will send the State a written notice of the elements missing from the application.

(3) CMS will publish on its Web site at regular intervals the status of all State submissions, including information received from the State while the State works with CMS to meet the demonstration application process set forth in this section.

(c) Demonstration extension request. A request to extend an existing demonstration under sections 1115 (a), (e), and (f) of the Act will be considered only if it is submitted at least 12 months prior to the expiration date of the demonstration when requesting an extension under section 1115(e) of the Act or 6 months prior to the expiration date of the demonstration when requesting an extension under section 1115(a) or (f) of the Act, unless a longer time frame is specified in the Special Terms and Conditions for the original demonstration. An extension application, including an extension for the purpose of phasing out a demonstration, must be sent from the Governor of the State to the Secretary.

(1) Changes to existing demonstration. If an extension application includes substantial changes to the existing demonstration, CMS may, at its discretion, treat the application as an application for a new demonstration.

(2) Demonstration extension application. An application to extend an existing demonstration will be considered complete, for purposes of initiating the Federal-level public notice period, when the State provides the following:

(i) A historical narrative summary of the demonstration project, which includes the objectives set forth at the time the demonstration was approved, evidence of how these objectives have or have not been met, and the future goals of the program.

(ii) If changes are requested, a narrative of the changes being requested along with the objective of the change and the desired outcomes.

(iii) A list and programmatic description of the waivers and expenditure authorities that are being requested for the extension period, or a statement that the State is requesting the same waiver and expenditure authorities as those approved in the current demonstration.

(iv) Summaries of External Quality Review Organization (EQRO) reports, managed care organization (MCO) and State quality assurance monitoring, and any other documentation of the quality of and access to care provided under the demonstration, such as the CMS Form 416 EPSDT/CHIP report.

(v) Financial data demonstrating the State's historical and projected expenditures for the requested period of the extension, as well as cumulatively over the lifetime of the

demonstration. This includes a financial analysis of changes to the demonstration requested by the State.

(vi) An evaluation report of the demonstration, inclusive of evaluation activities and findings to date, plans for evaluation activities during the extension period, and if changes are requested, identification of research hypotheses related to the changes and an evaluation design for addressing the proposed revisions.

(vii) Documentation of the State's compliance with the public notice process set forth in § 431.408 of this subpart, including the post-award public input process described in § 431.420(c) of this subpart, with a report of the issues raised by the public during the comment period and how the State considered the comments when developing the demonstration extension application.

(3) CMS may request, or the State may propose application modifications, as well as additional information to aid in the review of an application to extend a demonstration. If an application modification substantially changes the original demonstration design, CMS may, at its discretion, direct an additional 30-day public comment period.

(4) Upon application from the State, the Secretary may extend existing demonstration projects on a temporary basis for the period during which a successor demonstration is under review, without regard to the date when the application was submitted.

(d) Approvals. Approval of a new demonstration or a demonstration extension will generally be prospective only and Federal Financial Participation (FFP) will not be available for changes to the demonstration that have not been approved by CMS.

§ 431.416 Federal public notice and approval process.

(a) General. Within 15 days of receipt of a complete application from the State for a new demonstration project or an extension of a previously approved demonstration project, CMS will:

(1) Send the State a written notice informing the State of receipt of the demonstration application, the date in which the Secretary received the State's demonstration application, the start dates of the 30-day Federal public notice process, and the end date of the 45-day minimum Federal decision-making period.

(2) Publish the written notice acknowledging receipt of the State's completed application on its Web site within the same 15-day timeframe.

(b) Public comment period. Upon notifying a State of a completed application, CMS will solicit public comment regarding such demonstration application for 30 days by doing the following:

(1) Publishing the following on the CMS Web site:

(i) The written notice of CMS receipt of the State's complete demonstration application.

(ii) Demonstration applications, including supporting information submitted by the State as part of the complete application, and associated concept papers, as applicable.

(iii) The proposed effective date of the demonstration.

(iv) Addresses to which inquiries and comments from the public may be directed to CMS by mail or email.

(2) Notifying interested parties through a mechanism, such an electronic mailing list, that CMS will create for this purpose.

(c) Public disclosure. CMS will publish on its Web site, at regular intervals, appropriate information, which may include, but is not limited to the following:

(1) Relevant status update(s);

(2) A listing of the issues raised through the public notice process.

(d) Publishing of comments. (1) CMS will publish written comments electronically through its Web site or an alternative Web site.

(2) CMS will review and consider all comments received by the deadline, but will not provide written responses to public comments. While comments may be submitted after the deadline, CMS cannot assure that these comments will be considered.

(e) Approval of a demonstration application. (1) CMS will not render a final decision on a demonstration application until at least 45 days after notice of receipt of a completed application, to receive and consider public comments.

(2) CMS may expedite this process under the exception to the normal public notice process provisions in § 431.416(g) of this subpart.

(f) Administrative record. (1) CMS will maintain, and publish on its public Web site, an administrative record that may include, but is not limited to the following:

(i) The demonstration application from the State.

(ii) The State's disaster exemption request and CMS' response, if applicable.

(iii) Written public comments sent to the CMS and any CMS responses.

(iv) If an application is approved, the final special terms and conditions, waivers, expenditure authorities, and award letter sent to the State.

(v) If an application is denied, the disapproval letter sent to the State.

(vi) The State acceptance letter, as applicable.

(vii) Specific requirements related to the approved and agreed upon terms and conditions, such as implementation reviews, evaluation design, quarterly progress reports, annual reports, and interim and/or final evaluation reports.

(viii) Notice of the demonstration's suspension or termination, if applicable.

(2) To ensure that the public has access to all documentation related to the demonstration project, including the aforementioned items, we will also provide a link to the State's public Web site.

(g) Exemption from the normal public notice process. (1) CMS may waive, in whole or in part, the Federal and State public notice procedures to expedite a decision on a proposed demonstration or demonstration extension request that addresses a natural disaster, public health emergency, or other sudden emergency threats to human lives.

(2) The Secretary may exempt a State from the normal public notice process or the required time constraints imposed in this section or § 431.408(a) of this subpart when the State demonstrates to CMS the existence of unforeseen circumstances resulting from a natural disaster, public health emergency, or other sudden emergency that directly threatens human lives that warrant an exception to the normal public notice process.

(i) The State is expected to discharge its basic responsibilities in submitting demonstration applications to the Secretary as required in § 431.412 of this subpart.

(ii) Such applications will be posted on the CMS Web site.

(3) A State must establish (or meet) all of the following criteria to obtain such an exemption from the normal public notice process requirements:

(i) The State acted in good faith, and in a diligent, timely, and prudent manner.

(ii) The circumstances constitute an emergency and could not have been reasonably foreseen.

(iii) Delay would undermine or compromise the purpose of the demonstration and be contrary to the interests of beneficiaries.

(4) CMS will publish on its Web site any disaster exemption determinations within 15 days of approval, as well as the revised timeline for public comment or post-award processes, if applicable.

§ 431.420 Monitoring and compliance.

(a) General. (1) Any provision of the Social Security Act that is not expressly waived by CMS in its approval of the demonstration project are not waived, and States may not stop compliance with any of these provisions not expressly waived. Waivers may be limited in scope to the extent necessary to achieve a particular purpose or to the extent of a particular regulatory requirement implementing the statutory provision.

(2) States must comply with the terms and conditions of the agreement between the Secretary and the State to implement a State demonstration project.

(b) Implementation reviews. (1) The terms and conditions will provide that the State will perform periodic reviews of the implementation of the demonstration.

(2) CMS will review documented complaints that a State is failing to comply with requirements specified in the special terms and conditions and implementing waivers of any approved demonstration.

(3) CMS will promptly share with the State complaints that CMS has received and will also provide notification of any applicable monitoring and compliance issues.

(c) Post award. Within 6 months after the implementation date of the demonstration and annually thereafter, the State must hold a public forum--

(1) To solicit comments on the progress of a demonstration project.

(2) At which members of the public have an opportunity to provide comments and in such time as to include a summary of the forum in the quarterly report associated with the quarter in which the forum was held, as well as in its annual report to CMS.

(3) The public forum to solicit feedback on the progress of a demonstration project must occur using one of the following:

(i) A Medical Care Advisory Committee that operates in accordance with § 431.412 of this subpart.

(ii) A commission or other similar process, where meetings are open to members of the public, and would afford an interested party the opportunity to learn about the demonstration's progress.

(iii) The State must publish the date, time, and location of the public forum in a prominent location on the State’s public Web site, at least 30 days prior to the date of the planned public forum.

(4) [Reserved]

(d) Terminations and suspensions. (1) The Secretary may suspend or terminate a demonstration in whole or in part, any time before the date of expiration, whenever it determines that the State has materially failed to comply with the terms of the demonstration project.

(2) The Secretary may also withdraw waivers or expenditure authorities based on a finding that the demonstration project is not likely to achieve the statutory purposes.

(3) The terms and conditions for the demonstration will detail any notice and appeal rights for the State for a termination, suspension or withdrawal of waivers or expenditure authorities.

(e) Closeout costs. When a demonstration is terminated, suspended, or if waivers or expenditure authority are withdrawn, Federal funding is limited to normal closeout costs associated with an orderly termination of the demonstration or expenditure authority, including service costs during any approved transition period, and administrative costs of disenrolling participants.

(f) Federal evaluators. (1) The State must fully cooperate with CMS or an independent evaluator selected by CMS to undertake an independent evaluation of any component of the demonstration.

(2) The State must submit all requested data and information to CMS or the independent evaluator.

§ 431.424 Evaluation requirements.

(a) General. States are permitted and encouraged to use a range of appropriate evaluation strategies (including experimental and other quantitative and qualitative designs) in the application of evaluation techniques with the approval of CMS.

(b) Demonstration evaluations. Demonstration evaluations will include the following:

(1) Quantitative research methods. (i) These methods involve the empirical investigation of the impact of key programmatic features of the demonstration.

(ii) CMS will consider alternative evaluation designs when quantitative designs are technically infeasible or not well suited to the change made by the demonstration.

(2) Approaches that minimize beneficiary impact. The evaluation process must minimize burden on beneficiaries and protect their privacy in terms of implementing and operating the policy approach to be demonstrated while ensuring the impact of the demonstration is measured.

(c) Evaluation design plan. (1) The State will submit and receive CMS approval of a design for an evaluation of the demonstration project and publish this document to the State's public Web site within 30 days of CMS approval.

(2) The draft demonstration evaluation design must include all of the following:

(i) A discussion of the demonstration hypotheses that are being tested including monitoring and reporting on the progress towards the expected outcomes.

(ii) The data that will be utilized and the baseline value for each measure.

(iii) The methods of data collection.

(iv) A description of how the effects of the demonstration will be isolated from those other changes occurring in the State at the same time through the use of comparison or control groups to identify the impact of significant aspects of the demonstration.

(v) A proposed date by which a final report on findings from evaluation activities conducted under the evaluation plan must be submitted to CMS.

(vi) Any other information pertinent to the State's research on the policy operations of the demonstration operations.

(d) Evaluations for demonstration extensions. (1) In the event that the State requests to extend the demonstration beyond the current approval period under the authority of section 1115(a), (e), or (f) of the Act, the State must submit an interim evaluation report as part of the State's request for a subsequent renewal of the demonstration.

(2) State evaluations must be published on the State's public Web site within 30 days of submission to CMS.

(e) Approved evaluation designs. The State must publish the CMS-approved demonstration evaluation design on the State's public Web site within 30 days of CMS approval.

(f) Federal evaluations. The State must comply with all requirements set forth in this subpart.

(g) Federal public notice. CMS will post, or provide a link to the State's public Web site, all evaluation materials, including research and data collection, on its Web site for purposes of sharing findings with the public within 30 days of receipt of materials.

§ 431.428 Reporting requirements.

(a) Annual reports. The State must submit an annual report to CMS documenting all of the following:

(1) Any policy or administrative difficulties in the operation of the demonstration.

(2) The status of the health care delivery system under the demonstration with respect to issues and/or complaints identified by beneficiaries.

(3) The impact of the demonstration in providing insurance coverage to beneficiaries and uninsured populations.

(4) Outcomes of care, quality of care, cost of care and access to care for demonstration populations.

(5) The results of beneficiary satisfaction surveys, if conducted during the reporting year, grievances and appeals.

(6) The existence or results of any audits, investigations or lawsuits that impact the demonstration.

(7) The financial performance of the demonstration.

(8) The status of the evaluation and information regarding progress in achieving demonstration evaluation criteria.

(9) Any State legislative developments that may impact the demonstration.

(10) The results/impact of any demonstration programmatic area defined by CMS that is unique to the demonstration design or evaluation hypothesis.

(11) A summary of the annual post-award public forum, including all public comments received regarding the progress of the demonstration project.

(b) Submitting and publishing annual reports. States must submit a draft annual report to CMS no later than 90 days after the end of each demonstration year, or as specified in the demonstration's STCs. The State must publish its draft annual report on its public Web site within 30 days of submission to CMS.

(1) Within 60 days of receipt of comments from CMS, the State must submit to CMS the final annual report for the demonstration year.

(2) The final annual report is to be published on the State's public Web site within 30 days of approval by CMS.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: March 9, 2011.

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Donald M. Berwick,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: July 15, 2011.

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Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

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