

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

whether they are applying for a patient advocate position, for an at-large standing position, or as an industry representative. Potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts in order to permit evaluation of possible sources of financial conflict of interest. Department policy prohibits multiple committee memberships. A federal advisory committee member may not serve on more than one committee within an agency at the same time.

Members are invited to serve for overlapping 2-year terms. A member may continue to serve after the expiration of the member's term until a successor is named. Any interested person may nominate one or more qualified persons. Self-nominations are also accepted. Individuals interested in the representative positions must include a letter of support from the organization or interest group they would represent.

Dated: July 26, 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-10340 and CMS-10630]

Agency Information Collection Activities: Proposed Collection; 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including

any of the following subjects: The necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by October 4, 2016.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send 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) that are 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.

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:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10340 Collection of Encounter Data From: Medicare Advantage Organizations, Section 1876 Cost HMOs/CMPS, Section 1833 Health

Care Prepayment Plans (HCPPS), and PACE Organizations
CMS-10630 The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460

Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Collection of Encounter Data From: Medicare Advantage Organizations, Section 1876 Cost HMOs/CMPS, Section 1833 Health Care Prepayment Plans (HCPPS), and PACE Organizations; *Use:* We collect encounter data or data on each item or service delivered to enrollees of Medicare Advantage (MA) plans offered by MA organizations. The MA organizations currently obtain this data from providers. We collect this information using standard transaction forms and code sets. We will use the data for determining risk adjustment factors for payment, updating the risk adjustment model, calculating Medicare DSH percentages, Medicare coverage purposes, and quality review and improvement activities. The data is also used to verify the accuracy and validity of the costs claimed on cost reports. For PACE organizations, encounter data would serve the same purpose it does related to the MA program and would be submitted in a similar manner. *Form Number:* CMS-10340 (OMB control number: 0938-1152); *Frequency:* Weekly, bi-weekly, and monthly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 691; *Total Annual Responses:* 18,854,605; *Total Annual Hours:* 54,054. (For policy questions regarding this collection contact Michael Massimini at 410-786-1566.)