approval of Georgia's attainment date extension request for the Atlanta Area for the 1997 8-hour ozone NAAQS.

IV. Proposed Actions

EPA is proposing to approve Georgia's June 9, 2010, request for EPA to grant a one-year extension (from June 15, 2010, to June 15, 2011) of the Atlanta Area attainment date for the 1997 8-hour ozone NAAQS because EPA believes that Georgia has met the statutory requirements for such an extension. EPA's belief is based on its preliminary determination that the state is in compliance of the requirements and commitments associated with the EPA-approved implementation plan, and on the belief that the 4th highest daily 8-hour ozone average concentration for 2009 for the Atlanta Area is below the 1997 8-hour ozone NAAQS as required by the CAA. As provided in 40 CFR 51.907, if EPA finalizes this action, it will extend, by one year, the deadline by which the Atlanta Area must attain the 1997 8-hour ozone NAAQS. It will also extend the timeframe by which EPA must make an attainment determination for the area. EPA notes that this proposed action only relates to the initial one-year extension. As noted in Section 181(a)(5) of the CAA, areas may qualify for up to 2 one-year extensions. If requested at a future date, EPA will make a determination of the appropriateness of a second one-year extension for the Atlanta Area for the 1997 8-hour ozone NAAQS in a separate rulemaking.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve SIP submissions and requests that comply with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing the state's request for an extension of the 1997 8-hour ozone NAAQS attainment date for the Atlanta Area, EPA's role is to approve the state's request, provided that it meets the criteria of the CAA. Accordingly, this proposed action merely approves a state request for an extension of the 1997 8-hour ozone NAAQS attainment date as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub.L.104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: September 3, 2010.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 2010–23317 Filed 9–16–10; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 431

[CMS–2325–P]

RIN 0938–AQ46

Medicaid Program; Review and Approval Process for Section 1115 Demonstrations

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement provisions of section 10201(i) of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) 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 proposed rule would increase the degree to which information about Medicaid and CHIP demonstration applications and approved demonstration projects are publicly available and promote greater transparency in the review and approval of demonstrations. It would also codify existing statutory requirements pertaining to tribal consultation for section 1115 demonstration projects.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 16, 2010.

ADDRESSES: In commenting, please refer to file code CMS–2325–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2325–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the

following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2325–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period and, thus, may not be considered timely.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Steven Rubio, (410) 786–1782, or Yolanda Reese, (410) 786–9898.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Acronyms

To assist the reader, the following is a list of the terms to which we refer by acronym in this proposed rule.

The Act—The Social Security Act
The Affordable Care Act—The Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148)
CHIP—The Children's Health Insurance Program
CMS—The Centers for Medicare & Medicaid Services
EQRO—External Quality Review Organization
FFP—Federal Financial Participation
GAO—Government Accountability Office
HHS—The Department of Health and Human Services
MCO—Managed Care Organization
The Recovery Act—The American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5)
SMDL—State Medicaid Directors' Letter
Title XIX—Grants to States for Medical Assistance Programs of the Social Security Act.
Title XXI—State Children's Health Insurance Program of the Social Security Act.

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 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 provide coverage or improve 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 law. 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 title XIX or XXI.

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

Over time, efforts were made to assure meaningful public involvement in the development and review of State demonstration projects. In the September 27, 1994 **Federal Register** on (59 FR 49249), the Department of Health and Human Services (HHS) published a notice 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.

The September 27, 1994 **Federal Register** notice listed examples of potential approaches States could use to solicit public comments, such as the State legislative process and hearings

conducted by State commissions, and it established a process for public input at the Federal level, including providing notice to interested parties when the Federal government receives a demonstration request. The September 27, 1994 **Federal Register** notice also established timeframes for the Federal government to receive and review public comments before acting on a State demonstration request.

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.

The 2002 SMDL (#02–007) did not address the Federal level of review. Over the years some aspects of the Federal demonstration review process described in the September 27, 1994 **Federal Register** notice were abandoned. 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 found that, since 1998, HHS had not complied with the Federal 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.

As we were considering potential processes and procedures for this proposed rule, we reviewed these GAO findings, various legislative proposals, and we conducted a listening session with stakeholders and States. 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.

The stakeholder representatives generally expressed the need for better opportunities for the public to provide meaningful input into the development of State demonstration applications and the Federal review and approval process. These advocates expressed concern that the policies employed in demonstrations have far-reaching impact, and can happen with little meaningful stakeholder input into policy development at the Federal and State levels unlike the legislative and rulemaking processes, which have established mechanisms that assure some degree of transparency. They also expressed the view that since demonstrations allow States to "not comply" with requirements that the Congress put into law, the need for meaningful public input into these demonstrations is great. States agreed that public input is important although were concerned that any new requirements established under the new law could be administratively burdensome, and potentially duplicative of existing State policies and procedures. Some States reported that their existing public notice requirements and State legislative processes were strong and sufficient to ensure meaningful public input at the State level.

Recently, the Federal government has made a broad commitment to transparency and public input, and this commitment informs the Secretary's approaches to ensuring transparency in this proposed rule. 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.

3. Guidance Related to Tribal Consultation

Over time, a different but related set of concerns has emerged about the need to ensure that Indian and Tribal governments be assured input into policies that impact Tribal governments, organizations, and Native Americans. In order 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." 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. 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 required 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 required at least 60 days notice to federally-recognized Tribes before submission of a State's intent to submit a demonstration application or the extension of a previously approved section 1915 and/or 1115 waiver.

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 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 Indian beneficiaries. 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 within 180 days of enactment 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 title XIX and XXI of the Act. The law 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 with respect to applications for demonstration projects.

In this proposed rule, we seek 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 review of demonstration proposals. This rule will also 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 the Secretary's 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. Provisions of the Proposed Rule

This proposed rule would address the Affordable Care Act provisions requiring transparency in the process of developing and approving demonstrations. Consistent with the intention of these provisions, which is to ensure transparency and meaningful public input, we are soliciting public comments on this proposed rule's impact on beneficiaries, providers, and States, and as well as in the administrative processes, the timeframes described within the rule and the projected impact in sound policymaking at the State and Federal levels. At the end of this comment period, we will review the comments and take the comments into consideration before we issue a subsequent final rule. In the processes and timeframes that we propose in this rule, we have tried to ensure that the public has a full opportunity to provide meaningful input into the development and review of section 1115 Medicaid and CHIP demonstrations consistent with the law while not impeding the process of developing, reviewing, approving, and implementing demonstrations. We welcome public comment on the balance this rule strikes between ensuring input and minimizing unnecessary administrative burden or delay, as well as the extent to which the rule ensures meaningful public comment at the State and Federal levels.

We note that the procedures set forth in this proposed rule include procedures for submitting, publishing, and issuing public notices, applications, annual reports and other documents. In many cases, these procedures would allow for electronic documents, either as an alternative or a supplement to a printed document. Electronic documents should comply with all applicable civil rights requirements related to accessibility, including the requirements under section 508 of the Americans with Disabilities Act. Compliance with these requirements is necessary both to ensure accessibility by the public and to ensure accessibility by Federal employees who need to review the documents.

In developing this rule, CMS reviewed prior guidance we issued regarding transparency in the waiver process, including the September 27, 1994 **Federal Register** notice, and legislative proposals, including those that were proposed during the legislative process that resulted in the Affordable Care Act. These past guidance and proposals informed the development of the time requirements relating to the public comment period for new demonstrations and extending demonstrations; notifying organizations of the receipt of demonstration applications; acknowledging, if feasible, comments made; and refraining from approving or disapproving applications until public comments could be considered. In addition, as part of the task of establishing rules for the submission and review of demonstration proposals, we are codifying many of our existing processes to help create a more consistent demonstration submission and review process for States and to clarify for States, the Federal government, and the public when the public notice and input requirements take effect.

A. Section 1115 Demonstrations (Subpart G)

1. Basis and Purpose (§ 431.400)

To incorporate the policies and implement the statutory provisions described above, we propose adding 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.

2. Coordination with Section 1332 Waivers (§ 431.402)

Section 1332(a(5) of the Affordable Care Act requires the Secretary to develop a process for coordinating and consolidating the State waiver processes applicable under the provisions of section 1332 of the Affordable Care Act(as set forth in 45 CFR part 155), and the existing waiver processes applicable under titles XIX and XXI of the Social Security Act, and any other Federal law relating to the provision of health care items or services. Section 1332(a)(5) further requires the process developed by the Secretary to permit a State to submit a single application for a waiver under any and all of such provisions. The State waiver application processes applicable under section 1332 of the Affordable Care Act will be published in a separate rulemaking document. We have consulted with the Department in developing the demonstration application processes in this proposed rule and we will work to ensure that our final procedures are coordinated with section 1332 waiver application requirements.

3. Definitions (§ 431.404)

We are proposing to define the following terms as they are used in our current section 1115 demonstration review practices. In new § 431.404, we define the terms "demonstration," "public notice," and "section 1332 waiver" that are used in new subpart G under 42 CFR part 431.

4. 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, in § 431.408, we propose a process that promotes transparency, facilitates public involvement and input, and encourages sound decision-making as demonstration applications are designed at the State level.

In order to facilitate public involvement in the development of section 1115 demonstration applications, we propose in § 431.408(a)(1) that States issue a public notice with a comment period of at least 30 days prior to the State's submission of a new demonstration application or an application for an extension of an existing demonstration to CMS for review. Because meaningful input requires notice of the nature of the demonstration application or extension, we propose that the notice must include the following:

- A summary program description, including the goals and objectives to be implemented or extended under the demonstration project.
- The proposed health care delivery system and the eligibility requirements, benefit coverage, and cost sharing (for example, premiums, copayments, and deductibles) required of or available to individuals that will be impacted by the demonstration, and how the provisions vary from the State's current program features.
- An estimate of the expected increase or decrease in annual aggregate expenditures by population group impacted by the demonstration.
- An estimate of historic coverage data, as well as coverage projections expected over the term of the demonstration for each category of beneficiary whose health care coverage is impacted by the demonstration.
- The hypothesis and evaluation parameters of the demonstration.
- The locations and Internet address of where copies of the demonstration application will be available for public review and comment.
- Postal and Internet email addresses where written comments may be sent and reviewed by the public, and the timeframe during which comments will be accepted.
- The location, date, and time of at least two public hearings convened by the State to seek public input on the demonstration application.

The September 27, 1994 **Federal Register** notice (59 FR 49249) provided general principles and guidelines governing demonstration projects, as well as a public notice process designed to ensure that interested parties have an opportunity to provide input on State demonstration applications. In proposed § 431.408(a)(2)(i), we have expanded the methods for States to provide public notice that were first outlined in the September 27, 1994 **Federal Register** notice. We propose requiring the State to publish its public notice process, its public input process, planned hearings, and demonstration application(s) either on a 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. Public notice shall also be provided in at least one of the following publications:

- 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
- The newspaper of widest circulation in each city or county with a population of 50,000 or more, provided that such notice is provided at least 30 days prior to the demonstration application's submission to CMS.

If the State utilizes a mechanism, such as an electronic mailing list, to notify interested parties of the demonstration application(s), the State may dispense with the notice procedures in § 431.408(a)(2)(i)(A) and (B).

In § 431.408(a)(3), consistent with the provisions of the Affordable Care Act, we propose that States would hold at least two public hearings regarding the State's demonstration application. These hearings must occur at least 20 days prior to the State's submission of a demonstration application to CMS for review. A State would have broad discretion to select the types of public forums it would rely on, choosing at least two of the following public forums:

- The Medical Care Advisory Committee that operates in accordance with § 431.408; or
- A commission or other similar process, where meetings are open to members of the public; or
- 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
- 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.

For the purposes of developing a coordinated process that is consistent with the provisions of section 5006(e) of the Recovery Act regarding tribal consultation at § 431.408(b), we define State consultation activities to include a consultation to solicit advice from the Indian Tribes, Indian health programs, and Urban Indian Organizations prior to the publication and submission of any application, or extension of a demonstration when it has a direct impact on Indians, Indian health

providers or Urban Indian Organizations.

Under § 431.408(b)(1), we propose that States with federally-recognized Indian tribes, Indian health programs, and/or urban Indian organizations, must include with their demonstration applications (for a new or renewed demonstration) evidence to CMS that the tribes and Indian health programs and Urban Indian Organizations in the State were notified in writing of the State's intent to submit a request for a new demonstration or extension, at least 60 days prior to the anticipated submission date of the demonstration application. This 60-day notice is not new and is consistent with previous guidance on this matter.

Under § 431.408(b)(2), we propose that consultation activities will be conducted in a manner consistent with the State approved consultation process outlined in the State's Medicaid State Plan.

Under § 431.408(b)(4), we propose that documentation of the State's consultation activities should be part of the application for any demonstration submitted to CMS for review and consideration, and must include issues raised and the potential resolution of such issues.

We welcome comments on the requirements proposed in this section of the rule. Specifically, we are interested in receiving comments regarding activities that would provide the public opportunities to provide meaningful input into the development of State demonstration applications while ensuring that the demonstration process can move forward in a timely and efficient manner.

5. Application Procedures: Initial Demonstration Applications Content (§ 431.412(a))

In reviewing section 1115 demonstration applications, CMS requests information from States in order to determine the nature, scope, and impact of the demonstration request. In this rule, we propose 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 would be considered complete for the purposes of initiating the Federal review process described below. A request would be complete, for this purpose, when the State has submitted to CMS the following information:

- A demonstration program description, and goals and objectives that will be implemented under the demonstration project.
- The description of the proposed health care delivery system, eligibility requirements, benefit coverage, and cost sharing (for example, premiums, copayments, and deductibles) required of individuals that will be impacted by the demonstration.
- An estimate of the expected increase or decrease in annual aggregate expenditures by population group impacted by the demonstration. If available, include historic data for these populations.
- An estimate of historic coverage and enrollment data (as appropriate) and estimated projections expected over the term of the demonstration for each category of beneficiary whose health care coverage is impacted by the demonstration.
- Other demonstration program features that require the State to not follow the provisions of the Medicaid and CHIP programs.
- The type of waivers and expenditure authorities that the State believes to be necessary to authorize the demonstration.
- The research hypothesis or 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.
- Written evidence of the State's compliance with the public notice requirements set forth in § 431.408, with a report of key issues raised by the public during the comment period, which shall be no less than 30 days, and how the State took those comments into consideration when developing the demonstration application.

We also propose that after a request for a new demonstration or renewal of existing demonstration is considered complete, CMS may request, or the State may propose application modifications, as well as additional information to aid in the application review. If an application modification substantially changes the original demonstration design, CMS may, at its discretion, direct an additional 30 day public comment period. We also clarify that nothing in this proposed rule precludes 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.

6. Application Procedures: Demonstration Applications (§ 431.412(b))

We propose adding § 431.412(b) to describe 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 would be helpful to States, stakeholders, and CMS in the review of section 1115 demonstrations. We invite comments on the components of this application process.

Under § 431.412(b)(1), we propose to formally notify the State in writing within 15 days of receipt of a complete application for a new demonstration project or extension of an existing demonstration project. This notice triggers the start of the 30-day Federal public comment period. We chose these timeframes and action steps to effectively communicate to States the current status and sequential steps in the demonstration review process. We clarify that this notice of a "complete" application process is based on a preliminary review for the purpose of beginning the public comment period at the Federal level. It does not preclude CMS requests for additional or supplemental information, that would support or inform a final decision on the application, and it also does not prevent the State from supplying any additional information that it determines would aid CMS' review of its application. The notice simply represents a determination that the application is sufficient for the Federal review to commence.

In order to inform the State and the public of the status of the demonstration or proposed activity, under § 431.412(b)(2), we propose to provide the State a written notice within 15 days of receipt of a demonstration application that CMS determines is incomplete. In such notice, CMS will identify the elements missing from the application.

Under § 431.412(b)(3), we propose to publish on our web site at regular intervals the status of all State submissions, including information received from the State while CMS works with the State to meet the demonstration application process set forth in this section.

7. Application Procedures: Demonstration Extension Request (§ 431.412(c))

Generally, demonstrations may be extended up to 3 years under sections 1115(a), 1115(e), and 1115(f) of the Act. 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), we propose that, at least 30 days prior to a State's submission of a request for review under those sections, the State 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, we propose that the State must provide a written summary to CMS of the key 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), we propose that 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.

In § 431.412(c), we propose that a demonstration extension request or phase out plan 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 its discretion, treat the application as an application for a new demonstration.

To ensure an appropriate review of request to extend existing demonstrations and to provide information to the public for purposes of public comment, we propose a list of information States should provide CMS to facilitate public comment on and, CMS review of section 1115 demonstration extensions. In § 431.412(c)(2), we propose that a demonstration extension application submitted by the State will be considered complete by CMS when the State provides the following:

- A historical narrative summary of the demonstration project identifying the objectives set forth at the time the demonstration was approved and evidence of how these objectives have or have not been met, as well as future goals of the demonstration.
- If changes are requested, a narrative of the changes being requested along with the objective of the change and the desired outcomes.
- The types of waivers and expenditure authorities that are being requested in the extension period, or a statement that the State is requesting the same waiver and expenditure authorities as those approved in the current demonstration, as applicable.
- 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 care provided under the demonstration.
- Financial data demonstrating the 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.
- 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.
- Written evidence of the State's compliance with the public notice process set forth in § 431.408, including the post-award public input process described in § 431.420(c) with a report of key issues raised by the public during the comment period and how the State took those comments into consideration when developing the demonstration extension application.

We clarify that, while a request for an extension of a demonstration may preliminarily be considered "complete," it does not preclude CMS requests for additional or supplemental information, to support or inform a final decision on the application, and it also does not prevent the State from supplying any additional information that it determines would aid CMS' review of its application. If an application modification substantially changes the original demonstration design, CMS may, at its discretion, direct an additional 30-day public comment period.

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

We chose the timeframes and action steps outlined in this subpart to effectively communicate to States and concerned stakeholders the current status and sequential steps in the demonstration review process. This approach would standardize and improve transparency in the section 1115 demonstration review process. In addition, by clearly communicating this process, we are striving to minimize confusion around the demonstration review process, satisfy key stakeholders' need for information and improve communication at the Federal level.

In § 431.416(a), we propose that within 15 days of receipt of a complete demonstration application for a new demonstration project or an extension of an existing demonstration project, CMS will send the State a written notice informing the State of the following:

- CMS' receipt of the request.
- The beginning of the 30-day Federal public notice process.

Under § 431.416(b) we propose to solicit public comment for demonstration applications received for at least a 30-day period through a variety of mechanisms, specifically by:

- Publishing demonstration applications and associated concept papers, if any, on the CMS Web site.
- Publishing the written notice of receipt of the State's request for CMS to review and consider the demonstration application.
- Publishing the proposed effective date of the demonstration.
- Publishing where inquiries and comments from the public may be directed to CMS via mail or e-mail.
- Notifying interested parties through an electronic mailing list that CMS will create for this purpose and will be available to all interested parties.
- Additional actions that may be warranted to comply with Federal policies regarding consultation with Indian tribes.

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

For the purpose of advising interested stakeholders of the status of demonstrations under CMS review, CMS proposes to publish on its website at regular intervals appropriate information, which may include, but is not limited to the following:

- Relevant status update(s).
- A listing of the issues raised through the public notice process.

Under § 431.416(d), we propose 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 propose not to render a final decision on a demonstration application until at least 45 days after notice of receipt of a completed application. This accommodates the 30-day notice period, as well as time to review the comments without unduly prolonging the review period. Some demonstration applications are particularly complex and will require a longer review period. The timeframes here provide for the minimum review period except in the case of emergencies.

Under § 431.416(f), we propose to maintain an administrative record which will generally consist of the following:

- The demonstration application from the State.
- Public comments (including Congressional comments) sent to the CMS and any CMS responses.
- For an approved application, the final special terms and conditions, waivers, expenditure authorities, and award letter sent to the State.
- The State's acceptance letter.

We invite comment on all aspects of the demonstration development and review process, including what elements of the administrative record should be posted after a decision has been made, and how CMS can balance the need for transparency and the need for an expeditious review process.

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

For an exception to the normal public notice process to exist, there must be unforeseen circumstances beyond the State's control that makes advance public notice impractical due to unusual circumstances the State could not reasonably foresee including, but not limited to, an emergent occurrence such as fire or earthquake or flood.

The Secretary may grant the State an exception to the normal public notice process or from the timeliness requirement when the State demonstrates all of the following:

- The State acted in good faith.
- The State acted in a diligent, timely, and prudent manner.
- The circumstances constitute an emergency and could not have been reasonably foreseen.
- Delay would undermine or compromise the purpose of the demonstration and be contrary to the interests of the beneficiaries.

9. Monitoring and Compliance (§ 431.420)

As section 1115 demonstrations have a significant impact on beneficiaries, States and the Federal Government, we are proposing processes and methodologies to assure we have adequate and appropriate information regarding the effectiveness of section 1115 demonstrations. Under § 431.420(a), we propose 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. States must, within the timeframes specified in law, regulation, interpretive policy or guidance, come into compliance with any changes in Federal law, regulation, or interpretive policy affecting State demonstration projects, unless the provision being changed is expressly waived or identified as not applicable. States must comply with the terms and conditions of the agreement between the Secretary and the State to implement a State demonstration project or the demonstration will be suspended or terminated in whole or in part by the Secretary.

Under proposed § 431.420(b), as part of the special terms and conditions of any demonstration project, States will conduct periodic evaluations related to the implementation of the demonstration. CMS would review, and when appropriate investigate, 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.

Another manner in which we propose strengthening our public notice procedures first set forth in the September 27, 1994 **Federal Register** notice is the post-implementation public forums. To assure continued public input after the initial 6 months of the demonstration's implementation, and annually thereafter, the States shall hold a public forum to solicit comments on the progress of the demonstration. The public forum must occur using either:

- The Medical Care Advisory Committee that operates in accordance with § 431.408; or
- A State legislative process, 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.

Under § 431.420(c), we propose 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 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.

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 as described in Under § 431.420(e).

Under § 431.420(f), should we undertake an independent evaluation of any component of the demonstration, we propose 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.

10. Evaluation Requirements (§ 431.424)

Under § 431.424(a), we propose 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.

Under proposed § 431.424(b), demonstration evaluations will include the following criteria:

- *Quantitative Research Methods:* Quantitative research methods that involve the systematic empirical investigation of quantitative properties and phenomena and their relationships, are the preferred approach for most demonstrations. CMS will consider alternative evaluation designs when quantitative designs are technically infeasible or not well suited to the change made by the demonstration.
- *Approaches that minimize Beneficiary Impact:* The Secretary is issuing a requirement that the evaluation process must be as un-intrusive as possible to the beneficiaries in terms of implementing and operating the policy approach to be demonstrated,

while ensuring that critical lessons are learned from the demonstration.

Under § 431.424(c), we propose 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 design. The draft evaluation design must include:

- A discussion of the demonstration hypotheses that are being tested including monitoring and reporting on the progress towards the expected outcomes.
- The data to be utilized and the baseline value for each measure.
- The methods of data collection.
- How the effects of the demonstration will be isolated from those other initiatives occurring in the State.
- A proposed date by which a final report on findings from evaluation activities conducted under the evaluation plan must be submitted to CMS.
- Any other information pertinent to the State's summative or formative research via the demonstration operations.

Under proposed § 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, the State should include an interim evaluation report as part of the State's request for each subsequent renewal.

Under § 431.424(e), we propose that States publish the approved demonstration evaluation design on the State's public Web site.

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

Under § 431.424 (g),we propose to post all evaluation materials, including research and data collection, on our Web site for purposes of sharing findings with the public.

11. Reporting Requirements (§ 431.428)

In order for CMS to effectively monitor the implementation of a demonstration, we propose States to submit an annual report, as described in § 431.428(a), documenting the following:

- Any policy or administrative difficulties in the operation of the demonstration.
- The status of the health care delivery system under the demonstration.
- The impact of the demonstration in providing insurance coverage to beneficiaries and uninsured populations.
- Outcomes of care, quality of care, cost of care and access to care for demonstration populations.
- The results of beneficiary satisfaction surveys grievances and appeals.
- The results of any audits or lawsuits that impact the demonstration.
- The financial performance of the demonstration.
- The status of the evaluation and information regarding Progress in achieving demonstration evaluation criteria.
- Any State legislative developments that impact the demonstration.
- The results/impact of any demonstration programmatic area as defined by CMS that is unique to the demonstration design or evaluation hypothesis.
- A summary of the annual post-award public forum, including all public comments received regarding the progress of the demonstration project.

Under § 431.428(b), we propose States to 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.

Given the discretionary nature regarding demonstration approval, CMS is committed to relying on annual reports and other evaluations when making decisions on demonstration changes and renewals including information in such reports and whether the State has complied with reporting requirements.

III. 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

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 a previously approved 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, an extension of a previously approved demonstration project will require 40 hours to comply with the requirements in this section. The estimated annual burden associated with this section is 600 hours at a cost of $12,402.00.

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. 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 at § 431.408(a)(2)(i) through (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 publication listed at § 431.408(a)(2)(i) through (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 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 Organizations or all three of the aforementioned entities, to consult with the Indian tribes, Indian Health programs and Urban Indian Organizations in the State, before submitting a demonstration application. Section 431.408(b)(2) specifies that consultation activities must be conducted in a manner consistent with the State approved consultation process outlined in the State's Medicaid State Plan. Section 431.408(b)(3) further specifies that the State must submit evidence to CMS that the Indian Tribes, Indian Health programs, and Urban Indian Organizations were notified in writing of the State's intent to submit an application for a new demonstration project, or an extension of an existing demonstration project, at least 60 days prior to the anticipated submission date of the application. Section 431.408(b)(4) explains that documentation of the State's consultation activities must be included in the demonstration application, such as, the date and location of the consultation and must include issues raised and the potential resolution for such issues.

The burden associated with these is both the time and effort necessary for a State to conduct its tribal consultations and the time and effort necessary to notify CMS of the State's compliance with § 431.408(b)(3). 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, notify the Indian Tribes in writing of its intent to submit 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 $12,402.00.

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. 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, 5 applications annually. Similarly we estimate that it will take 200 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 1000 hours at a cost of $20,067.00.

Section 431.412(c) specifies that a State must submit a request to extend an existing demonstration under sections 1115(a), (e) and (f) of the Act at least 12 months prior to the expiration date of the 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. The total estimated annual burden is 1600 hours at a cost of $33,072.00.

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 40 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 600 hours at a cost of $12,402.00.

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)(1)(i) through (ii) 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)(1)(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 proposed 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. 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 80 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 1,200 hours at a cost of $24,804.00.

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 renewal 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 80 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 800 hours at a cost of $16,536.00.

Section 431.424(e) established that States will publish CMS-approved demonstration evaluation designs on their State public Web site. We estimate that it will take 36 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 540 hours at a cost of $11,161.80.

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 24 hours for each State to comply with this reporting requirement. We further estimate that the total estimated annual burden associated with this requirement is 360 hours at a cost of $7,441.20.

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. The burden associated with 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 2 hours to comply with this requirement. The total estimated annual burden associated with this requirement is 30 hours at a cost of $620.10.

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	40	600	20.67	12,402.00	0	12,402.00
§ 431.408(b)	0938–New	15	1	40	600	20.67	12,402.00	0	12,402.00
§ 431.412(a) and (b)	0938–New	5	1	200	1000	20.67	20,067.00	0	20,067.00
§ 431.412c	0938–New	10	1	160	1600	20.67	33,072.00	0	33,072.00
§ 431.420	0938–New	15	1	40	600	20.67	12,402.00	0	12,402.00
§ 431.424(c)	0938–New	15	1	80	1,200	20.67	24,804.00	0	24,804.00
§ 431.424(d)	0938–New	10	1	80	800	20.67	16,536.00	0	16,536.00
§ 431.424(e)	0938–New	15	1	36	540	20.67	11,161.80	0	11,161.80
§ 431.428(b)	0938–New	15	1	24	360	20.67	7,441.20	0	7,441.20
§ 431.428(b)(2)	0938–New	15	1	2	30	20.67	620.10	0	620.10
Total	.....	130	10	.....	7,330	.....	150,908.10	0	150,908.10

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS–2325–P];

Fax: (202) 395–6974; or

E-mail: OIRA_submission@omb.eop.gov.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 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 Order 12866 directs 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). A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects of $100 million or more in any 1 year. This proposed rule is estimated to have an overall economic impact of $113,726.90 annually. 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 of small businesses, 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 proposed rule would 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 proposed rule would 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 2010, that threshold is approximately $135 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 would not mandate expenditures in the threshold amount of $135 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. As CMS was considering potential proposals to make in this proposed rule, CMS conducted a listening session in May 2010 with more than 20 representatives of stakeholder organizations and also held a separate listening session open to officials from all 50 States, the District of Columbia and U.S. Territories. The stakeholder representatives expressed concern that the policies employed in demonstrations have far-reaching impact, yet can happen with little meaningful stakeholder input into policy development at the Federal and State levels. They also expressed the view that since demonstrations allow States to "not comply" with requirements that the Congress put into law, the need for meaningful public input into these demonstrations is great. States agreed that public input is important, and while some States expressed concern that new requirements established by CMS could be potentially burdensome, other States reported that their existing public notice requirements and existing State legislative processes were strong and sufficient enough to ensure meaningful public input at the State level. Since this regulation will not impose substantial direct costs on State or local governments, the requirements of Executive Order 13132 are not applicable. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 431

Health care, Health insurance, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services propose to amend 42 CFR chapter IV as follows:

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

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 title XIX or XXI.

(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.

§ 431.402 Coordination with section 1332 waivers.

(a) *States may apply jointly.* States may submit a single application for waivers under section 1332 of the Affordable Care Act and demonstration projects under section 1115 of the Act that involve titles VIII, XIX, and XXI of the Act, provided that such application complies with the procedural requirements for section 1332 waivers, as described at 45 CFR part 155, and the procedural requirements described in this part.

(b) [Reserved]

§ 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.

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.

Section 1332 waiver means a Waiver for State Innovation under section 1332 of the Affordable Care Act.

§ 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 to be submitted to CMS, 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 be 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 changes to the demonstration requested by the State.

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

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

(iii) Postal and Internet e-mail addresses where written comments may be sent and reviewed by the public, and the timeframe during 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, and the demonstration application(s) 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. The State shall also publish the public notice in at least one of the following publications:

(A) 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

(B) The newspaper of widest circulation in each city or county with a population of 50,000 or more, provided that such notice is provided at least 30 days prior to the submission of the demonstration application to CMS.

(ii) If the State utilizes a mechanism, such as an electronic mailing list, to notify interested parties of the demonstration application(s), the State may dispense with the notice procedures in paragraphs (a)(2)(ii)(A) and (B) of this section.

(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 regarding the State's demonstration application using at least two of the following public forums:

(i) The Medical Care Advisory Committee that operates in accordance with § 431.408; 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) *Tribal consultation.* A State with federally recognized Indian tribes, Indian health programs, and/or Urban Indian Organizations shall include a process to consult with the Indian tribes, Indian Health programs and Urban Indian 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.

(1) The consultation with the federally-recognized Indian tribes, Indian health programs and Urban Indian Organizations must occur 60 days prior to the publication and submission of an application for a new demonstration project or a renewal for a previously approved demonstration project when it has a direct impact on Indians, Indian health providers or Urban Indian Organizations.

(2) The consultation activities must be conducted in a manner consistent with the State approved consultation process outlined in the State's Medicaid State Plan.

(3) The State must include in its application evidence that the Indian Tribes and Indian Health programs and Urban Indian Organizations were notified in writing of the State's intent to submit an application for a new demonstration project or a renewal of a previously approved demonstration project, at least 60 days prior to the anticipated submission date of the application.

(4) Documentation of the State's consultation activities must be included in the demonstration application, such as, the date and location of the consultation and must include issues raised and the potential resolution for such issues.

§ 431.412 Application procedures.

(a) *Initial demonstration applications 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 part, and includes 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, co-payments, and deductibles) required of individuals that 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 type of waivers 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 evidence of the State's compliance with the public notice requirements set forth in § 431.408, with a report of the key issues raised by the public during the comment period, which shall be no less than 30 days, and whether 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.

(b) *Demonstration applications 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 should comply with all applicable civil rights requirements related to accessibility, including the requirements under Section 508 of the Americans with Disabilities Act.

(1) As per § 431.416(a), 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 and the start date of the 30-day Federal public notice process set forth in § 431.416. Such notice 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. It also 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. 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 care provided under the demonstration.

(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) Written evidence of the State's compliance with the public notice process set forth in § 431.408, including the post-award public input process described in § 431.420(c) of this part, with a report of the key issues raised by the public during the comment period and whether 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.

(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 send the State a written notice informing the State of receipt of the 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.

(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, if any.

(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 e-mail.

(2) Notifying interested parties through 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.* CMS will publish all comments electronically. CMS will review and consider all such comments, but will not provide written responses to public comments.

(e) *Approval of a demonstration application.* CMS will not render a final decision on a demonstration application until at least 45 days after notice of receipt of a completed application, in order to receive and consider public comments. However, CMS may expedite this process under the exception to the normal public notice process provisions in Section § 431.416(g).

(f) *Administrative record.* CMS will maintain an administrative record that may include, but is not limited to the following:

(1) The demonstration application from the State.

(2) Public comments sent to the CMS and any CMS responses.

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

(4) The State acceptance letter.

(g) *Exception to the normal public notice process.* CMS may exercise its discretionary authority to bypass, in whole or in part, the Federal and State public notice procedures in order to expedite a decision on a proposed demonstration or demonstration renewal that addresses a natural, social, economic or similar disaster.

(1) The Secretary may exempt a State from the normal public notice process or the required time constraints imposed in this section or paragraph (a) of § 431.408 when the State demonstrates to CMS there is the existence of unforeseen circumstances that warrant an exception to the normal public notice process. The State is expected to discharge its basic responsibilities in submitting demonstration applications to the Secretary as required in § 431.412 of this subpart. Such applications will be posted on the CMS Web site.

(2) An exception from the normal public notice process exists when the Secretary finds that there are unforeseen circumstances beyond the State's control that makes full compliance with the public notice and comment provision impractical, including, but not limited to, an emergent occurrence such as fire or earthquake or flood.

(3) A State must establish (or meet) all of the following criteria to obtain an exception from the normal public notice process or the timeliness requirement set forth in § 431.408(a) of this subpart:

(i) The State acted in good faith.

(ii) The State acted in a diligent, timely, and prudent manner.

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

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

§ 431.420 Monitoring and compliance.

(a) *General.* (1) States must comply with all applicable Federal laws, regulations, interpretive policy statements and interpretive guidance unless expressly waived by the demonstration. States must, within the timeframes specified in law, regulation, policy or guidance, come into compliance with any changes in Federal law, regulation, or policy affecting State demonstration projects, unless the provision being changed is expressly waived or identified as not applicable.

(2) States must comply with the terms and conditions of the agreement between the Secretary and the State to implement a State demonstration project or the demonstration will be suspended or terminated, in whole or in part, by the Secretary.

(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.

(c) *Post award.* Within 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. The State must hold the public forum in such time as to include a summary of the forum in its annual report to CMS.

(1) 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 § 431.408.

(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.

(2) [Reserved]

(d) *Terminations and suspensions.* The Secretary reserves the 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.

(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 true experimental, scientific, and qualitative designs) in the application of evaluation techniques with CMS' approval.

(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 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.

(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) 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.* 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. State evaluations must be published on the state's public Web site.

(e) *Approved evaluation designs.* The State must publish the CMS-approved demonstration evaluation design on the State's public Web site.

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

(g) *Federal public notice.* CMS will post all evaluation materials, including research and data collection, on its Web site for purposes of sharing findings with the public.

§ 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.

(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 grievances and appeals.

(6) The results of any audits 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 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.

(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 draft and final annual reports are to be published on the State's public Web site.

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

Dated: August 16, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: September 9, 2010.

Kathleen Sebelius,

Secretary of Health and Human Services.

[FR Doc. 2010–23357 Filed 9–16–10; 8:45 am]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Chapter 2

Defense Federal Acquisition Regulation Supplement; Material Inspection and Receiving Report (DFARS Case 2009–D023)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule with request for comments.

SUMMARY: DoD is issuing a proposed rule to update Defense Federal Acquisition Regulation Supplement (DFARS), Appendix F, Material Inspection and Receiving Report, to incorporate procedures for using the electronic Wide Area Workflow Receiving Report required for use in most contracts in lieu of the DD Form 250, Material Inspection and Receiving Report, which is now used mostly on an exception basis.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before November 16, 2010, to be considered in the formation of the final rule.

ADDRESSES: Respondents may submit comments via the Internet at *http://www.regulations.gov.* As an alternative, respondents may e-mail comments to *dfars@osd.mil.* Please cite DFARS Case 2009–D023 in the subject line of e-mailed comments.

Respondents that cannot submit comments using either of the above methods may submit comments to: Defense Acquisition Regulations System, OUSD(AT&L)DPAP/DARS, Attn: Ms. Mary Overstreet, 3060 Defense Pentagon, Room 3B855, Washington, DC