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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10243]

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

AGENCY: Centers for Medicare & Medicaid Services, HHS.

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 September 6, 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:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Testing Experience and Functional Tools: Functional Assessment Standardized Items (FASI) Based on the CARE Tool; *Use:* In 2012, CMS funded a project entitled, Technical Assistance to States for Testing Experience and Functional Tools (TEFT) Grants. One component of this demonstration is to amend and test the reliability of a setting-agnostic, interoperable set of data elements, called "items," that can support standardized assessment of individuals across the continuum of care. Items that were created for use in post-acute care settings using the Continuity Assessment Record and Evaluation (CARE) tool have been adopted, modified, or supplemented for use in community-based long-term services and supports (CB-LTSS) programs. This project will test the reliability and validity of the function-related assessment items, now referred to as Functional Assessment Standardized Items (FASI), when applied in community settings, and in various

populations: Elders (65 years and older); younger adults (18-64) with physical disabilities; and adults of any age with intellectual or developmental disabilities, with severe mental illness, or with traumatic brain injury.

Individual-level data will be collected two times using the TEFT FASI Item Set. The first data collection effort will collect data that can be analyzed to evaluate the reliability and validity of the FASI items when used with the five waiver populations. Assessors will conduct functional assessments in client homes using the TEFT FASI Item Set. Changes may be recommended to individual TEFT FASI items, to be made prior to releasing the TEFT FASI items for use by the states. The FASI Field Test Report will be released to the public.

The second data collection will be conducted by the states to demonstrate their use of the FASI data elements. The assessment data could be used by the states for multiple purposes. They may use the standardized items to determine individual eligibility for state programs, or to help determine levels of care within which people can receive services, or other purposes. In the second round of data collection, states will demonstrate their proposed uses, manage their FASI data collection and conduct their own analysis, to the extent they propose to do such tasks. The states have been funded under the demonstration grant to conduct the round 2 data collection and analysis. These states will submit reports to CMS describing their experience in the Round 2 data collection, including the items they collected, how they planned to use the data, and the types of challenges and successes they encountered in doing so. The reports may be used by CMS in their evaluation of the TEFT grants.

Subsequent to the publication of our 60-day **Federal Register** notice (May 2, 2016; 81 FR 26235), we have made several minor modifications to the form. The changes are intended to further protect participant identification and improve the response efficiency by removing several checkboxes that we were using for item screening purposes. The instructions were revised accordingly. The revisions have no impact on our 60-day burden estimates. *Form Number:* CMS-10243 (OMB control number: 0938-1037); *Frequency:* On occasion; *Affected Public:* Individuals and Households; *Number of Respondents:* 5,650; *Total Annual Responses:* 5,650; *Total Annual Hours:* 2,825. (For policy questions regarding this collection contact Allison Weaver at 410-786-4924.)

Dated: August 2, 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

Centers for Medicare & Medicaid Services

[CMS-3335-N]

Medicare Program; Request for Nominations for Members for the Medicare Evidence Development & Coverage Advisory Committee

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: This notice announces the request for nominations for membership on the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). Among other duties, the MEDCAC provides advice and guidance to the Secretary of the Department of Health and Human Services (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) concerning the adequacy of scientific evidence available to CMS in making coverage determinations under the Medicare program.

The MEDCAC reviews and evaluates medical literature and technology assessments, and hears public testimony on the evidence available to address the impact of medical items and services on health outcomes of Medicare beneficiaries.

DATES: Nominations must be received by Tuesday, September 6, 2016.

ADDRESSES: You may mail nominations for membership to the following address: Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Attention: Maria Ellis, 7500 Security Boulevard, Mail Stop: S3-02-01, Baltimore, MD 21244 or send via email to MEDCACnomination@cms.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Maria Ellis, Executive Secretary for the MEDCAC, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Coverage and Analysis Group, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410-786-0309) or via email at Maria.Ellis@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary signed the initial charter for the Medicare Coverage Advisory Committee (MCAC) on November 24, 1998. A notice in the **Federal Register** (63 FR 68780) announcing establishment of the MCAC was published on December 14, 1998. The MCAC name was updated to more accurately reflect the purpose of the committee and on January 26, 2007, the Secretary published a notice in the **Federal Register** (72 FR 3853), announcing that the Committee's name changed to the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). The current Secretary's Charter for the MEDCAC is available on the CMS Web site at: <http://www.cms.hhs.gov/FACA/Downloads/medcaccharter.pdf>, or you may obtain a copy of the charter by submitting a request to the contact listed in the **FOR FURTHER INFORMATION** section of this notice.

The MEDCAC is governed by provisions of the Federal Advisory Committee Act, Pub. L. 92-463, as amended (5 U.S.C. App. 2), which sets forth standards for the formulation and use of advisory committees, and is authorized by section 222 of the Public Health Service Act as amended (42 U.S.C. 217A).

We are requesting nominations for candidates to serve on the MEDCAC. Nominees are selected based upon their individual qualifications and not solely as representatives of professional associations or societies. We wish to ensure adequate representation of the interests of both women and men, members of all ethnic groups, and physically challenged individuals. Therefore, we encourage nominations of qualified candidates who can represent these interests.

The MEDCAC consists of a pool of 100 appointed members including: 94 at-large standing members (6 of whom are patient advocates), and 6 representatives of industry interests. Members generally are recognized authorities in clinical medicine including subspecialties, administrative medicine, public health, biological and physical sciences, epidemiology and biostatistics, clinical trial design, health care data management and analysis, patient advocacy, health care economics, medical ethics or other relevant professions.

The MEDCAC works from an agenda provided by the Designated Federal Official. The MEDCAC reviews and evaluates medical literature and technology assessments, and hears

public testimony on the evidence available to address the impact of medical items and services on health outcomes of Medicare beneficiaries. The MEDCAC may also advise the Centers for Medicare & Medicaid Services (CMS) as part of Medicare's "coverage with evidence development" initiative.

II. Provisions of the Notice

As of January 2017, there will be 31 membership terms expiring. Of the 31 memberships expiring, 3 are industry representatives, 1 is a patient advocate, and the remaining 27 membership openings are for the at-large standing MEDCAC membership.

All nominations must be accompanied by curricula vitae. Nomination packages should be sent to Maria Ellis at the address listed in the **ADDRESSES** section of this notice. Nominees are selected based upon their individual qualifications. Nominees for membership must have expertise and experience in one or more of the following fields:

- Clinical medicine including subspecialties
- Administrative medicine
- Public health
- Biological and physical sciences
- Epidemiology and biostatistics
- Clinical trial design
- Health care data management and analysis
- Patient advocacy
- Health care economics
- Medical ethics
- Other relevant professions

We are looking particularly for experts in a number of fields. These include cancer screening, genetic testing, clinical epidemiology, psychopharmacology, screening and diagnostic testing analysis, and vascular surgery. We also need experts in biostatistics in clinical settings, dementia treatment, minority health, observational research design, stroke epidemiology, and women's health.

The nomination letter must include a statement that the nominee is willing to serve as a member of the MEDCAC and appears to have no conflict of interest that would preclude membership. We are requesting that all curricula vitae include the following:

- Date of birth
- Place of birth
- Social security number
- Title and current position
- Professional affiliation
- Home and business address
- Telephone and fax numbers
- Email address
- List of areas of expertise

In the nomination letter, we are requesting that nominees specify