

Board of Governors of the Federal Reserve System, February 24, 2011.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 2011-4487 Filed 2-28-11; 8:45 am]

**BILLING CODE 6210-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Secretary's Advisory Committee on Human Research Protections; Notice of Meeting

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office for Human Research Protections.

**ACTION:** Notice.

**SUMMARY:** Pursuant to Section 10(a) of the Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C. App.), notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold its twenty-fourth meeting. The meeting will be open to the public. Information about SACHRP and the meeting agenda will be posted on the SACHRP Web site at: <http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html>.

**DATES:** The meeting will be held on Tuesday, March 8, 2011 from 8:30 a.m. until 5 p.m. and Wednesday, March 9, 2011 from 8:30 a.m. until 5 p.m.

**ADDRESSES:** U.S. Department of Health and Human Services, 200 Independence Avenue, SW., Hubert H. Humphrey Building, Room 800, Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:** Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections, or Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; 240-453-6900, fax: 240-453-6909; e-mail address: [Julia.Gorey@hhs.gov](mailto:Julia.Gorey@hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects.

On March 8, 2011, SACHRP will hear a panel presentation on the work of the Federal Demonstration Partnership,

followed by discussion. This will be followed by the report of the Subpart A Subcommittee (SAS), focusing on improvements to the informed consent process. SAS is charged with developing recommendations for consideration by SACHRP about the application of subpart A of 45 CFR part 46 in the current research environment. This subcommittee was established by SACHRP at its October 2006 meeting. The afternoon will close with a panel presentation on the reporting and return of individual research results, including issues associated with the Clinical Laboratory Improvement Amendments.

On March 9, 2011, the morning will open with a panel discussion on the reporting and return of aggregate research results, including a report on the status of ClinicalTrials.gov. The Subcommittee on Harmonization (SOH) will end the meeting with a report on their work to date. The SOH was established by SACHRP at its July 2009 meeting, and is charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination. Public comment will be heard on both days. Public attendance at the meeting is limited to space available. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact persons. Members of the public will have the opportunity to provide comments on both days of the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed materials distributed to SACHRP members for this scheduled meeting should submit materials to the Executive Director, SACHRP, prior to the close of business on March 4, 2011.

An unforeseen administrative matter delayed this notice being submitted to the **Federal Register** for publication.

Dated: February 23, 2011.

**Jerry Menikoff,**

*Director, Office for Human Research Protections, Executive Secretary, Secretary's Advisory Committee on Human Research Protections.*

[FR Doc. 2011-4473 Filed 2-28-11; 8:45 am]

**BILLING CODE 4150-36-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-185, CMS-10303 and CMS-10379]

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of currently approved collection; *Title of Information Collection:* Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and of State Exemption Under State Laboratory Programs and Supporting Regulations; *Form No.:* CMS-R-185 (OMB#: 0938-0686); *Use:* The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation/licensure process is at least equal to or more stringent than those of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). If an accreditation organization is approved, the laboratories that it accredits are "deemed" to meet the CLIA requirements based on this accreditation. Similarly, if a State licensure program is determined to have requirements that are equal to or more stringent than those of CLIA, its laboratories are considered to be exempt from CLIA certification and requirements. The information collected will be used by HHS to: determine comparability/equivalency of the accreditation organization standards

and policies or State licensure program standards and policies to those of the CLIA program; to ensure the continued comparability/equivalency of the standards; and to fulfill certain statutory reporting requirements; *Frequency*: Occasionally; *Affected Public*: Private Sector: Business or other for-profits, Not-for-profit institutions; *Number of Respondents*: 8; *Total Annual Responses*: 96; *Total Annual Hours*: 384. (For policy questions regarding this collection contact Minnie Christian at 410-786-3339. For all other issues call 410-786-1326.)

**2. Type of Information Collection**  
*Request*: Revision of currently approved collection; *Title of Information*: Medicare Gainsharing Demonstration Evaluation: Physician Focus Groups; *Use*: The proposed physician focus groups are part of the evaluation of the Centers for Medicare and Medicaid Services (CMS)'s Medicare Physician Hospital Collaboration Demonstration. The Congress, under Section 646 of the Medicare Modernization Act (MMA) of 2003 permitted CMS to conduct demonstrations to test methods for the provision of incentives for improving the quality and safety of care and achieving the efficient allocation of resources. The primary goal of the demonstration is to evaluate gainsharing as means to align physician and hospital incentives to improve quality and efficiency. This demonstration plans to use the physician focus group protocols approved by OMB for the DRA 5007 Gainsharing Demonstration. *Form Number*: CMS-10303 (OMB#: 0938-1103); *Frequency*: Once; *Affected Public*: Private Sector, Business or other for profits; *Number of Respondents*: 288; *Total Annual Responses*: 144; *Total Annual Hours*: 144 (For policy questions regarding this collection contact William Buczko at 410-786-6593. For all other issues call 410-786-1326.)

**3. Type of Information Collection**  
*Request*: New Collection; *Title of Information Collection*: Rate Increase Disclosure and Review Reporting Requirements (45 CFR Part 154) *Use*: Under the Section 1003 of the Affordable Care Act (Section 2794 of the Public Health Service Act), the Secretary, in conjunction with the States, is required to establish a process for the annual review, beginning with the 2010 plan year, of unreasonable increases in premiums for health insurance coverage. Section 2794 directs the Secretary to ensure the public disclosure of information of unreasonable rate increases and justification for those increases.

### General Information

On December 23, 2010, HHS published a proposed regulation in the **Federal Register** defining the unreasonable rate review process and issuer reporting and disclosure requirements (Rate Increase Disclosure and Review Proposed Rule, 75 FR 81004). The proposed regulation establishes the following reporting requirements:

- **The Preliminary Justification**: This data collection is required of all health insurance issuers for all rate increases that exceed the "subject to review" reporting threshold as defined in the proposed rule. This information will be posted on an HHS Web site.
- **Rate Review Final Determination**: This data collection requires States with effective rate review programs and HHS to report their review findings and unreasonable rate increase determinations on all rate increases that are subject to review. This information will be posted on an HHS Web site.
- **The Final Justification for an Unreasonable Rate Increase**: This data collection is required of health insurance issuers that elect to implement a rate increase that is determined to be unreasonable based on State or HHS review. This information will be posted on the Health Insurance Issuer's Web site and on an HHS Web site.

### Preliminary Justification

CCIIO is also requesting comments on the presentation and content of the consumer information contained in Parts I and II of the Preliminary Justification. Specifically, CCIIO would like comments on the usefulness and clarity of this information for consumers. Additionally, the Preliminary Justification is designed to limit burden on health insurance issuers by collecting data that most issuers should have readily available either through their State rate filing requirements or internal rate making analysis. CCIIO is requesting comments on the extent to which the data elements and definitions utilized in the Preliminary Justification align with current industry data collection and reporting standards.

The Preliminary Justification consists of three parts, Part I: Rate Increase Summary, Part II: Written Explanation of the Rate Increase, and Part III: Rate Filing Documentation. Issuers must complete Parts I and II for all rate increases that exceed the reporting threshold as defined in the proposed rule. As described in the preamble of the proposed rule, this information

would be collected to provide consumers with basic information on all rate increases that are subject to review under the rate review program. Under the proposed rule, "subject to review" rate increases would be reviewed by either States or HHS, depending on whether a State has an effective rate review program. Issuers would only be required to submit Part III of the Preliminary Justification when HHS is conducting the review of a "subject to review" rate increase. Accordingly, Part III requires health insurance issuers to provide detailed rate data that would be used for the purposes of conducting thorough actuarial reviews and for making determinations about whether rate increases are unreasonable. This Notice contains the following information about the Preliminary Justification:

- **Preliminary Justification Issuer Instructions**: Health insurance issuer instructions for completing all three parts of the Preliminary Justification.
- **Part I Worksheet**: A standardized Excel worksheet that must be used to complete Part I of the Preliminary Justification.
- **Sample internet display of the Rate Review Consumer Disclosure**: Information provided in the Preliminary Justification would be posted on an HHS Web site. This sample display shows how the information contained in the Part I Worksheet would be displayed to consumers.

### Rate Review Final Determination

Under the proposed rule States and HHS would have to provide a Rate Review Final Determination at the close of their review of all "subject to review" rate increases. The Rate Review Final Determination must provide the State's or HHS' determination on whether a rate increase is 'unreasonable'. Section 154.301(a)(3) of the proposed rule provides a list of actuarial review elements that must be taken into account as part of the rate review process. The Final Determination must provide a brief statement explaining how the review of elements set forth in § 154.301(a)(3) caused the State or HHS to arrive at its determination that the rate is unreasonable.

The Rate Review Final Determination will be entered into a data entry text box in the Rate Review Data Collection System. HHS is estimating that this statement would be approximately a paragraph in length. There is no specific form or set of instructions associated with this reporting requirement, apart from the reporting requirements provided in the proposed rule. The information provided in the Rate

Review Final Determination will be posted as part of the rate review consumer disclosure information on an HHS Web site.

**Final Justification for an Unreasonable Rate Increase**

The proposed rule states that if a health insurance issuer implements a rate increase determined by HHS or a State to be unreasonable, the health insurance issuer must provide a Final Justification for an Unreasonable Rate Increase. In the Final Justification, issuers would have to provide a short statement about why they are electing to implement an unreasonable rate increase. This statement would be entered into a data entry text box in the Rate Review Data Collection System and would not need to be more than a paragraph or two in length. There is no form or instructions associated with this statement apart from the requirements provided in the proposed regulation.

The Final Justification Statement will be posted on an HHS Web site in the same location as the Preliminary Justification and Rate Review Final Determination. Additionally, health insurance issuers implementing rate increases that were determined to be unreasonable, must post all of this information—the Preliminary Justification, the Rate Review Final Determination, and the Final Justification Statement on their Web sites for a period of 3 years.

Form Number: CMS-10379; (OMB Control No. 0938-NEW) *Frequency:* Annually; *Affected Public:* Private Sector; *Number of Respondents:* 1,543 *Number of Responses:* 1,546; *Total Annual Hours:* 8,418. (For policy questions regarding this collection, contact Sally McCarty at (301) 492-4489 or RateReview@hhs.gov. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-

mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office at 410-786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *May 2, 2011*:

1. Electronically. You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. By regular mail. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: February 23, 2011.

**Martique Jones,**

*Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2011-4552 Filed 2-25-11; 11:15 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Child Care and Development Fund Tribal Plan Preprint—ACF-118-A.

*OMB No.:* 0970-0198.

*Description:* The Child Care and Development Fund (CCDF) Plan (the Plan) for Tribes (Indian Tribes, Tribal consortia and Tribal organizations) is

required from each CCDF Lead agency in accordance with Section 658E of the Child Care and Development Block Grant Act of 1990, as amended (Pub. L. 101-508, Pub. L. 104-193, and 42 U.S.C. 9858). The implementing regulations for the statutorily required Plan are set forth at 45 CFR 98.10 through 98.18. The Plan, submitted on the ACF 118-A, is required biennially, and remains in effect for two years. The Plan provides ACF and the public with a description of, and assurance about, the Tribal child care program. The ACF 118-A is currently approved through September 30, 2011, making it available to Tribes needing to submit Plan Amendments through the end of the FY 2011 Plan Period. However, on July 1, 2011, Tribes will be required to submit their FY 2012-2013 Plans for approval by September 30, 2011. Consistent with the statute and regulations, ACF requests revision of the ACF 118-A with minor corrections and modifications.

The Office of Child Care(OCC) has given thoughtful consideration to the comments received from the 1st Public Notice. OCC has revised the document to reflect some of the changes made to minimize the burden of the collection of information on respondents. The revised document contains revisions to improve the accuracy and clarity of questions in order to improve the quality of information that is collected. This second Public Comment Period provides an opportunity for the public to submit comments to the Office of Management and Budget (OMB).

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*Respondents:*

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CCDF Tribal Plan .....	257	0.5	120	15,420

*Estimated Total Annual Burden Hours:* 15,420.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for

Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests

should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the