

[medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAA&](http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAA&). We will no longer be providing paper copies of the handouts for the meeting. Electronic copies of all the meeting materials will be on the CMS Web site no later than 2 business days before the meeting. We encourage the participation of appropriate organizations with expertise in TRD clinical research. This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, we may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 4, 2016. Your comments should focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following Web site prior to the meeting: <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAA&>. We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed. Speakers presenting at the MEDCAC meeting should include a full disclosure slide as their second slide in their presentation for financial interests (for example, type of financial association—consultant, research support, advisory board, and an indication of level, such as minor association < \$10,000 or major association > \$10,000) as well as intellectual conflicts of interest (for example, involvement in a federal or nonfederal advisory committee that has discussed the issue) that may pertain in any way to the subject of this meeting. If you are representing an organization, we require that you also disclose conflict of interest information for that organization. If you do not have a PowerPoint presentation, you will need to present the full disclosure information requested previously at the beginning of your statement to the Committee.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the

chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register online at <http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3> or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone number(s), fax number, and email address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified that the seating capacity has been reached.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a federal government building; therefore, federal security measures are applicable. The Real ID Act, enacted in 2005, establishes minimum standards for the issuance of state-issued driver's licenses and identification (ID) cards. It prohibits Federal agencies from accepting an official driver's license or ID card from a state unless the Department of Homeland Security determines that the state meets these standards. Beginning October 2015, photo IDs (such as a valid driver's license) issued by a state or territory not in compliance with the Real ID Act will not be accepted as identification to enter Federal buildings. Visitors from these states/territories will need to provide alternative proof of identification (such as a valid passport) to gain entrance into CMS buildings. The current list of states from which a Federal agency may accept driver's licenses for an official purpose is found at <http://www.dhs.gov/real-id-enforcement-brief>. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.

- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.

- Inspection, via metal detector or other applicable means, of all persons entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

V. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Authority: 5 U.S.C. App. 2, section 10(a).

Dated: February 18, 2016.

Kate Goodrich,

Director, Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10407]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect

information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the 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.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by March 28, 2016.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 *OR*, Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies

must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Summary of Benefits and Coverage and Uniform Glossary; *Use:* The Affordable Care Act amends the Public Health Service Act (PHS Act) by adding section 2715 "Development and Utilization of Uniform Explanation of Coverage Documents and Standardized Definitions." This section directs the Secretary, in consultation with the National Association of Insurance Commissioners (NAIC) and a working group comprised of stakeholders, to develop standards for use by a group health plan and a health insurance issuer in compiling and providing to applicants, enrollees, and policyholders and certificate holders a summary of benefits and coverage (SBC) explanation that accurately describes the benefits and coverage under the applicable plan or coverage. Section 2715 also requires 60-days advance notice of any material modification in any of the terms of the plan or coverage that is not reflected in the most recently provided summary and the development of standards for the definitions of terms used in health insurance coverage.

This information collection will ensure that approximately 90 million consumers shopping for or enrolled in private, individually purchased, or non-federal governmental group health plan coverage receive the consumer

protections of the Affordable Care Act. Employers, employees, and individuals will use this information to compare coverage options prior to selecting coverage and to understand the terms of, and extent of medical benefits offered by, their coverage (or exceptions to such coverage or benefits) once they have coverage. The Departments received comments in response to the ICR and they have been addressed in the Appendix. *Form Number:* CMS-10407 (OMB Control Number: 0938-1146); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments, Private Sector; *Number of Respondents:* 126,544; *Total Annual Responses:* 41,154,000; *Total Annual Hours:* 324,853. (For policy questions regarding this collection contact Michelle Koltov at (301) 492-4225).

Date: February 24, 2016.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Head Start Grant Application and Budget Instruments.

OMB No.: 0970-0207.

Description: The Office of Head Start is proposing to renew, without changes, the Head Start Grant Application and Budget Instrument, which standardizes the grant application information that is requested from all Head Start and Early Head Start grantees applying for continuation grants. The application and budget forms are available in a password-protected, Web-based system. Completed applications can be transmitted electronically to Regional and Central Offices. The Administration for Children and Families believes that this application form makes the process of applying for Head Start program grants more efficient for applicants.

Respondents: Head Start and Early Head Start grantees.